Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation

28-35-135c. Definitions.

As used in these regulations, each of the following terms shall have the meaning specified in this regulation:

(a) "Cabinet radiography using radiation machines" means industrial radiography that is conducted in an enclosed, interlocked cabinet that prevents the radiation machine from operating unless all openings are securely closed and that is sufficiently shielded so that every location on the cabinet's exterior meets the conditions for an unrestricted area as specified in K.A.R. 28-35-214a.

(b) "Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure, called a "cabinet," that is independent from existing architectural structures except the floor on which the cabinet could be placed. The cabinet is intended for the following purposes:

(1) To contain at least that portion of a material being irradiated;

(2) to provide radiation attenuation; and

(3) to exclude personnel from the interior of the cabinet during the generation of X-rays.

This term shall include all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An X-ray tube that is used within a shielded part of a building, or X-ray equipment that may temporarily or occasionally incorporate portable shielding, shall not be considered a cabinet X-ray system.

(c) "Calendar quarter" means at least 12 but not more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January. Subsequent calendar quarters shall be arranged so 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. A licensee or registrant shall not change the method of determining and observing

calendar quarters for purposes of these regulations except at the beginning of a calendar year.

(d) "Calibration" means the determination of either of the following:

(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.

(e) "Camera" means a radiographic exposure device.

(f) "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

(g) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(h) "Certifiable cabinet X-ray system" means an existing, uncertified X-ray system that has been modified to meet the certification requirements specified in 21 C.F.R. 1020.40, dated April 1, 2019, which is hereby adopted by reference.

(i) "Certificate holder" means a person that has been issued a certificate of compliance or other package approval by the commission.

(j) "Certificate of compliance" and "CoC" mean the certificate issued by the commission under subpart D of 10 C.F.R. part 71, approving the design of a package for the transportation of radioactive material.

(k) "Certificate of registration" means a document issued by the department, the commission, or an agreement state given sealed source and device registry authority by the commission acknowledging the registration of a sealed source or device containing a sealed source.

(l) "Certified cabinet X-ray system" means a cabinet X-ray system that has been certified as manufactured and assembled as specified in 21 C.F.R. 1020.40, which is adopted by reference in subsection (h).

(m) "Certified components" means the components of X-ray systems that are subject to regulations promulgated under public law 90-602, the radiation control for health and safety act of 1968 as amended.

(n) "Certified system" means any X-ray system that has one or more certified components.

(o) "Certifying entity" means an independent certifying organization or state regulatory program meeting the requirements in K.A.R. 28-35-293.

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

(q) "Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acids, and polycarboxylic acids.

(r) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. For the purposes of these regulations, "lung class" and "inhalation class" shall be considered equivalent terms. Materials are classified as D, W, or Y, which applies to the following range of clearance half-times:

(1) For class D, fewer than 10 days;

(2) for class W, from 10 through 100 days; and

(3) for class Y, more than 100 days.

(s) "Coefficient of variation" and "C" mean the ratio of the standard deviation to the mean value of a population of observations. This ratio is estimated using the following equation:

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

where

s = Estimated standard deviation of the population

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

x_i = ith observation in sample

(t) "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.

(u) "Collimator" means a radiation shield that is placed at the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

(v) "Committed dose equivalent" and "$H_{T,50}$" mean 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.

(w) "Committed effective dose equivalent" and "$H_{E,50}$" mean 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 ($H_{E,50} = \sum w_T H_{T,50}$).

(x) "Computed tomography" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data, including by cone beam-computed tomography.

(y) "Consortium" means an association of medical use licensees and a positron emission tomography (PET) radionuclide production facility in the same geographical area that jointly own or share the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium shall be located at an educational institution, a federal facility, or a medical institution.

(z) "Contact therapy" means therapy in which the X-ray tube port is put in contact with, or within five centimeters of, the surface being treated.

(aa) "Contact therapy system" means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than five centimeters.

(bb) "Contamination" means the presence of a radioactive substance on a surface in quantities of more than 0.4 Bq/cm^2 ($1x10^{-5}$ $\mu Ci/cm^2$) for beta and gamma emitters and low-toxicity alpha emitters, or 0.04 Bq/cm^2 ($1x10^{-6}$ $\mu Ci/cm^2$) for all other alpha emitters.

(cc) "Control cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

(dd) "Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

(ee) "Controlled area" means an area outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

(ff) "Control panel" means that part of the X-ray system where the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors are mounted.

(gg) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.
(hh) "Cooling curve" means the graphical relationship between the heat units stored and the cooling time.
(ii) "Criticality safety index" and "CSI" have the meaning specified for "criticality safety index (CSI)" in 10 C.F.R. 71.4, dated January 1, 2019. This definition is hereby adopted by reference.
(jj) "Curie" means a unit of activity. One curie (Ci) is the quantity of radioactive material that decays at the rate of 3.7×10^{10} transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie ($_{m}$Ci) = 0.001 curie = 3.7×10^{7} tps. One microcurie (μCi) = 0.000001 curie = 3.7×10^{4} tps.
(Authorized by K.S.A. 48-1607; implementing K.S.A. 2020 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended May 4, 2018; amended April 1, 2022.)