

Department of State
Division of Publications
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Sequence Number: 02-21-24
 Rule ID(s): 10044-10045
 File Date: 2/28/2024
 Effective Date: 5/28/2024

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission, or entity in accordance with § 4-29-121(b).

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, Tennessee
Zip:	37243
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Revision Type (check all that apply):

- Amendment
 New
 Repeal
- Content based on previous emergency rule filed on _____
 Content is identical to the emergency rule

Rule(s) (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that ALL new rule and repealed rule numbers are listed in the chart below. 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. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). 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 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 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 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 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 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 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

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

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

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner on 01/17/2024, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 11/14/2023

Rulemaking Hearing(s) Conducted on: (add more dates). 01/11/2024

Date: January 17, 2024

Signature: 


Name of Officer: David W. Salyers, P.E.

Title of Officer: Commissioner

Agency/Board/Commission: Commissioner of the Department of Environment and Conservation

Rule Chapter Number(s): Chapters 0400-20-10 and 0400-20-13

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.


Jonathan Skrmetti
Attorney General and Reporter
Feb. 27, 2024
Date

Department of State Use Only

Filed with the Department of State on: 2/28/2024

Effective on: 5/28/2024


Tre Hargett
Secretary of State

RECEIVED

Feb 28 2024, 2:29 pm

Secretary of State
Division of Publications

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

There were no comments received during the public comment period.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

- (1) The type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from the proposed rule.

The affected organizations could include dentists, physicians, and medical facilities licensed to use radioactive materials in their practice as well as registered users of radiation producing machines. The bulk of this rulemaking focuses on miscellaneous corrections of existing rules and the impact is minimal.

- (2) The projected reporting, recordkeeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

This rulemaking requires no additional reporting, no additional recordkeeping, and no other administrative costs to remain in compliance with the proposed rule. No additional professional skills are necessary for preparation of reports or records as a result of this rule.

- (3) A statement of the probable effect on impacted small businesses and consumers.

This rulemaking will provide a positive effect on impacted businesses in that the licensed businesses will have a more clearly defined expectation of being compliant.

- (4) A description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the proposed rule that may exist, and to what extent the alternative means might be less burdensome to small business.

The Department is not aware of a less burdensome, less intrusive, or less costly alternative method of achieving the objectives of the proposed rule. The adoption of these rules will substantially codify existing federal law.

- (5) A comparison of the proposed rule with any federal or state counterparts.

The amended rules, when effective, will make our rules comparable to the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations (SSRs): Part V- Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material. In addition, the rulemaking references 10 C.F.R. Part 37 – Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material. Adoption of these rules is necessary to align with federal regulations.

- (6) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

Exemption of small businesses from any part of the requirements proposed in these rules could lead to confusion about the exact requirements necessary for compliance. In addition, small businesses are required to adhere to licensing standards in the same manner as larger entities. The consequences of not adopting these rules could affect the State of Tennessee status as an NRC Agreement State.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228, "On any rule and regulation proposed to be promulgated, the proposing agency shall state in a simple declarative sentence, without additional comments on the merits or the policy of the rule or regulation, whether the rule or regulation may have a projected financial impact on local governments. The statement shall describe the financial impact in terms of increase in expenditures or decrease in revenues."

The Department anticipates that these amended rules will not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The amendments bring the regulations of the Division of Radiological Health into compliance with changes that the U.S. Nuclear Regulatory Commission 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 0400-20-10 and Chapter 0400-20-13 to update regulatory requirements as follows:

- Miscellaneous corrections to clarify registration and inspection procedures as well as 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.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The rulemaking is pursuant to T.C.A. § 68-202-206 authorizing the Commissioner to promulgate rules and regulations for implementation of the Radiological Health Service Act. In addition, 10 C.F.R. part 150 defines activity in Agreement States as well as the regulatory authority of the Nuclear Regulatory Commission within Agreement States.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

No representatives of any potentially affected company or organization have urged adoption or rejection of these amendments.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

The Department is not aware of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule.

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

This rulemaking is not likely to increase or decrease state or local government revenue or expenditures.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

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Department of Environment and Conservation
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- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Alli Williamson
Legislative Liaison

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

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312 Rosa L. Parks Avenue, 2nd Floor
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- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

- (1) A description of the action proposed, the purpose of the action, the legal authority for the action and the plan for implementing the action.

The action proposed is the adoption of the rules contained herein amending Chapters 0400-20-10 and 0400-20-13 to maintain compatibility with federal regulations that is required for Tennessee to maintain its status as an Agreement State. These rules are implemented pursuant to T.C.A. § 68-202-206 authorizing the Commissioner to promulgate rules for implementation of the Radiological Health Service Act.

