



REGULATORY GUIDELINES FOR DENTAL RADIATION MACHINES

REFERENCE - CODE OF MARYLAND REGULATIONS 26.12.01.01

May 2013



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

**1800 Washington Boulevard
BALTIMORE, MARYLAND 21230**

MARYLAND REGULATIONS

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.

“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.

“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

The definitions are self-explanatory.

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/cm²).

(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 (7 mg/cm^2).

(10) “Total effective dose equivalent “ (TEDE) means the sum of the effective 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.

<p>“Dose equivalent” [See “Dose”]</p> <p>“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.</p> <p>“Effective dose equivalent” [See “Dose”]</p> <p>“Embryo/fetus” means the developing human organism from conception until the time of birth.</p> <p>“Exposure” means being exposed to ionizing radiation or to radioactive material.</p> <p>“<u>Exposure</u>” 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 <u>exposure</u> is the roentgen (R). See A.13 “Units of Exposure and Dose” for SI equivalent.</p> <p>“<u>Exposure rate</u>” means the <u>exposure</u> per unit of time, such as roentgen per minute and milliroentgen per hour.</p> <p>“External dose” [See “Dose”]</p> <p>“Extremity” means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.</p> <p>“Eye dose equivalent” [See “Dose”]</p>	
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“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.75, 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.

“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.75, 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 2.58×10^{-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.

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.

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.

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

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.

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

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

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

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

<p>(b) Each licensee and registrant shall make available, upon inspection by the Agency, records maintained pursuant to these regulations.</p> <p><u>Section A.6 Tests.</u></p> <p>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:</p> <ul style="list-style-type: none"> (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. <p><u>Section A.7 Additional Requirements.</u></p> <p>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.</p> <p><u>Section A.8 Violations.</u></p> <p>An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any</p>	<p>The Agency may perform certain tests to the radiation machine and to the automatic processor or manual tank to ensure the optimum performance. These include:</p> <ul style="list-style-type: none"> kVp Accuracy and Reliability Timer Accuracy and Reliability Tube Output <p>The Agency may add requirements if necessary to protect public health, safety, and the environment.</p> <p>The Agency may obtain court injunctions or orders.</p>
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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.

Section A.9 Impounding.

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

Section A.10 Prohibited Uses.

(c) No person shall possess 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.

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.

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.

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

B.6 – refer to COMAR 26.12.01.01.
COMAR 26.12.02 – regulations concerning radiation machines that undergo the certification process.
Your radiation machine must be disabled by a registered service company.

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



Mail correspondence to:
Maryland Department of the Environment Phone: 410-537-3193
Radiological Health Program, Suite 750 or toll-free at
1800 Washington Boulevard 1-800-633-6101
Baltimore, MD 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:

<p>(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</p> <p>(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.</p> <p><u>Section A.17 Public Posting of the Notices of Violation</u></p> <p>(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.</p> <p>(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.</p> <p><u>Section B.2 Definitions.</u></p> <p>“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.</p> <p>“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.</p>	<p>Giving the agency false information is forbidden.</p>  <p>The definitions are self-explanatory.</p>
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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 μ Sv (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, pending relocation or transfer to an authorized recipient, are exempt from the requirements of this Part for a period not to exceed 20 days.

(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;

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

If you notified the agency in writing and have provided adequate 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.

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



<p>(iii) The relocation of a radiation machine to a new facility location; or</p> <p>(iv) The purchase of the facility or radiation machine in the facility.</p> <p>(b) Complete application forms for registration furnished by the Agency that contain all the information required by the forms and accompanying instructions;</p> <p>(c) Designate on the application form an individual to be responsible for radiation protection.</p> <p>(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).</p> <p><u>Section B.7 Issuance of Notice of Registration.</u></p> <p>(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. Each certificate of registration shall be publicly posted by the radiation machine facility.</p> <p>(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.</p>	<p>Visit our website at www.mde.state.md.us to obtain registration forms.</p> <ol style="list-style-type: none"> 1. Click on the word “Air” on the left side of screen 2. Click on Radiological Health 3. Click on X-ray Application Forms and Guidance 4. Download the RX1, Payment Transmittal Form, and Instructions for Registering New Facilities <p>You must name an individual who is responsible for the radiation machine.</p>  <p>A certificate of registration will be issued if the application is complete, meets all the requirements, and the fee is paid.</p> <p>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.</p>
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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.

