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Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission:	Environment and Conservation
Division:	Radiological Health
Contact Person:	Andrew Holcomb
Address:	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 15 th Floor Nashville, TN 37243
Phone:	(615) 532-3038
Email:	Andrew.Holcomb@tn.gov

Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact:	ADA Coordinator
Address:	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 22nd Floor Nashville, Tennessee 37243
Phone:	1-866-253-5827 (toll free) or 615-532-0200 Hearing impaired callers may use the TN Relay Service 1-800-848-0298
Email:	kathryn.reitz@tn.gov

Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	Conference Room H, 3 rd Floor		
Address 2:	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue		
City:	Nashville, Tennessee		
Zip:	37243		
Hearing Date:	01/11/2024		
Hearing Time:	10:00 AM	<input checked="" type="checkbox"/> CST/CDT	<input type="checkbox"/> EST/EDT

Alternate Hearing Option

Method 1:	Microsoft Teams meeting Join on your computer, mobile app or room device Click here to join the meeting Meeting ID: 298 205 878 457 Passcode: QZKWXA Download Teams Join on the web
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	Video Conference ID: 116 584 933 0 Alternate VTC instructions
Method 3:	Or call in (audio only) +1 629-209-4396,,131930254# United States, Nashville Phone Conference ID: 131 930 254# Find a local number Reset PIN Learn More Meeting options

Additional Hearing Information:

If it is hard for you to read, speak, or understand English, TDEC may be able to provide translation or interpretation services free of charge. Please contact Carolyn Sekoral at (615) 532-0417 for more information. Si le resulta difícil leer, hablar o entender inglés, TDEC puede proporcionar servicios de traducción o interpretación sin cargo. Comuníquese con Carolyn Sekoral al (615) 532-0417 para obtener más información.

The purpose of this rulemaking is to bring the rules of the Division of Radiological Health into compliance with changes that the U.S. Nuclear Regulatory Commission (NRC) has made to Title 10 of the Code of Federal Regulations. This compatibility is required for Tennessee to maintain its status as an Agreement State. The rulemaking amends Chapters 0400-20-07 and 0400-20-13 to update regulatory requirements as follows:

- Miscellaneous corrections to clarify registration and inspection procedures and to better align with Nuclear Regulatory Commission language.
- Correct mathematical formula to represent that an indefinite number of nuclides may be included in the calculation of activity of Category 1 and Category 2 material.

The draft rules may be accessed for review at <https://www.tn.gov/environment/ppo-public-participation/ppo-public-participation/ppo-radiation.html>.

Oral or written comments are invited at the hearing. In addition, written comments may be submitted to Andrew Holcomb at the Division of Radiological Health, William R. Snodgrass Tennessee Tower, 312 Rosa L. Parks Avenue, 15th Floor, Nashville, Tennessee 37243 or at Andrew.Holcolm@tn.gov, prior to or following the public hearing. However, the Division must receive comments in its Central Office by 4:30 p.m. Central Time, January 12, 2024, to assure consideration. For further information, please contact Andrew Holcomb at the above address, telephone number: (615) 532-0364, or by e-mail: Andrew.Holcomb@tn.gov.

Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) (ALL chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
0400-20-10	Licensing and Registration
Rule Number	Rule Title
0400-20-10-.13	Special Requirements for Issuance of Specific Licenses
0400-20-10-.24	Registration
0400-20-10-.27	Inspections
0400-20-10-.29	Reciprocal Recognition of Licenses

Chapter Number	Chapter Title
0400-20-13	Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material
Rule Number	Rule Title
0400-20-13-.08	Appendix to Chapter 0400-20-13

Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <https://sos.tn.gov/products/division-publications/rulemaking-guidelines>.

Chapter 0400-20-10
Licensing and Registration

Amendments

Subpart (i) of part 2 of subparagraph (a) of paragraph (10) of Rule 0400-20-10-.13 Special Requirements for Issuance of Specific Licenses is amended by deleting it in its entirety and substituting instead the following:

- (i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 ~~CFR 207.20(a)~~ C.F.R. § 207.17(a);

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

Paragraph (1) of Rule 0400-20-10-.24 Registration is amended by deleting it in its entirety and substituting instead the following:

- (1) The owner or person having possession of any radiation machine or accelerator, except those specifically exempted in Rule 0400-20-10-.07, shall register such sources within 10 days after acquisition of such machine. Prior to processing a request for registration, the FDA Clearance 510K number specific to the particular device must be provided to the Division. The owner or possessor of any accelerator shall substitute an application for certified registration required in Chapter 0400-20-09. The application for certified registration must be received by the Department within 10 days after acquisition of the accelerator; however, an accelerator may not be energized until registered pursuant to Chapter 0400-20-09. In addition, every person who provides inspections as provided for in paragraph (4) of Rule 0400-20-10-.27 and every person who assembles, installs, or services radiation machines shall register with the Division of Radiological Health, Tennessee Department of Environment and Conservation. Registration under this rule shall be on Department Form RHS 8-4, Form RHS 8-4a or Form RHS 8-4b, as appropriate, as furnished by the Department and may be obtained from the Division of Radiological Health, at the address given in Rule 0400-20-04-.07. A registration fee in accordance with the Classification and Fee Schedule in paragraph (3) of this rule shall be due upon receipt of an invoice from the Division of Radiological Health following the submittal of the completed registration form. The check for the fee shall be made payable to "Treasurer, State of Tennessee."

