

**RULES
OF
TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION**

**CHAPTER 0400-20-04
GENERAL PROVISIONS**

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0400-20-04-.01 PURPOSE.

These regulations are intended to establish standards of radiation protection and are promulgated pursuant to provisions of Tennessee Code Annotated, Title 68, Chapter 202 and do not in any way exempt any person from the provisions of the Code. These regulations are intended to be consistent with the safe use of radiation machines and radioactive materials.

Authority: T.C.A. §§ 68-202-101 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.02 SCOPE.

Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation, provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulations by the U.S. Nuclear Regulatory Commission.

Authority: T.C.A. §§ 68-202-101 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.03 EFFECTIVE DATE.

The provisions of these regulations shall be effective on the date of issue.

Authority: T.C.A. §§ 68-202-101 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.04 DEFINITIONS.

- (1) As used in these regulations, these terms have the definitions set forth below. (For additional definitions used only in Chapters 0400-20-05, 0400-20-06, 0400-20-07, 0400-20-08 and 0400-20-09, see Rules 0400-02-05-.32, 0400-20-06-.03, 0400-20-07-.05, 0400-20-08-.03 and 0400-20-09-.03.)
 - (a) 1. "A₁" means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Table A-1 of Schedule 10-6 in Rule 0400-20-10-.38, or may be derived in accordance with the procedures prescribed in Schedule 10-6 in Rule 0400-20-10-.38.

(Rule 0400-20-04-.04, continued)

2. "A₂" means the maximum activity of radioactive material, other than special form material, LSA and SCO material, permitted in a Type A package. This value is either listed in Table A-1 of Schedule 10-6 in Rule 0400-20-10-.38, or may be derived in accordance with the procedure prescribed in Schedule 10-6 in Rule 0400-20-10-.38.
- (b) "Accelerator-produced radioactive material" means any material made radioactive by a particle accelerator.
 - (c) "Agreement State" means any state with which the U.S. Nuclear Regulatory Commission has entered into an effective agreement under Section 274 b. of the Atomic Energy Act of 1954, as amended (73 Statute 689).
 - (d) "Alert" means a classification for events that are in progress, may occur or have occurred that could lead to a release of radioactive material(s) but that the release is not expected to require a response by an offsite response organization to protect persons offsite.
 - (e) "Authorized nuclear pharmacist". Defined in Rule 0400-20-07-.05.
 - (f) "Authorized user". Defined in Rule 0400-20-07-.05.
 - (g) "Barrier" means attenuating materials used to reduce radiation exposure.
 1. "Primary". Barrier sufficient to attenuate the useful beam to the required degree at a distance no greater than 8 centimeters beyond the barrier.
 2. "Secondary". Barrier sufficient to attenuate scattered and leakage radiation to the required degree at a distance no greater than 8 centimeters beyond the barrier.¹
 - (h) "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.
 - (i) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract or private carrier, or by civil aircraft.
 - (j) "Certificate holder" means a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Commission (U.S. NRC).
 - (k) "Certificate of Compliance" (CoC) means the certificate issued by the U.S. NRC under 10 CFR 71 subpart D which approves the design of a package for the transportation of radioactive material.
 - (l) "Close reflection by water" means immediate contact by water of sufficient thickness for maximum reflection of neutrons.

¹ It is reasonable to assume that individuals will not occupy the area within 8 centimeters of the barrier continuously.

(Rule 0400-20-04-.04, continued)

- (m) "Consignment" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.
- (n) "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in 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 must be located at an educational institution or a Federal facility or a medical facility.
- (o) "Containment system" means the assembly of components of the packaging intended to retain the radioactive material during transport.
- (p) "Conveyance" means:
 - 1. For transport by public highway or rail: any transport vehicle or large freight container;
 - 2. For transport by water: any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and
 - 3. For transport by aircraft: any aircraft.
- (q) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.
- (r) "Criticality safety index" (CSI) means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in paragraphs (10) and (11) of Rule 0400-20-10-.30 and 10 CFR 71.59.
- (s) "Curie". Defined in Rule 0400-20-05-.34.
- (t) "Cyclotron" means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles and is commonly used for production of short half-life radionuclides for medical or veterinary use.
- (u) "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:
 - 1. Release of the property for unrestricted use and termination of the license; or
 - 2. Release of the property under restricted conditions and the termination of the license.
- (v) "Deuterium" means, for the purposes of subparagraph (5)(b) and paragraph (10) of Rule 0400-20-10-.30, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.
- (w) "Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