Section B.9 Renewal of Notice of Registration.

(a) The Agency will grant an application for renewal of registration upon receipt of all documentation and fees required by the Agency.

(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.

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. The registrant shall notify the Agency of installation, disposal or disablement of radiation machines within 30 days following such action by providing the Agency with a copy of a completed Form MDE RX24 signed and dated by a State registered service provider.

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

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.

Refer to Appendix B (located at the end of the document).

If you decide to relocate, or terminate your registration, or ownership has changed, 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



<p><u>Section B.10A Compliance with Regulations.</u></p> <p>All owners, operators, or possessors of a radiation machine(s) shall comply with all applicable requirements of COMAR 26.12.01,.02, and .03. Any Agency Form RX-2 or RX-2a citing a regulation violation(s) which is presented to a radiation machine facility during or following an inspection by an Agency or State-licensed private inspector constitutes a notice to the facility that a violation(s) has been observed by the inspector. An as-found violation(s):</p> <p>(1) Must be corrected and written evidence of correction submitted to the Agency within the time frame set by the Agency (if a certified facility, the correction(s) must be verified by the State-licensed private inspector); and</p> <p>(2) Is (are) subject to the penalty provisions of Subtitle 5, “Enforcement” of Title 8, “Radiation” of the Environment Article, Annotated Code of Maryland, which include the facility’s liability for a monetary penalty for each day that each violation occurs or continues, subject to the penalty amount and imposition limits set forth in the Statute.</p> <p><u>Section B.11 Approval Not Implied.</u></p> <p>No person, in any advertisement, shall refer to the fact that he/she or his/her 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.</p>	<p>Correct your violations and submit documentation.</p>
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Section B.14 Possession, Storage or Modification of Radiation Machines.

(a) No person shall modify a radiation machine, or any other auxiliary equipment that functions with the radiation machine, to produce the result desired by use of the machine, in such a manner that the machine or auxiliary equipment fails to operate properly or otherwise does not meet one or more provision(s) of these regulations.

(b) Each person owning or operating a radiation machine facility shall direct the operation of a radiation machine through administrative controls to ensure that the requirements of these regulations are met.

(c) Except as provided under B.6, no registrant shall possess, use, or store a radiation machine for more than 20 days which:

(1) Does not meet the requirements of COMAR 26.12 “Radiation Management”,

(2) Is located in a radiation machine facility that is not registered as required by B.5,

(3) Has been installed or serviced by any person who is not registered with the Agency as a service provider in accordance with B.6, or

(4) Has been modified as described in B.14(a) above.

Do not tamper with your radiation machine(s).

A radiation machine(s) must be registered with State if used or possessed for more than 20 days unless it has been rendered inoperable or removed by a registered service provider.

(d) A radiation machine that does not meet the requirements of B.14(a), B.14(b), and B.14(c) must, within 20 days, be

(1) Rendered internally inoperable, in a manner approved by the Department, by a service provider registered under B.6; or

(2) Removed from the facility by a service provider registered under B.6.

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

“Declared pregnant woman” means a woman who has voluntarily informed the licensee or registrant, 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

The definitions are self-explanatory.