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

Subparagraph (c) of paragraph (4) of Rule 0400-20-10-.27 Inspections is amended by deleting it in its entirety and substituting instead the following:

- (c) Who ~~are staff inspectors, or who~~ have paid an annual registration fee to the Division; and

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

Paragraph (1) of Rule 0400-20-10-.29 Reciprocal Recognition of Licenses is amended by deleting it in its entirety and substituting instead the following:

- (1) Subject to these regulations, any individual in another state who holds a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State, and issued by the agency having primary jurisdiction, where the licensee maintains an office for directing the licensed activities and at which radiation safety records are normally maintained, may possess or use the licensed radioactive material to conduct the activities authorized by such license within this State for a period not in excess of 180 days in any ~~period of 12 consecutive months~~ calendar year and will be considered, without obtaining a specific licensing document from this Division, a licensee of this State provided that:
 - (a) The out-of-state licensing document does not limit the activity authorized by such document to specified installations or locations;

- (b) The out-of-state licensee notifies the Division in writing at least ~~3~~ three days prior to each entry into this State to engage in such activity. Such notification shall indicate the location, period, type of proposed possession, use and supervisor within this State, and shall be accompanied by a copy of the pertinent licensing document or shall indicate in the notification that such licensing document has previously been submitted to this Division. If for a specific case, the ~~3~~ three-day period would impose an undue hardship, the Division may authorize such person to proceed sooner upon notification by telephone of intent to conduct the proposed activity provided that the licensee shall file in writing the information required in this paragraph within ~~3~~ three days of the telephone notification;
- (c) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the provisions of this rule except by transfer to a person:
 1. Specifically licensed by the Division, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive such material; or
 2. Exempt from the requirements for a license for such material under subparagraph (1)(a) of Rule 0400-20-10-.04;
- (d) The out-of-state licensee complies with all applicable regulations of the Division and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Division; and
- (e) The Division may require the out-of-state licensee to supply such other information as the Division may request.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

Chapter 0400-20-13
Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material

Amendment

Rule 0400-20-13-.08 Appendix to Chapter 0400-20-13 is amended by deleting it in its entirety and substituting instead the following:

0400-20-13-.08 Appendix to Chapter 0400-20-13

Table 1--Category 1 and Category 2 Threshold

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Table 1 – Category 1 and Category 2 Threshold

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241.....	60	1,620	0.6	16.2
Americium-241/Be.....	60	1,620	0.6	16.2
Californium-252.....	20	540	0.2	5.40
Cobalt-60.....	30	810	0.3	8.10
Curium-244.....	50	1,350	0.5	13.5
Cesium-137.....	100	2,700	1	27.0
Gadolinium-153.....	1,000	27,000	10	270
Iridium-192.....	80	2,160	0.8	21.6
Plutonium-238.....	60	1,620	0.6	16.2
Plutonium-239/Be.....	60	1,620	0.6	16.2
Promethium-147.....	40,000	1,080,000	400	10,800

Radium-226.....	40	1,080	0.4	10.8
Selenium-75.....	200	5,400	2	54.0
Strontium-90.....	1,000	27,000	10	270
Thulium-170.....	20,000	540,000	200	5,400
Ytterbium-169.....	300	8,100	3	81.0

Note: Calculations Concerning Multiple Sources or Multiple Radionuclides

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this chapter.

- I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this chapter apply.
- II. First determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

- R_1 = total activity for radionuclide 1
 R_2 = total activity for radionuclide 2
 R_n = total activity for radionuclide n
 AR_1 = activity threshold for radionuclide 1
 AR_2 = activity threshold for radionuclide 2
 AR_n = activity threshold for radionuclide n

$$\sum_{\pm}^{\#} \left[\frac{R_{\pm}}{AR_{\pm}} + \frac{R_{\pm}}{AR_{\pm}} + \frac{R_{\pm}}{AR_{\pm}} \right] \geq 1.0$$

$$\frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \dots + \frac{R_n}{AR_n} \geq 1.0$$

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: November 14, 2023

Signature: _____

Name of Officer: Beth Shelton

Title of Officer: Director of the Division of Radiological Health

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Filed with the Department of State on: _____

Tre Hargett
Secretary of State