(Rule 0400-20-04-.04, continued)

- (x) "Disposal facility" means a land disposal site that is used for the isolation of radioactive waste from the biosphere.
- (y) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey and statistical techniques.
- (z) Reserved.
- (aa) "Dose". Defined in Rule 0400-20-05-.32.
- (bb) "DOT" and "U.S. DOT" means the United States Department of Transportation. U.S. DOT regulations are found in Code of Federal Regulations Title 49 Transportation.
- (cc) "Emergency procedures" means the written pre-planned steps to be taken in the event of actual or suspected exposure of individuals to excessive radiation. This procedure should include the names and telephone numbers of individuals to be contacted as well as directives for processing the film badge or other personnel-monitoring device.
- (dd) "Exclusive use" (or "sole use" or "full load") means sole use by a single consignor of a conveyance for which all initial, intermediate and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier shall ensure that personnel having radiological training and resources appropriate for safe handling of the consignment perform any loading or unloading. The consignor shall issue specific written instructions for maintenance of exclusive use shipment controls and include them with the shipping paper information provided to the carrier by the consignor.
- (ee) "Exposure"² means a measure of the ionization produced in air by X or gamma radiation. It is the sum of the electrical charges on all of the ions of one sign produced in air, when all electrons liberated by photons in a volume element of air are completely stopped in air, divided by the mass of the air in the volume element. The special unit of exposure is the roentgen.
- (ff) "Fissile material" means plutonium-238, the radionuclides: plutonium-239, plutonium-241, uranium-233, uranium-235 or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in subparagraph (5)(b) of Rule 0400-20-10-.30.
- (gg) "Fissile material package". See "Package"
- (hh) "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel processing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.
- (ii) "Generator" means a person whose activities with radioactive material are such that waste is generated that is distinctly separate and/or distinct from materials received.

² It is reasonable to assume that individuals will not occupy the area within 8 centimeters of the barrier continuously.

(Rule 0400-20-04-.04, continued)

- (jj) “Graphite” means, for the purposes of subparagraph (5)(b) and paragraph (10) of Rule 0400-20-10-.30, graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.
- (kk) “Human use” (or “medical use”) means the intentional internal or external administration of radiation or radioactive materials to individuals under the supervision of an authorized user.
- (ll) “Interlock” means a device for precluding access to any area of radiation hazard by automatically eliminating the hazard upon entry by personnel or parts of their body.
- (mm) “Licensed material” means radioactive, by-product, source, or special nuclear material received, possessed, used, or transferred under a general or specific license issued by the Division pursuant to the regulations in this chapter, or issued by the U.S. NRC or an agreement state pursuant to equivalent regulations.
- (nn) “Licensing State” means any state with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM.
- (oo) “Low specific activity (LSA) material” means radioactive material with limited specific activity which is nonfissile or is expected under subparagraph (5)(b) of Rule 0400-20-10-.30, and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one three groups:
 - 1. LSA-I
 - (i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing only naturally occurring radioactive radionuclides which are not intended to be processed for the use of these radionuclides; or
 - (ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or
 - (iii) Radioactive material for which the A_2 value is unlimited; or
 - (iv) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with Schedule 10-6 in Rule 0400-20-10-.38.
 - 2. LSA-II
 - (i) Water with tritium concentration up to 20 Ci/liter (0.8 terrabequerel/liter); or
 - (ii) Other material in which the activity is distributed throughout and the average specific activity does not exceed 1 (E-4) A_2 /gram for solids and gases or 1 (E-5) A_2 /gram for liquids.
 - 3. LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of the U.S. NRC regulations 10 CFR 71.77, in which:

(Rule 0400-20-04-.04, continued)