<p>coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.</p> <p>“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.</p> <p><u>Section D.101 Radiation Protection Programs.</u></p> <p>(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 that are as low as is reasonably achievable (ALARA).</p> <p><u>Section D.201 Occupational Dose Limits for Adults.</u></p> <p>(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:</p> <p>(i) An annual limit, which is the more limiting of:</p> <p>(1) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or</p> <p>(2) The sum of the deep dose equivalent and</p>	<p>You must maintain radiation exposures as low as reasonably achievable (ALARA).</p> <p>D.206 – refer to COMAR 2.12.01.01.</p> <p>There are annual radiation dose limits for workers, pregnant women, and the public.</p> <p>5,000 millirem for workers 500 millirem in 9 months for pregnant occupational workers 100 millirem to the general public</p>
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<p>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).</p> <p>(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:</p> <p>(1) A lens dose equivalent of 0.15 Sv (15 rem), and</p> <p>(2) A shallow-dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.</p> <p>(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.206(f)(i) and (ii).</p> <p>(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Agency. 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</p>	<p>15,000 millirem for the lens of the eye</p> <p>50,000 millirem for the skin and extremity</p> <p>D.206(f)(i) and (ii) – refer to COMAR 26.12.01.01.</p> <p>The Agency interprets the dose received by the collar badge to represent the dose received by the individual assigned to the badge.</p>
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<p>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.</p> <p>(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.</p> <p><u>Section D.207 Occupational Dose Limits for Minors.</u></p> <p>The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in D.201.</p> <p><u>Section D.208 Dose to an Embryo/Fetus.</u></p> <p>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 recordkeeping requirements.</p> <p>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.</p> <p>c. The dose equivalent to an embryo/fetus is the sum of:</p>	<p>D.205e. refers to COMAR 26.12.01.01.</p> <p>Annual dose is 500 millirem for any individual under 18 years old.</p> <p>For 9 months the dose is 500 millirem for a pregnant women. Should not exceed more than 50 millirem per month.</p>
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<p>(i) The deep dose equivalent to the declared pregnant woman; and</p> <p>(ii) The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.</p> <p>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.</p> <p><u>Section D.301 Dose Limits for Individual Members of the Public.</u></p> <p>a. Each licensee or registrant shall conduct operations so that:</p> <p>i. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) 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 disposal of radioactive material into sanitary sewerage in accordance with D.1003, and</p> <p>ii. The dose in any unrestricted area from external</p>	<p>Facilities must ensure and/or demonstrate that dose from the radiation machines will not expose the general public to more than 100 millirem per year. G. 75 and D.1003 – refer to COMAR 26.12.01.01.</p> <p>Facilities must also ensure and/or demonstrate that dose from the</p>
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<p>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.</p> <p>d. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited</p> <p><u>Section D.502 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.</u></p> <p>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:</p> <p>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:</p> <p>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.;</p> <p>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 0.15 rem (1.5</p>	<p>An investigation by the Agency will be initiated to determine the root cause.</p> <p>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.</p> <p>If badges are turned in monthly – monitor for 6 months consecutively.</p> <p>If badges are turned in quarterly – monitor for 1 year consecutively.</p> <p>Note that physical changes to location or type of machines in the facility require resumption of monitoring as described above.</p>
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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 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.

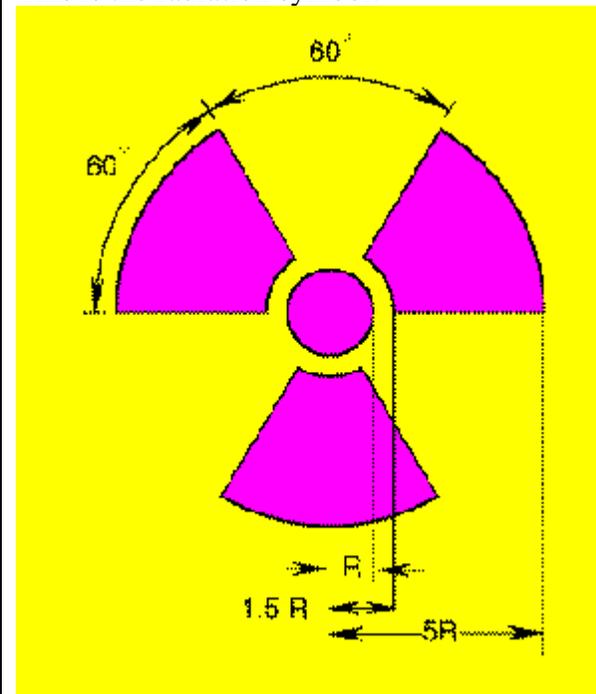
a. Standard Radiation Symbol. Unless otherwise authorized by the Agency, the symbol prescribed by D.901 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

