

CHAPTER 41
SAFETY REQUIREMENTS FOR THE USE OF
RADIATION MACHINES AND CERTAIN USES
OF RADIOACTIVE MATERIALS

841—41.1(198C) X-rays in the healing arts.

41.1(1) Scope. This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment and imaging systems 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.

a. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 401—Chapters 18 to 42.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of May 18, 2008.

41.1(2) Definitions. For the purpose of this chapter, the definitions of 401—Chapters 18 and 42 may also apply. The following are specific to 401—Chapter 41.

"**Accessible surface**" means the internal surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

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

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

"**Attenuation block**" means a block or stack, having dimensions .20 centimeters by 20 centimeters by 20 centimeters, of type 1100 aluminum alloy or other material having equivalent attenuation.

"**Automatic exposure control (AEC)**" means a device which automatically controls one or more technique factors in order to obtain at a predetermined location(s) a required quantity of radiation (see also "Photometer"); (includes devices such as photometers and ion chambers.)

"**Base density**" means the optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

"**Base plus fog density**" means the optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base plus fog density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

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

"**C-arm X-ray system**" means an X-ray system in which the image receptor and X-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"**Camera**" means a light-tight case, usually made of thin, low X-ray absorption plastic, for holding X-ray film. One or two intensifying screens for the conversion of X-rays to visible light photons are mounted inside the camera so that they are in close contact to the film.

"**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," the Food and Drug Administration.

"**Certified system**" means any X-ray system which has one or more certified components.

"**Coefficient of variation**" or "**C**" means the ratio of the standard deviation to the mean value of a

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