- (i) The radioactive material is distributed throughout a solid or a collection of solid objects or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and
 - (ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven (7) days, would not exceed $0.1 A_2$; and
 - (iii) The average specific activity of the solid does not exceed $2 (E-3) A_2/\text{gram}$.
- (pp) “Low toxicity alpha emitters” means natural uranium, depleted uranium, natural thorium, uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than ten (10) days.
- (qq) “Major processors” means persons processing or handling radioactive materials exceeding Type X quantities³ as unsealed sources or material.
- (rr) “Maximum normal operating pressure” means the maximum gauge pressure that would develop in the containment system in a period of one (1) year under the heat condition specified in 10 CFR 71.71(c)(1), in the absence of venting, external cooling by an ancillary system or operational controls during transport.
- (ss) “NARM” means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source or special nuclear material.
- (tt) “Natural radioactivity” means radioactivity of naturally occurring nuclides.
- (uu) “Natural thorium” means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).
- (vv) “Normal form radioactive material” means radioactive material that has not been demonstrated to qualify as special form radioactive material.
- (ww) “Operating procedures” means detailed written instructions including, but not limited to, the normal operation of equipment and movable shielding, closing of interlock circuits, manipulation of controls, radiation monitoring procedures for personnel and areas, testing of interlocks and record keeping requirements.
- (xx) “Optimum interspersed hydrogenous moderation” means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.
- (yy) “Ore refineries” means all non-exempt processors of a radioactive material ore.
- (zz) “Package” means the packaging together with its radioactive contents as presented for transport.

³ Type X quantities are defined in Tables RHS 2–1, RHS 2–2 and RHS 2–3 as contained in Chapter 0400-20-05. For purposes of Rule 0400-20-04-.04, where there is involved a combination of radioactive materials licensed, the method of deriving a Type X quantity is as specified in Rule 0400-20-05-.162(1)(b).

(Rule 0400-20-04-.04, continued)

1. "Fissile material package" or "Type AF package", "Type BF package", Type B(U)F package" or "Type B(M)F package" means a fissile material packaging together with its fissile material contents.
 2. "Type A package" means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the U.S. DOT regulations in 49 CFR 173.
 3. "Type B package" means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbf/in²) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see U.S. DOT regulations in 49 CFR 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.
- (aaa) "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of this chapter. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system and auxiliary equipment may be designated as part of the packaging.
- (bbb) "Particle accelerator" means any device used to impart kinetic energy to electrically charged particles including but not limited to electrons, protons, deuterons, and helium ions. For the purpose of these regulations "accelerator" includes equipment designed for and used only for the production of x-rays of 0.9 MeV or greater and equipment capable of discharging nuclear particles into a medium external to the accelerating device. For purposes of this definition, "accelerator" is an equivalent term.
- (ccc) "Physician" means an individual licensed by the State to dispense drugs in the practice of medicine.
- (ddd) "Qualified individual". Defined in Rule 0400-20-06-.03.
- (eee) "Qualified expert" means, for purposes of subparagraph (2)(g) and (m) of Rule 0400-20-09-.21, a person:
1. Who is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics or X-Ray and Radium Physics; or

(Rule 0400-20-04-.04, continued)

2. Who has the following ⁴ minimum training and experience:
 - (i) A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;
 - (ii) One year of full-time training in therapeutic radiological physics; and
 - (iii) One year of full-time experience in a therapy facility including personal calibration and spot check of at least one teletherapy unit.
- (fff) "Rad" is defined in subparagraph (1)(b) of Rule 0400-20-05-.33.
- (ggg) "Radiation machine" means any device capable of producing radiation except devices that produce radiation through utilization of a radioactive material.
- (hhh) "Radioactive material" means any material, solid, liquid or gas, which emits radiation spontaneously.
- (iii) "Radiological Safety Officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.
- (jjj) "Rem" is defined in subparagraph (1)(c) of Rule 0400-20-05-.33.
- (kkk) "Research and development" means theoretical analysis, exploration or experimentation; or extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes. Research and development includes the experimental production and testing of models, devices, equipment, materials and processes. Research and development does not include the internal or external administration of radiation or radioactive material to individuals.
- (III) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, subsurface materials, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Chapter 0400-20-05.