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

This is the radiation symbol:



<p>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.</p> <p>e. The licensee or registrant shall retain each required form or record until the Agency terminates each pertinent license or registration requiring the record, or for such time as the Agency shall determine.</p> <p><u>Section D.1201 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.</u></p> <p>a. <u>Immediate Report.</u> 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.</p> <p>b. <u>Following Report.</u> 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:</p> <p style="padding-left: 40px;">i. A description of the licensed or registered source of radiation involved, including, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and</p> <p style="padding-left: 40px;">ii. A description of the circumstances under which</p>	<p>All records must be kept until the Agency notifies the facility that the registration has been cancelled.</p> <p>If your x-ray machine is lost or stolen, you must notify the Agency immediately by telephone (410-537-3193) and notify the Agency within 24 hours in writing.</p> <p>Within 30 days from your telephone call, send the agency a written report that includes these details:</p> <ul style="list-style-type: none"> - 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
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<p>the loss or theft occurred; and</p> <ul style="list-style-type: none"> iii. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and 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. <p>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.</p> <p>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.</p> <p><u>Section F.2 Definitions.</u> As used in this part, the following definitions apply:</p>	<p>The definitions are self-explanatory.</p>
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“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.

“Authorized provider” means a licensed healing arts practitioner, which is limited to the following professions: physician, podiatrist, chiropractor, dentist, and veterinarian.

“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:

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

“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.

“Dental tomographic x-ray unit” means any unit or system used for taking tomograms of parabolically curved objects such as the dentition, jawbones and other bony structures of the head and dento-facial region. Systems may include the capability and software for 3-D imaging.

“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, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector, 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

<p>(2) radiation produced when the exposure switch or timer is not activated.</p> <p>“mA” means milliamperere.</p> <p>“mAs” means milliamperere second.</p> <p>“Mobile x-ray equipment” (See “X-ray equipment”)</p> <p>“Patient” means an individual subjected to healing arts examination, diagnosis, or treatment.</p> <p>“Peak tube potential” means the maximum value of the potential difference across the x-ray tube during an exposure.</p> <p>“PID” (See Position indicating device”)</p> <p>“Portable x-ray equipment” (See “X-ray equipment”)</p> <p>“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.</p> <p>“Protective apron” means an apron made of radiation absorbing materials used to reduce radiation exposure.</p> <p>“Protective barrier” means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:</p>	
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<p>(1) “Primary protective barrier” means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.</p> <p>(2) “Secondary protective barrier” means a barrier sufficient to attenuate the stray radiation to the required degree.</p> <p>“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.</p> <p>“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.</p> <p>“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.</p> <p>“Rating” means the operating limits as specified by the component manufacturer.</p> <p>“Recording” means producing a retrievable form of an image resulting from x-ray photons.</p> <p>“Scattered radiation” means radiation that, during passage through matter, has been deviated in direction (See “Direct</p>	
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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 (SID)” means the distance from the source to the center of the input surface of the image receptor.

“Source-skin distance (SSD)” means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

“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 operation 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.

“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.

