than one-half second, the indication of x-ray production shall be actuated for one-half second. Indicators at or near the housing of the scanning mechanism shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(2) For systems that allow high voltage to be applied to the x-ray tube continuously and that control the emission of x-ray with a shutter, the radiation emitted may not exceed 0.88 milligray (vice 100 milliroentgen exposure) in 1 hour at any point 5 cm outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements average over an area of 100 square cm with no linear dimension greater than 20 cm.

(j) *Scan increment accuracy.* The deviation of indicated scan increment from actual scan increment may not exceed 1 millimeter. Compliance shall be measured as follows: The determination of the deviation of indicated versus actual scan increment shall be based on measurements taken with a mass 100 kilograms or less, on the patient support device. The patient support device shall be incremented from a typical starting position to the maximum incrementation distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(k) *CT number mean and standard deviation.* (1) A method shall be provided to calculate the mean and standard deviation of CT numbers for an array of picture elements about any location in the image. The number of elements in this array shall be under user control.

(2) The manufacturer shall provide specific instructions concerning the use of the method provided for calculation of CT number mean and standard deviation in addition to other information provided according to §1020.30(h).

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(5) **Exposure** means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.

(6) **External surface** means the outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.

(7) **Floor** means the underside external surface of the cabinet.

(8) **Ground fault** means an accidental electrical grounding of an electrical conductor.

(9) **Port** means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.

(10) **Primary beam** means the x radiation emitted directly from the from the target and passing through the window of the x-ray tube.

(11) **Safety interlock** means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.

(12) **X-ray system** means an assemblage of components for the controlled generation of x-rays.

(13) **X-ray tube** means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) **Requirements**—(1) **Emission limit.** (i) Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface.

(ii) Compliance with the exposure limit in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over a cross-sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface, and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x radiation.

(2) **Floors.** A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

(3) **Ports and apertures.** (i) The insertion of any part of the human body through any port into the primary beam shall not be possible.

(ii) The insertion of any part of the human body through any aperture shall not be possible.

(4) **Safety interlocks.** (i) Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

(ii) Each access panel shall have at least one safety interlock.

(iii) Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with paragraph (c)(6)(ii) of this section shall be necessary for resumption of x-ray generation.

(iv) Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

(5) **Ground fault.** A ground fault shall not result in the generation of x-rays.

(6) **Controls and indicators for all cabinet x-ray systems.** For all systems to which this section is applicable there shall be provided:

(i) A key-actuated control to insure that x-ray generation is not possible with the key removed.

(ii) A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.
(iii) Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled “X-RAY ON”.

(iv) Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled “X-RAY ON”.

(7) Additional controls and indicators for cabinet x-ray systems designed to admit humans. For cabinet x-ray systems designed to admit humans there shall also be provided:

(i) A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

(ii) No means by which x-ray generation can be initiated from within the cabinet.

(iii) Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.

(iv) A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second.

(v) Signs indicating the meaning of the warning signals provided pursuant to paragraphs (c)(7) (iii) and (iv) of this section and containing instructions for the use of the control provided pursuant to paragraph (c)(7)(i) of this section. These signs shall be legible, accessible to view, and illuminated when the main power control is in the “on” position.

(8) Warning labels. (i) There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

CAUTION: X-RAYS PRODUCED WHEN ENERGIZED

(ii) There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement:

CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED—X-RAY HAZARD

(9) Instructions. (i) Manufacturers of cabinet x-ray systems shall provide for purchasers, and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current, and duty cycle ratings of the x-ray generation equipment; adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system; and a schedule of maintenance necessary to keep the system in compliance with this section.

(ii) Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure that the system is in compliance with applicable provisions of this section when assembled, installed, adjusted and tested as directed.

(10) Additional requirements for x-ray baggage inspection systems. X-ray systems designed primarily for the inspection of carry-on baggage at airline
railroad, and bus terminals, and at
similar facilities, shall be provided
with means, pursuant to paragraphs
(c)(10)(i) and (ii) of this section, to in-
sure operator presence at the control
area in a position which permits sur-
veillance of the ports and doors during
generation of x-radiation.

(i) During an exposure or preset suc-
cession of exposures of one-half second
or greater duration, the means pro-
vided shall enable the operator to ter-
minate the exposure or preset succes-
sion of exposures at any time.

(ii) During an exposure or preset suc-
cession of exposures of less than one-
half second duration, the means pro-
vided may allow completion of the ex-
posure in progress but shall enable the
operator to prevent additional expo-
sures.

(d) Modification of a certified system.
The modification of a cabinet x-ray
system, previously certified pursuant
to §1010.2 by any person engaged in the
business of manufacturing, assembling
or modifying cabinet x-ray systems
shall be construed as manufacturing
under the act if the modification af-
fects any aspect of the system's per-
formance for which this section has an
applicable requirement. The manufac-
turer who performs such modification
shall rectify and reidentify the sys-
tem in accordance with the provisions
of §§1010.2 and 1010.3 of this chapter.

[39 FR 12986, Apr. 10, 1974]

PART 1030—PERFORMANCE
STANDARDS FOR MICROWAVE
AND RADIO FREQUENCY EMIT-
TING PRODUCTS

AUTHORITY: 21 U.S.C. 351, 352, 360, 360e–360j,
360hh–360ss, 371, 381.

§ 1030.10 Microwave ovens.

(a) Applicability. The provisions of
this standard are applicable to micro-
wave ovens manufactured after October
6, 1971.

(b) Definitions—(1) Microwave oven
means a device designed to heat, cook,
or dry food through the application of
electromagnetic energy at frequencies
assigned by the Federal Communi-
cations Commission in the normal ISM
heating bands ranging from 890 mega-
hertz to 6,000 megahertz. As defined in
this standard, "microwave ovens" are
limited to those manufactured for use
in homes, restaurants, food vending, or
service establishments, on interstate
carriers, and in similar facilities.

(2) Cavity means that portion of the
microwave oven in which food may be
heated, cooked, or dried.

(3) Door means the movable barrier
which prevents access to the cavity
during operation and whose function is
to prevent emission of microwave en-
ergy from the passage or opening which
provides access to the cavity.

(4) Safety interlock means a device or
system of devices which is intended to
prevent generation of microwave en-
ergy when access to the cavity is pos-
sible.

(5) Service adjustments or service pro-
cedures means those servicing methods
prescribed by the manufacturer for a
specific product model.

(6) Stirrer means that feature of a
microwave oven which is intended to
provide uniform heating of the load by
constantly changing the standing wave
pattern within the cavity or moving
the load.

(7) External surface means the outside
surface of the cabinet or enclosure pro-
vided by the manufacturer as part of
the microwave oven, including doors,
doors handles, latches, and control
knobs.

(8) Equivalent plane-wave power den-
sity means the square of the root-mean-
square (rms) electric field strength di-
vided by the impedance of free space
(377 ohms).

(c) Requirements—(1) Power density
limit. The equivalent plane-wave power
density existing in the proximity of the
external oven surface shall not exceed 1
milliwatt per square centimeter at any
point 5 centimeters or more from the
external surface of the oven, measured
prior to acquisition by a purchaser,
and, thereafter, 5 milliwatts per square
centimeter at any such point.

(2) Safety interlocks. (i) Microwave
ovens shall have a minimum of two op-
erative safety interlocks. At least one
operative safety interlock on a fully
assembled microwave oven shall not be
operative by any part of the human
body, or any object with a straight
insertable length of 10 centimeters.