⁴ Licensees or certified registrants that utilize persons who do not meet these criteria for minimum training and experience may request a variance excepting them from the requirements of using qualified experts. The request should include:

1. The name of the proposed individual,
2. A description of his or her training and experience including information similar to that specified in Rule 0400-20-04-.04,
3. Reports of at least one calibration and spot-check program based on measurements personally made by the proposed individual within the last 10 years, and
4. Written endorsement of the technical qualifications of the proposed individual from personal knowledge by a physicist certified by the American Board of Radiology in one of the specialties listed in Rule 0400-20-04-.04.

The variance request should be addressed to the Division of Radiological Health, at the address given in Rule 0400-20-04-.07.

(Rule 0400-20-04-.04, continued)

(mmm) "Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58×10^{-4} coulomb per kilogram of air.

(nnn) "Sealed source" is defined in Rule 0400-20-07-.05.

(ooo) "Site area emergency" means a classification for events that are in progress, may occur or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

(ppp) "Source of radiation" means material that emits radiation spontaneously, or apparatus that produces, or may produce when the associated controls are operated, one or more forms of radiation.

(qqq) "Special form radioactive material" means radioactive material that satisfies the following conditions:

1. It either is a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
2. The piece or capsule has at least one dimension not less than 5 millimeters (0.197 inch); and
3. It satisfies the requirements specified by the U.S. Nuclear Regulatory Commission 10 CFR 71.75. A special form encapsulation designed in accordance with the U.S. NRC requirements of 10 CFR 71.4 in effect on June 30, 1983 (see 10 CFR 71, revised as of January 1, 1983), and constructed before July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with U.S. NRC requirements of 10 CFR 71.4 in effect on March 31, 1996, (see 10 CFR 71, revised as of January 1, 1983), and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation shall meet the specifications of this definition.

(rrr) "Special nuclear material in quantities not sufficient to form a critical mass" means:

1. Uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235;
2. Uranium-233 in quantities not exceeding 200 grams;
3. Plutonium in quantities not exceeding 200 grams; or
4. Any combination of them in accordance with the following formula. For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all kinds of special nuclear material in combination shall not exceed 1 (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

(sss) "Specific activity" means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(Rule 0400-20-04-.04, continued)

(ttt) "Spent nuclear fuel or Spent fuel" means fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least 1 year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

(uuu) "SRPAR" means State Regulations for Protection Against Radiation.

(vvv) "State" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(www) "Surface contaminated object" (SCO) means a solid object that is not itself classed as radioactive material but that has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

1. SCO-I: A solid object on which:

- (i) The removable (non-fixed) contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1 E-4 microcurie (4 becquerels) per square centimeter (cm^2) for beta and gamma and low toxicity alpha emitters or 1 E-5 microcuries (0.4 becquerel) per cm^2 for all other alpha emitters;
- (ii) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1 microcurie (4 E+4 becquerels) per square centimeter (cm^2) for beta and gamma and low toxicity alpha emitters or 0.1 microcurie (4 E+3 becquerels) per cm^2 for all other alpha emitters; and
- (iii) The removable (nonfixed) contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1 microcurie (4 E+4 becquerels) per square centimeter (cm^2) beta and gamma and low toxicity alpha emitters or 0.1 microcurie (4 E+3 becquerels) per cm^2 for all other alpha emitters.

2. SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

- (i) The removable contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1 E-2 microcurie (400 becquerels) per square centimeter (cm^2) for beta and gamma and low toxicity alpha emitters or 1 E-3 microcurie (40 becquerels) per cm^2 for all other alpha emitters;
- (ii) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 20 microcuries (8 E+5 becquerels) per square centimeter (cm^2) for beta and gamma and low toxicity alpha emitters or 2 microcuries (8 E+4 becquerels) per cm^2 for all other alpha emitters; and
- (iii) The removable (nonfixed) contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 20 microcurie (8 E+5 becquerels)

(Rule 0400-20-04-.04, continued)

per square centimeter (cm^2) for beta and gamma and low toxicity alpha emitters or 2 microcurie ($8 \text{ E}+4$ becquerels) per cm^2 for all other alpha emitters.

