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 Rule ID(s): 5381
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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

| | |
|---------------------------------|--|
| Agency/Board/Commission: | Environment and Conservation |
| Division: | Radiological Health |
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. 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-.24 | Registration |
| 0400-20-10-.31 | Fees for Licenses |
| 0400-20-10-.34 | Supplemental Fees For Calendar Year 2013 |

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.in.us/sos/rules/1360/1360.htm>)

Chapter 0400-20-10
Licensing and Registration

Amendments

Subparagraph (a) of paragraph (3) of Rule 0400-20-10-.24 Registration is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (a) shall read as follows:

(a) Radiation Machines

CLASS I

Dental Radiation Machines: \$85.00 per tube

All diagnostic equipment used exclusively for dental diagnostic procedures.

CLASS II

Priority Two Medical Radiation Machines: \$195.00 per tube

All medical diagnostic x-ray equipment, not in Class III, used exclusively for medical or veterinary diagnostic procedures.

CLASS III

Priority One Medical Radiation Machines: \$286.00 per tube

All diagnostic x-ray equipment used in radiologists' offices, orthopedic surgeon's offices or hospitals exclusively for medical diagnostic procedures.

CLASS IV

Therapy Medical Radiation Machines: \$390.00 per tube

All x-ray equipment with energies less than 0.9 MeV used for the purpose of medical or veterinary radiation therapy.

CLASS V

Priority Two Industrial and Educational Radiation Machines: \$780.00 per tube

Closed-beam analytical radiation machines, gauges or industrial radiation machines used in shielded room or cabinet radiography.

CLASS VI

Priority One Industrial and Educational Radiation Machines: \$1,170.00 per tube

All x-ray machines used for industrial radiography and all open-beam analytical x-ray machines and all radiation machines not specifically included in Class I, II, III, IV, V, VII.

CLASS VII

| | |
|--|--|
| Accelerators: | \$2,600.00 annual fee, plus an initial fee of \$375.00 per maximum nominal rated MeV for initial certified registration review (initial review fee not to exceed \$150,000.00) |
| All devices defined as accelerators as per "State Regulations for Protection Against Radiation." | |

Subparagraph (b) of paragraph (3) of Rule 0400-20-10-.24 Registration is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (b) shall read as follows:

- | | | |
|-----|--|----------|
| (b) | A person providing inspection services as permitted by paragraph (4) of Rule 0400-20-10-.27 shall pay an annual registration fee of eight hundred fifty dollars. | \$850.00 |
|-----|--|----------|

Subparagraph (c) of paragraph (3) of Rule 0400-20-10-.24 Registration is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (c) shall read as follows:

- | | | |
|-----|---|----------|
| (c) | A person providing assembly/installation/servicing shall pay an annual registration fee of eight hundred fifty dollars. | \$850.00 |
|-----|---|----------|

Subparagraph (f) of paragraph (3) of Rule 0400-20-10-.24 Registration is amended by deleting it in its entirety.

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

Paragraph (6) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$150.00" from the paragraph and replacing it with "\$350.00" so that, as amended, paragraph (6) shall read as follows:

- | | | |
|-----|---|----------|
| (6) | CATEGORY GL ----- | \$350.00 |
| | Any person possessing radioactive material, under the terms of any general license issued these regulations, in a form or device on which a test for leakage of radioactive material is required. | |

Paragraph (7) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$300.00" from the paragraph and replacing it with "\$425.00" so that, as amended, paragraph (7) shall read as follows:

- | | | |
|-----|--|----------|
| (7) | CATEGORY 1 ----- | \$425.00 |
| | A specific license for source material used exclusively for shielding radiation. | |

Paragraph (8) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$600.00" from the paragraph and replacing it with "\$850.00" so that, as amended, paragraph (8) shall read as follows:

- | | | |
|-----|--|----------|
| (8) | CATEGORY 2 ----- | \$850.00 |
| (a) | Reserved. | |
| (b) | The application, use or possession of radioactive material as chromatography sources or gauges not requiring assignment to another category. | |
| (c) | The application, use or possession of radioactive material for in vitro use only, total quantity not to exceed 200 microcuries. | |

- (d) Any person who packages or containerizes, loads transport vehicles or ships radioactive materials to a licensed disposal/processing facility in Tennessee. In addition to application and annual maintenance fees, there is also a levied fee of two cents per pound (\$0.02/lb) on all items contaminated or potentially contaminated with radioactive material or on low-level radioactive waste received at a processing, storage, disposal or refurbishing facility in Tennessee.