- (2) A determination that the action is the least-cost method for achieving the stated purpose.

This rulemaking is the least-cost method to achieve the stated purpose. As an Agreement State, the Department is required to maintain a degree of compatibility with the Nuclear Regulatory Commission (NRC) regulations. Therefore, our rulemaking is not allowed a high degree of latitude to make significant changes.

- (3) A comparison of the cost-benefit relation of the action to nonaction.

These rulemaking amendments are being promulgated to meet legislative and regulatory requirements as an Agreement State with the NRC. The cost of these rules is anticipated to be the work hours dedicated to making the rulemaking effective. If the rules are not promulgated, the absence of legislative compatibility could affect our status as an Agreement State via heightened oversight which would necessitate many avoidable work hours dedicated to the oversight requirements. Based on this comparison, the benefits of moving forward with this rulemaking outweigh the costs.

- (4) A determination that the action represents the most efficient allocation of public and private resources.

This action represents the most efficient allocation of public and private resources because the cost of the State's administration will be absorbed by existing resources, and it will keep licensees in compliance with the changes to Title 10 of the Code of Federal Regulations mandated by the NRC.

- (5) A determination of the effect of the action on competition.

This rulemaking will have no significant effect on competition in the marketplace because all participants are subject to the same requirements.

- (6) A determination of the effect of the action on the cost of living in the geographical area in which the action would occur.

Cost of living in the geographical area in which the action would occur will not be affected.

- (7) A determination of the effect of the action on employment in the geographical area in which the action would occur.

It is not anticipated that the action will affect employment.

- (8) The source of revenue to be used for the action.

The action can be accommodated with existing resources.

- (9) A conclusion as to the economic impact upon all persons substantially affected by the action, including an analysis containing a description as to which persons will bear the costs of the action and which persons will benefit directly and indirectly from the action.

The rulemaking will allow the Department to maintain a level of compatibility with the NRC. It is not anticipated that this rulemaking will impose substantial increased costs on affected parties. The Department anticipates that some licensees will experience an increased amount of employee time devoted to compliance with these rules. The rulemaking will also allow for a better understanding and control of licensed material or registered items by clarifying language and becoming more in compliance with NRC regulations.

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Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission, or entity in accordance with § 4-29-121(b).

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Revision Type (check all that apply):

Amendment Content based on previous emergency rule filed on _____
 New Content is identical to the emergency rule
 Repeal

Rule(s) (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that ALL new rule and repealed rule numbers are listed in the chart below. Please enter only ONE Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
0400-20-10	Licensing and Registration
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0400-20-10-.13	Special Requirements for Issuance of Specific Licenses
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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. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). 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 this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner on 01/17/2024, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 11/14/2023

Rulemaking Hearing(s) Conducted on: (add more dates). 01/11/2024

Date: January 17, 2024

Signature: _____

Name of Officer: David W. Salyers, P.E.

Title of Officer: Commissioner

Agency/Board/Commission: Commissioner of the Department of Environment and Conservation

Rule Chapter Number(s): Chapters 0400-20-10 and 0400-20-13

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Jonathan Skrmetti
Attorney General and Reporter

Date

Department of State Use Only

Filed with the Department of State on: _____

Effective on: _____

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

There were no comments received during the public comment period.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

- (1) The type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from the proposed rule.

The affected organizations could include dentists, physicians, and medical facilities licensed to use radioactive materials in their practice as well as registered users of radiation producing machines. The bulk of this rulemaking focuses on miscellaneous corrections of existing rules and the impact is minimal.

- (2) The projected reporting, recordkeeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

This rulemaking requires no additional reporting, no additional recordkeeping, and no other administrative costs to remain in compliance with the proposed rule. No additional professional skills are necessary for preparation of reports or records as a result of this rule.

- (3) A statement of the probable effect on impacted small businesses and consumers.

This rulemaking will provide a positive effect on impacted businesses in that the licensed businesses will have a more clearly defined expectation of being compliant.

- (4) A description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the proposed rule that may exist, and to what extent the alternative means might be less burdensome to small business.

The Department is not aware of a less burdensome, less intrusive, or less costly alternative method of achieving the objectives of the proposed rule. The adoption of these rules will substantially codify existing federal law.

- (5) A comparison of the proposed rule with any federal or state counterparts.

The amended rules, when effective, will make our rules comparable to the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations (SSRs): Part V- Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material. In addition, the rulemaking references 10 C.F.R. Part 37 – Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material. Adoption of these rules is necessary to align with federal regulations.