(xxx) "Therapeutic-type protective tube housing" means:

1. For x-ray therapy apparatus not capable of operating at 500 kVp or above, the following definition applies. An x-ray tube housing so constructed that the leakage radiation at a distance of 1-meter from the target does not exceed 1 roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.
2. For x-ray therapy apparatus capable of operating at 500 kVp or above, the following definition applies. An x-ray tube housing so constructed that the leakage radiation at a distance of 1-meter from the target does not exceed 0.1 percent of the useful beam exposure rate at 1-meter from the target, for any of its operating conditions.
3. In either case, small areas of reduced protection are acceptable providing the average radiation exposure over any area of 100 square centimeters at 1-meter distance from the target does not exceed the values given above. However, no linear dimension of the area used to obtain the average shall exceed 20 centimeters.
4. See part (1)(a)15 of Rule 0400-20-06-.05 for leakage requirements for contact therapy apparatus.

(yyy) "These regulations" means "State Regulations for Protection Against Radiation."

(zzz) "Transport index" (TI) means the dimensionless number (rounded up to the next tenth) placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by the maximum radiation level in millirem per hour at 1-meter (3.3 feet) from the external surface of the package (equivalent to multiplying the maximum radiation level in millisievert(s) per hour at 1-meter (3.3 feet) by 100). The transport index is determined as follows:

1. For non-fissile material packages, the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at 1-meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at 1-meter (3.3 ft)); or
2. For fissile material packages, the number determined by multiplying the maximum radiation level in millisievert per hour at 1-meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at 1-meter (3.3 ft)), or, for criticality control purposes, the number obtained as described in 10 CFR 71.59, whichever is larger.

(aaaa) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Table A-1, Schedule 10-6, Rule 0400-20-10-.37, or may be determined by procedures described in Schedule 10-6, Rule 0400-20-10-.37.

(bbbb) "Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

(Rule 0400-20-04-.04, continued)

(cccc) "Unirradiated uranium" means uranium containing not more than $2\text{E}+3$ Bq of plutonium per gram of uranium-235, not more than $9\text{E}+6$ Bq of fission products per gram of uranium-235, and not more than $5\text{E}-3$ g of uranium-236 per gram of uranium-235.

(dddd) "Units of radioactivity". Defined in Rule 0400-20-05-.34.

(eeee) "Unrefined and unprocessed ore" means ore in its natural form before any processing, such as grinding, roasting, beneficiating or refining.

(ffff) "Uranium - natural, depleted, enriched" means:

1. Natural uranium: uranium with the naturally occurring distribution of uranium isotopes (about 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).
2. Depleted uranium: uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.
3. Enriched uranium: uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(gggg) "Useful beam" (or "primary beam") means that part of the radiation that passes through a window, aperture, cone or other collimating device.

(hhhh) "Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal at a land disposal facility. For the purposes of this definition, low-level waste is radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel or byproduct material as defined in Rule 0400-20-05-.32.

(iiii) "Waste handler" means a person who holds radioactive wastes for disposal and/or who actually disposes of radioactive wastes for other persons.

(jjjj) "Waste processor" means a waste handler who performs a physical and/or chemical activity on a material containing or contaminated with radioactive material.

(kkkk) "Worker" means an individual engaging in work under a license or registration issued by the Division and controlled by a licensee or registrant, but does not include the licensee or registrant.

- (2) Definitions of certain other words and phrases used in these regulations are set forth in other parts of these regulations where they specifically apply.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.05 RESERVED.

Authority: T.C.A. §§ 68-202-201 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.06 RESERVED.

Authority: T.C.A. §§ 68-202-201 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.07 NOTIFICATIONS, REPORTS AND OTHER COMMUNICATIONS.

- (1) Address notifications and reports required by these regulations, communications concerning these regulations and applications filed thereunder as follows:

- (a) Telephone notifications and communications, 7:00 a.m. Central Time to 4:30 p.m. Central Time, except weekends and holidays:

Division of Radiological Health 615-532-0364

- (b) Telephone notifications, all other times:

Tennessee Emergency Management Agency (TEMA): 1-800-262-3300

- (c) Applications, written notifications, reports and communications:

Division of Radiological Health
Tennessee Department of Environment and Conservation
William R. Snodgrass, Tennessee Tower 15th Floor
312 Rosa Parks Avenue
Nashville, Tennessee 37243

- (d) Facsimile communications:

Division of Radiological Health 615-532-0614

- (2) Reserved.