<p>“X-ray tube” means any electron tube which is designed to be used primarily for the production of x-rays.</p> <p><u>Section F.3 General Requirements.</u></p> <p>(a) <u>Administrative Controls.</u></p> <p>(1) <u>Registrant.</u> 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).</p> <p>(i) An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes.</p> <p>(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. A registrant must demonstrate that a dental radiation technologist employed by the registrant is adequately trained and competent to use a radiation machine as required under COMAR 10.44.19.07, and must conspicuously display the technologist’s certificate as required under COMAR 10.44.19.10.</p>	<p>You are responsible for the operation of your radiation machine.</p> <p>If your radiation machine does not meet the requirements set forth in these regulations, you may not use the machine.</p> <p>The operators must be registered and licensed through the Department of Health and Mental Hygiene.</p>
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<p>(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:</p> <ul style="list-style-type: none"> (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, if applicable; (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 patient shielding (e.g., gonad, etc.) to be used; and <p>(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.</p>	<p>You must have a technique chart for each x-ray machine and follow that chart. This is required for cephalometric machines and the newer panoramic machines.</p>
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<p>The operator shall be able to demonstrate familiarity with these procedures.</p> <p>(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:</p> <p>(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.</p> <p>(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.</p> <p>(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</p>	<p>Lead aprons should be used on patients to protect them from scatter radiation.</p>
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<p style="text-align: center;">the image receptor.</p> <p>(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.</p> <p>(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.</p> <p>(viii) When a patient or film must be provided with auxiliary support during a radiation exposure:</p> <p style="padding-left: 40px;">(a) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by Section F.3(a)(1)(iv), shall list individual projections where holding devices cannot be utilized;</p>	<p>Only qualified users may operate the x-ray machine.</p>
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- (b) Written safety procedures; as required by Section F.3(a)(1)(iv), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
- (c) The human holder shall be protected as required by Section F.3(a)(1)(v);
- (d) No individual shall be used routinely to hold film or patients; and
- (e) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.
- (f) The beam defining light, if present, shall be turned on during all exposures for which a human holder is used. The operator shall not initiate the exposure except on permission from the holder.

<p>(g) No individual who is occupationally exposed to radiation shall be required to hold patients during radiographic exposures.</p> <p>(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 requirements:</p> <p>(a) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations;</p> <p>(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality;</p> <p>(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</p> <p>(d) X-ray systems subject to Sec. F.6 shall not be utilized in procedures where the source to patient distance is less than</p>	<p>Minimum dose to the patient is achieved not only by the radiation machine operating according to manufacturer's specifications but:</p> <p>Ensuring that darkrooms are properly maintained.</p> <p>The timer should be set as low as possible.</p>
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30 centimeters.

(e) Filmless diagnostic x-ray systems shall use technique factors not to exceed the maximum of the technique range recommended by manufacturers' specifications to generate images.

(2) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system:

- (i) Maximum rating of technique factors;
- (ii) Model and serial numbers of all certified components;
- (iii) Aluminum equivalent filtration of the useful beam, including any routine variation;
- (iv) Tube rating charts and cooling curves;
- (v) Records of surveys, calibrations, maintenance, and effective modifications performed on the x-ray system(s) after October 9, 1995 with the names of persons who performed such services;
- (vi) For x-ray systems regulated by Sections

F.5, F.6, F.7, F.10, or F.11, a schedule of the maintenance necessary to keep the equipment in compliance, as required by Section B.12(d);

(a) Documentation, including logs, service tickets or completed work orders, indicating compliance with the manufacturer's recommended maintenance schedule;

(ix) A copy of all correspondence with this Agency regarding that x-ray system.

(3) X-ray Log.

(i) Each facility shall maintain an x-ray log containing the patient's name, the type of examinations, and the dates the examinations were performed.

(b) Image Production.

(1) All hard copy 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 percent; and

(ii) 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 ².

²/This test is described by Suleiman, O.H. et al. in the article “Automatic Film Processing: Analysis of 9 Years of Observation.” 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 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),

(b) Give an audible or visible signal

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.