- (6) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

Exemption of small businesses from any part of the requirements proposed in these rules could lead to confusion about the exact requirements necessary for compliance. In addition, small businesses are required to adhere to licensing standards in the same manner as larger entities. The consequences of not adopting these rules could affect the State of Tennessee status as an NRC Agreement State.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228, "On any rule and regulation proposed to be promulgated, the proposing agency shall state in a simple declarative sentence, without additional comments on the merits or the policy of the rule or regulation, whether the rule or regulation may have a projected financial impact on local governments. The statement shall describe the financial impact in terms of increase in expenditures or decrease in revenues."

The Department anticipates that these amended rules will not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A)** A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The amendments bring the regulations of the Division of Radiological Health into compliance with changes that the U.S. Nuclear Regulatory Commission 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 0400-20-10 and Chapter 0400-20-13 to update regulatory requirements as follows:

- Miscellaneous corrections to clarify registration and inspection procedures as well as 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.

- (B)** A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The rulemaking is pursuant to T.C.A. § 68-202-206 authorizing the Commissioner to promulgate rules and regulations for implementation of the Radiological Health Service Act. In addition, 10 C.F.R. part 150 defines activity in Agreement States as well as the regulatory authority of the Nuclear Regulatory Commission within Agreement States.

- (C)** Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

No representatives of any potentially affected company or organization have urged adoption or rejection of these amendments.

- (D)** Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

The Department is not aware of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule.

- (E)** An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

This rulemaking is not likely to increase or decrease state or local government revenue or expenditures.

- (F)** Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Andrew Holcomb
Division of Radiological Health
Department of Environment and Conservation
(615) 289-3384
Andrew.Holcomb@tn.gov

- (G)** Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Alli Williamson
Legislative Liaison

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

William R. Snodgrass Tennessee Tower
312 Rosa L. Parks Avenue, 2nd Floor
Nashville, Tennessee 37243
(629) 401-9485
Alii.F.Williamson@tn.gov

- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

- (1) A description of the action proposed, the purpose of the action, the legal authority for the action and the plan for implementing the action.
- The action proposed is the adoption of the rules contained herein amending Chapters 0400-20-10 and 0400-20-13 to maintain compatibility with federal regulations that is required for Tennessee to maintain its status as an Agreement State. These rules are implemented pursuant to T.C.A. § 68-202-206 authorizing the Commissioner to promulgate rules for implementation of the Radiological Health Service Act.
- (2) A determination that the action is the least-cost method for achieving the stated purpose.
- This rulemaking is the least-cost method to achieve the stated purpose. As an Agreement State, the Department is required to maintain a degree of compatibility with the Nuclear Regulatory Commission (NRC) regulations. Therefore, our rulemaking is not allowed a high degree of latitude to make significant changes.
- (3) A comparison of the cost-benefit relation of the action to nonaction.
- These rulemaking amendments are being promulgated to meet legislative and regulatory requirements as an Agreement State with the NRC. The cost of these rules is anticipated to be the work hours dedicated to making the rulemaking effective. If the rules are not promulgated, the absence of legislative compatibility could affect our status as an Agreement State via heightened oversight which would necessitate many avoidable work hours dedicated to the oversight requirements. Based on this comparison, the benefits of moving forward with this rulemaking outweigh the costs.
- (4) A determination that the action represents the most efficient allocation of public and private resources.
- This action represents the most efficient allocation of public and private resources because the cost of the State's administration will be absorbed by existing resources, and it will keep licensees in compliance with the changes to Title 10 of the Code of Federal Regulations mandated by the NRC.
- (5) A determination of the effect of the action on competition.
- This rulemaking will have no significant effect on competition in the marketplace because all participants are subject to the same requirements.
- (6) A determination of the effect of the action on the cost of living in the geographical area in which the action would occur.
- Cost of living in the geographical area in which the action would occur will not be affected.
- (7) A determination of the effect of the action on employment in the geographical area in which the action would occur.
- It is not anticipated that the action will affect employment.
- (8) The source of revenue to be used for the action.

The action can be accommodated with existing resources.

- (9) A conclusion as to the economic impact upon all persons substantially affected by the action, including an analysis containing a description as to which persons will bear the costs of the action and which persons will benefit directly and indirectly from the action.

The rulemaking will allow the Department to maintain a level of compatibility with the NRC. It is not anticipated that this rulemaking will impose substantial increased costs on affected parties. The Department anticipates that some licensees will experience an increased amount of employee time devoted to compliance with these rules. The rulemaking will also allow for a better understanding and control of licensed material or registered items by clarifying language and becoming more in compliance with NRC regulations.