Authority: T.C.A. §§ 68-202-101 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.08 APPLICATIONS FOR EXEMPTIONS.

The Department may, upon application by any person or upon its own initiative, grant exemptions, variances, or exceptions from the requirements of these regulations which are not prohibited by statute and which will not result in undue hazard to public health and safety or property.

Authority: T.C.A. §§ 68-202-101 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.09 PROHIBITED USES OF SOURCES OF RADIATION.

- (1) The use of sources of radiation may be prohibited when it is determined by the Department to be detrimental to public health and safety or property. This action to prohibit will be by issuance of a Commissioner Order or Emergency Order.
- (2) No person shall use sources of radiation in a manner to intentionally expose any individual except as specifically allowed by these regulations or by license, registration, or Certified Registration authorization. Use of sources of radiation on humans for research purposes must be specifically approved as provided for by the Department's policy on Experimental Exposure of Humans to Ionizing Radiation or in the case of radiopharmaceuticals by the U.S. Food and Drug Administration.

Authority: T.C.A. §§ 68-202-101 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.10 PROPRIETARY INFORMATION.

Proprietary information is defined as the below listed information supplied to the Division pursuant to the Radiological Health Service Act and is claimed in writing by the person required to supply the information as proprietary as follows:

- (1) Blueprints and flow diagrams of the individual's manufacturing processes covered by the registration, license and and/or application;
- (2) Detailed narrative of processes including listings of raw materials, composition and manufacturing protocol;
- (3) Customer lists; and
- (4) Individual medical records and/or radiation exposure records including bioassay results.

Authority: T.C.A. §§ 68-202-101 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.11 POSTING OF NOTICES TO WORKERS.

- (1) Each licensee or registrant shall post current copies of the following documents, as applicable, in a sufficient number of places to permit workers to observe them on the way to or from any particular licensed or registered activity location to which the document applies. Documents shall be placed in a conspicuous position and replaced if removed or altered:
 - (a) "State Regulations for Protection Against Radiation;"
 - (b) Radioactive material license, license conditions, documents incorporated into a license by reference and amendments thereto;
 - (c) Certified registration and amendments thereto;
 - (d) Registration of x-ray producing equipment;
 - (e) Operating and emergency procedures applicable to licensed or registered activities;
 - (f) Any written notice that these regulations have been violated shall be posted within 2 working days after receipt of the documents from the Division and the licensee's or registrant's response, if any, shall be posted within 2 working days after dispatch from the licensee or registrant. These documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.
 - (g) Form RHS 8-3 (Notice to Employees). Copies of this form may be obtained by writing the Division of Radiological Health at the address given in Rule 0400-20-04-.07.
- (2) Instead of posting a document specified in subparagraphs (1)(a) through (e) of Rule 0400-20-04-.11, the licensee or registrant may post a notice that describes the document and states where it may be examined.
- (3) Form RHS 8-3 (Notice to Employees).

(Rule 0400-20-04-.11, continued)

**TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH**

NOTICE TO EMPLOYEES

In "STATE REGULATIONS FOR PROTECTION AGAINST RADIATION", The Tennessee Department of Environment and Conservation has established standards for your protection against radiation hazards and certain provisions for the option of workers engaged in work under licenses or registrations issued by the Department.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to—

1. Apply these regulations to work under the license or registration. Licenses and Certified Registrations contain special conditions which shall be considered in addition to these regulations.
2. Post or otherwise make available to you a copy of the regulations, licenses, registrations, and operating procedures which apply to work in which you are engaged, and explain their provisions to you.
3. Post any written notice from the Department that the regulations have been violated and response to such notice.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the regulations, and the operating procedures which apply to the work in which you are engaged. You should observe their provisions for your own protection and protection of your co-workers.

AREAS COVERED BY THESE REGULATIONS

1. Limits on exposure to radiation and radioactive material in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Personnel monitoring, surveys and equipment;
4. Caution signs, labels and safety interlock equipment;
5. Exposure records and reports;
6. Option for workers regarding the Department's inspection; and
7. Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The Department's regulations require that your

employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in the license. The basic limits for exposure to employees are set forth in Rules 0400-20-05-.50, 0400-20-05-.53 and 0400-20-05-.55 of the regulations. These rules specify limits on exposure to radiation and exposure to concentrations of radioactive material in air and water.