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

<p style="text-align: center;">after a preset time, plus or minus 10% of the preset time.</p> <p>(iii) Film shall be developed in accordance with the appropriate time and temperature charts. Time and temperature charts matched to the film types in use in the facility shall be available and posted in the development work area.</p> <p>(3) <u>Chemical-Film Processing Control.</u></p> <p>(i) Chemicals shall be mixed in accord with the chemical manufacturer's recommendations.</p> <p>(ii) Replenishing of chemicals shall be sufficient to maintain the standards of F.3(b)(1) above.</p> <p>(iii) All processing chemicals shall be completely replaced at least every 3 months.</p> <p>(4) <u>Automatic Processors and Other Closed Processing Systems.</u> 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.</p>	<p>Follow the manufacturer's instructions for mixing chemicals.</p> <p>Chemicals must be changed a minimum of every 3 months and as often as required to maintain optimum processing. (This is dependent on the workload of the facility.)</p> <p>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.</p>
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<p>(5) <u>Film Fog Prevention.</u></p> <ul style="list-style-type: none"> (i) Film processing areas and devices shall be constructed so that film being processed, handled, or stored will be exposed only to light which has 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. <p>(6) <u>Soft Copy Image Production.</u></p> <ul style="list-style-type: none"> (i) <u>Display monitors.</u> The registrant shall use only appropriate display monitors that meet manufacturer's recommended specifications for diagnostic interpretation for image quality parameters. (ii) <u>Lasers.</u> The registrant shall use only appropriate lasers that meet manufacturer's recommended specifications for image quality parameters. 	<p>Your darkroom must not have any extraneous light leakage except for light from the proper safelight (for example: GBX 2 or equivalent).</p>
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<p>(iii) Replacement devices for electronic image retrieval or duplication instrumentation shall meet manufacturers' recommended specifications.</p> <p>c. <u>Quality Assurance.</u></p> <p>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:</p> <ol style="list-style-type: none"> (1) That the diagnostic quality of radiographic images will be maintained at the highest level; (2) That film processing systems, including electronic imaging collection systems, will be maintained at 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. <p>d. <u>Machine Maintenance.</u></p> <ol style="list-style-type: none"> (1) A registrant shall maintain each radiation machine in accordance with the manufacturer's recommended maintenance specifications. (2) If documentation regarding the recommended maintenance schedule is not available from the manufacturer, maintenance shall be performed on at least an annual basis. 	<p>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 to ensure low radiation to the patients (example: step wedge, time-temperature chart, etc.).</p> <p>A preventative maintenance (PM) service must be scheduled for all radiation machines located at the facility. PM reports must be maintained by the facility and submitted to the Department. PM reports can be submitted via email to pm@mde.state.md.us.</p>
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- (3) A registrant shall maintain documentation that the machine manufacturer’s recommended maintenance schedule has been met. Documentation to satisfy the requirements of this section shall include a detailed service report that includes the results of all tests performed by the registered service company.
- (4) Each registrant shall provide to the Agency written documentation as described in (d)(3) sufficient to demonstrate that the maintenance required under (d)(1) and (2) has been performed. Such documentation shall be provided to the Agency no later than thirty (30) days following performance of this maintenance.

Sec. 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, operating instructions and maintenance schedules are observed.”
- (e) Beam Quality.
 - (1) Half-Value Layer.
 - (i) The half-value layer of the useful beam for

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

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				
X-ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)		
Designed Operating Range (kVp)	Measured Potential (kVp)	Specified Dental Systems ¹	I. Other X-ray Systems ²	II. Other X-ray Systems ³
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

¹Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

²Dental x-ray systems designed for use with intraoral image

receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

³All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

(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.

(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 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

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.

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.

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.

These regulations apply to panoramic and cephalometric radiation machines.

