

INSTRUCTION SHEET

COMAR 26.12.01.01

Title: Regulations for the Control of Ionizing
Radiation (1994)

SUPPLEMENT No. 21

Instructions: Supplement 21 to the document "Regulations for the Control of Ionizing Radiation (1994)" includes the following pages (all pages are inclusive):

Remove Pages

Cover Sheet

F1 – F2

F31 – F31-1

Insert Pages

Cover Sheet

F1 – F2

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Verify to make certain that you have the pages listed above.

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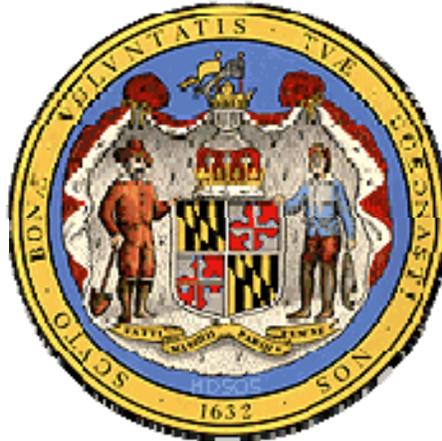
Code of Maryland Regulations 26.12.01.01

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REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)



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PART F

X RAYS IN THE HEALING ARTS

Sec. F.1 Scope. This part establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.

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

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

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

"Air kerma" means kerma in air (see definition of Kerma).

"Air kerma rate (AKR)" means the air kerma per unit time.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy¹ affording the same attenuation, under specified conditions, as the material in question.

"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.

"Attenuation block" means a block or stack, having dimensions at least 20 centimeters (cm) by 20 centimeters (cm) by 3.8 centimeters (cm) that is large enough to intercept the entire x-ray beam, of type 1100 aluminum alloy¹ or other materials having equivalent attenuation.

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

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

¹ The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"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.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

"C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

"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).

"Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

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

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

where:

s = Estimated standard deviation of the population.

\bar{x} = Mean value of observations in sample.

X_i = i^{th} observation sampled.

n = Number of observations in sample.

"Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"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.

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

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 be 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 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-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.