2. If you work where personnel monitoring is required and if you request information on your radiation exposures;
 - a. your employer must advise you annually of your exposure to radiation; and
 - b. your employer must give you a written report, following termination of your employment, of your radiation exposures.

INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Department. In addition, any worker or representative of workers who believes that there is a violation of the regulations or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Tennessee Department of Environment and Conservation, Division of Radiological Health, L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243–1532. The request must set forth the specific grounds for the notice, and must be signed by the worker or the representative of the workers. During inspections, Department inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which he believes contributed to or caused any violation as described above.

POSTING REQUIREMENT

(Rule 0400-20-04-.11, continued)

Copies of this notice must be posted in a sufficient number of places in every establishment where employees are employed in activities registered or licensed pursuant to Chapter 0400-20-10 to permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment.

Authority: T.C.A. §§ 68-202-101 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.12 INSTRUCTIONS TO WORKERS.

- (1) Each licensee or registrant is responsible that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1mSv):
 - (a)
 1. Shall be kept informed of the storage, transfer or use of sources of radiation;
 2. Shall be instructed:
 - (i) In the health protection problems associated with exposure to sources of radiation,
 - (ii) In precautions or procedures to minimize radiation exposure, and
 - (iii) In the purposes and functions of protective devices employed;
 3. Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable Division regulations, registrations and licenses for the protection of individuals from sources of radiation;
 4. Shall be instructed in any operating and emergency procedures applicable to the licensed or registered activities in which the individual is involved;
 5. Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition that may lead to or cause a violation of Division regulations, registration and licenses or unnecessary exposure to sources of radiation;
 6. Instructed in the appropriate response to warnings made in case of any unusual occurrence or malfunction that may involve exposure to sources of radiation;
 7. Shall be advised that workers may request radiation exposure reports under Rule 0400-20-05-.142.
- (2) In determining individuals subject to paragraph (1) of this rule, licensees and registrants shall consider assigned activities during normal and abnormal situations involving exposure to sources of radiation that can reasonably occur during the life of a licensed or registered facility. The extent of these instructions shall be commensurate with potential radiological health protection problems in the work place.

Authority: T.C.A. §§ 68-202-101 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

0400-20-04-.13 DELIBERATE MISCONDUCT.

- (1) This rule applies to any—
 - (a) Licensee or registrant;

(Rule 0400-20-04-.13, continued)

- (b) Certificate holder;
 - (c) Quality assurance program approval holder;
 - (d) Applicant for a license, certificate, or quality assurance program approval;
 - (e) Contractor (including a supplier or consultant) or subcontractor, to any person identified in subparagraph (1)(d) of this rule; or
 - (f) Employees of any person identified in subparagraphs (a) through (e) of this paragraph.
- (2) A person identified in paragraph (1) of this rule who knowingly provides to any entity, listed in subparagraphs (1)(a) through (e) of this rule, any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's certificate holder's, quality assurance program approval holder's, or applicant's activities under these regulations, shall not:
 - (a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, certificate holder, quality assurance program approval holder, or any applicant to be in violation of any rule, regulation or order; or any term, condition, or limitation of any license or registration, or certificate issued by the Division; or
 - (b) Deliberately submit to the Division, a licensee, a registrant, a certificate holder, a quality assurance program approval holder, an applicant for a license or registration, certificate, or quality assurance program approval, or a licensee's or registrant's, applicant's, certificate holder's or quality assurance program approval holder's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Division.
- (3) A person who violates subparagraph (2)(a) or (b) of this rule may be subject to possible civil and criminal penalties.
- (4) For the purposes of subparagraph (2)(a) of this rule, deliberate misconduct by a person means an intentional act or omission that the person knows:
 - (a) Would cause a licensee, registrant, certificate holder, quality assurance program approval holder, or applicant for a license, registration, certificate, or quality assurance program approval to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license, or registration, or certificate issued by the Division; or
 - (b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order or policy of a licensee, registrant, certificate holder, quality assurance program approval holder, applicant, contractor or subcontractor of any of them.

Authority: T.C.A. §§ 68-202-201 et seq. and 4-5-201 et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.