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

<p>(5) <u>X-ray Systems Other Than Those Described in F.6(a)(1),(2),(3), and (4).</u></p> <p>(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.</p> <p>(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 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.</p> <p>(iii) F.6(a)(5)(i) and (ii) may be met with a system that meets the requirements for a general purpose x-ray system as specified in F.6(a)(1) or, when alignment means are also provided, may be met with either:</p> <p>(a) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image</p>	
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<p>receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or</p> <p>(b) a beam limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.</p> <p>(6) <u>Source to Image Distance</u></p> <p>Except for certified systems, a method shall be provided to indicate the SID to within 2 inches.</p> <p>(b) <u>Radiation Exposure Control Devices.</u></p> <p>(1) Timers.</p> <p>(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</p>	<p>The x-ray timer must be accurate and shall stop x-ray production at a preset time.</p>
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<p>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.</p> <p>(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.</p> <p>(iii) Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero.</p> <p>(2) <u>X-ray Control.</u></p> <p>(ii) Each x-ray control shall be located in such a way as to meet the following requirements:</p> <p style="padding-left: 40px;">(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</p> <p style="padding-left: 40px;">(b) Mobile and portable x-ray systems which are:</p> <p style="padding-left: 80px;">(1) used for greater than 1 week</p>	<p>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.</p>
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<p>in the same location, i.e., a room or suite, shall meet the requirements of F.6(b)(2)(ii)(a);</p> <p>(2) used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirement of F.6(b)(2)(ii)(a) or the operator shall be protected by 6.5 feet (1.98m) high or greater protective barrier which is placed so as to intercept both direct radiation from the tube housing and radiation scattered from the patient; or</p> <p>(3) used to make an exposure(s) of a patient at the use location shall meet the requirement of F.6(b)(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; and</p>	
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<p>(c) Means shall be provided so that the operator can view the patient during the exposure.</p> <p>(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.</p> <p>(iii) <u>Accuracy.</u> Except for certified systems, means shall be provided to terminate an 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 10 percent of the indicated preset value.</p> <p>(4) <u>Reproducibility.</u> With a timer setting of 0.5 seconds or less, the average exposure period (\bar{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:</p>	<p>A mirror can be used to view the patient.</p> <p>A signal audible to the operation shall be exempted if the x-ray machine is manufactured before 1978.</p>
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$$\bar{T} \geq 5 (T_{\max} - T_{\min})$$

(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 (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{\max}) minus the minimum exposure (E_{\min}):

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

(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 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

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

Pertains to intraoral radiation machines.

<p>systems are covered in F.6.</p> <p>(a) <u>Source-to-Skin Distance.</u> 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:</p> <ul style="list-style-type: none"> (1) 18 centimeters if operable above 50 kVp, or (2) 10 centimeters if not operable above 50 kVp. <p>(b) <u>Field Limitation.</u></p> <ul style="list-style-type: none"> (1) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that: <ul style="list-style-type: none"> (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, shielded position indicating device shall be used. <p>(c) <u>Timers.</u> Means shall be provided to terminate the exposure at a preset time interval, preset product of current and</p>	<p>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 patient's skin. Most dental x-ray machines are manufactured to meet these requirements.</p> <p>The x-ray timer must be accurate and shall stop x-ray production at a preset time.</p>
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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 (\bar{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:

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

(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.

(d) X-ray Control.

(1) An x-ray control shall be incorporated into each x-ray system such that 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:

(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) Except where dental x-ray devices are specifically designed to be hand-held, 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.

(h) Additional Requirements Applicable to Certified Systems

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

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

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.

(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 milliamperere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

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

where \bar{X}_1 and \bar{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).

(i) Additional Requirements Applicable to Systems Designed Specifically to the Hand-Held.

(1) Each hand-held diagnostic x-ray device shall be FDA approved and registered with the Department for hand-held operation as part of the facility registration. Registration shall include a description of how the hand-held device(s) will be secured in accordance with F.7(i)(4)(i) below.

(2) Each individual operating a hand-held diagnostic x-ray device shall, before using the device, complete the manufacturer’s training for use of the device. The registrant shall maintain training certificates for operators of hand-held devices and make them available for inspection at the registered facility.

(3) Hand-held diagnostic x-ray devices shall comply with the following requirements:

(i) Reproducibility. When the equipment is

Hand-held units must be approved by FDA.

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.

(ii) 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 milliamperere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

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

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

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

(iv) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to “zero”.

(v) Beam Quality. All certified hand-held dental x-ray devices 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).

(4) The use of hand-held diagnostic x-ray devices shall be in accordance with the following:

(i) The device shall be secured between planned uses from unauthorized use or removal. A description of where and how the device will be secured shall be provided to the Department before first use of the device.

(ii) The device shall have an inherent safety mechanism to prevent accidental exposures when the device is “on” but not active between imaging procedures. The device shall be maintained in lock down (safety engaged) mode at all times between patient exposures so that the device cannot be accidentally operated.

(iii) The device shall have a permanent non-removable shield in order to protect the operator from backscatter of radiation.

(iv) Only persons who are licensed, registered or certified to operate radiographic equipment in Maryland may make exposures using the device.

(v) The operator of a device shall wear a whole-body dosimeter at all times when taking an exposure. ALARA practices shall be in place during use of the device.

(vi) The device shall not be operated if a person other than the patient, operator, and others directly involved in providing care, are present in the room in which the x-ray device will be operated. As provided in F.3(a)(1)(v), if such person(s) are required to be present for the purpose of aiding in the procedure, such person(s) shall be provided with and required to wear full body shielding of no less than 0.25 millimeter lead equivalent and shall be required to remain out of the direct beam. If other persons are present in the room who are not being treated and cannot be removed from the room, the shielding and distance requirements in F.3(a)(1)(v) shall apply.

(vii) Use of a hand-held device is allowed in dental offices as a replacement for or in addition to the use of permanent wall-mounted or free standing portable dental x-ray machines, when it is determined by the authorized provider that it is not possible or is not safe to attempt to expose a radiograph using a wall mounted or portable stand mounted x-ray machine. A device designed to be hand-held may be permanently installed in an appropriate support frame and used as a free-

A dental facility must have a wall mounted unit and then can acquire a hand-held unit. A hand-held unit can be used for non-routine purposes. A log is provided by the Department on which the facility must indicate why the hand-held unit was used versus the permanent wall mounted unit.

standing portable dental x-ray machine.

(viii) Use of a hand-held device in a school or group environment for screening purposes is prohibited, except hand-held devices may be used for health diagnostic purposes only after an authorized practitioner's oral examination of a patient as part of an overall screening procedure and finding of clinical indication for device use. Provisions for protection of persons other than the patient set forth in F.3(a)(1)(v) shall be enforced.

(ix) The registrant shall keep a log of the hand-held device's usage on a form as provided by the Department. Devices shall only be transported to and from the registered facility in accordance with the provisions of D.802(b). Commercial transportation is permitted only for receipt and repair of the device.

(x) The Department reserves the right to perform an unannounced audit limited to the use of hand-held devices at facilities that are registered to use such devices in order to ensure that hand-held devices at the facility are being utilized and stored in accordance with these regulations.

(xi) Missing or stolen hand-held devices shall be reported to the Department immediately. A written report of the loss including all available details shall be submitted to the Department within

24 hours.

(xii) Hand-held devices shall only be used with dental film speeds E or faster or with digital imaging.

Section J.11 Posting of Notices to Workers.

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

- (1) The regulations in this part, Part D and each applicable part of these regulations that apply to the activities authorized by the specific license or regulation;
- (2) The license, radiation machine certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;
- (3) The operating procedures applicable to activities under the license or registration; and
- (4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part A of these regulations, and any response from the licensee or registrant.

(b) If posting of a document specified in J.11(a)(1), (2), (3), or (4) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

Post the certificate of registration.

(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.

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.

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 Panorol.

~ 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:

The text on the left side of the page of the page is an unofficial version of the official rule found in COMAR 26.12.01.01

The language on the right side of the page addresses issues of compliance with the rules

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 1consecutive 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
6. Hand-held dental machine log – this log is used if a determination is made to use a hand-held unit versus a wall mounted unit. The reason must be denoted on the log.
7. The latest preventive maintenance service report for each radiation machine

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 (410-537-3193) 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.

3-D computed tomography dental imaging system is defined as a medical imaging technique used in treatment planning and diagnosis in implant dentistry. The device rotates around the person's head obtaining images.



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, Suite 750
Baltimore, MD 21230

Phone number: 410-537-3193 or 1-800-633-6101