Notwithstanding the requirements of this paragraph and Rule 0400-20-10-32, licensees with multiple sites within the state will be levied only one fee if items are moved directly from one site to another.

The operator of the disposal/processing facility shall collect the fee of two cents per pound (\$0.02/lb). For each calendar month, he shall remit the total of fees collected for the month to the Division of Radiological Health by the 25th day of the following month.

- (e) The application, use or possession of radioactive material for the calibration for hire of radiation detection, monitoring and measuring instruments.
- (f) The performance for hire of leak tests on sealed sources of radioactive material.

Paragraph (9) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$900.00" from the paragraph and replacing it with "\$1170.00" so that, as amended, paragraph (9) shall read as follows:

| | | |
|-----|---|------------|
| (9) | CATEGORY 3 ----- | \$1,170.00 |
| (a) | The application, use or possession of radioactive material, unless specific to a higher numbered category, by an academic institution, but does not include licenses authorizing all radioisotopes with atomic number 3 through 83. | |
| (b) | The possession and use of radioactive material for civil defense activities. | |
| (c) | The application, use or possession of radioactive material by a medical, institution or physicians for use in radiopharmaceuticals for the diagnosis or therapy of humans. | |
| (d) | Reserved. | |
| (e) | Reserved. | |
| (f) | Reserved. | |
| (g) | The application, use or possession of radioactive material for demonstration or training purposes. | |
| (h) | The application, use or possession of radioactive material for in vitro use only, total quantity exceeding 200 microcuries. | |
| (i) | The use of sealed sources for soil and/or construction materials testing at temporary job-sites by licensees with licensed authorization for no more than two (2) devices. | |
| (j) | The use of radioactive material as chromatography sources at temporary job-sites by licensees with licensed authorization for no more than two (2) devices. | |

- (k) The use of gauging and measuring devices at temporary job-sites by licensees with licensed authorization for no more than two (2) devices.

Paragraph (10) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$1500.00" from the paragraph and replacing it with "\$1950.00" so that, as amended, paragraph (10) shall read as follows:

- | | | |
|------|--|------------|
| (10) | CATEGORY 4 ----- | \$1,950.00 |
| | (a) The application, use or possession of radioactive material by a medical institution or physicians for interstitial, intracavitary or superficial treatment of humans using sealed sources, seeds or wires. | |
| | (b) The application, use or possession of radioactive material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-contained irradiators). | |
| | (c) The application, use or possession of radioactive material for analytical testing purposes. | |

Paragraph (11) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$2100.00" from the paragraph and replacing it with "\$2730.00" so that, as amended, paragraph (11) shall read as follows:

- | | | |
|------|--|------------|
| (11) | CATEGORY 5 ----- | \$2,730.00 |
| | (a) The use of radioactive material in research and development, manufacturing, testing, processing and assembling of products. This group includes the use of source material in the manufacture of items such as mantles, alloys, gases, liquids, metals, ceramics, glass or photographic products. | |
| | (b) The use of radioactive material in a process that incorporates that material into a product in exempt concentrations. | |
| | (c) The possession and use of radioactive material in curie quantities in a number of sources in gauges and gauging applications that require frequent changes and therefore frequent review of the program to ensure that the hazard potential does not exceed the scope of the radiation safety program. | |
| | (d) The use of a single radioactive material in the fabrication of sealed sources or ampoules. | |
| | (e) The receipt of prepackaged radioactive material waste from other persons by a nuclear waste handler for storage for less than three (3) months before, transfer only to persons licensed to receive or dispose of the material. | |
| | (f) The use of sealed sources for soil and/or construction materials testing at temporary job-sites by licensees with licensed authorization for more than two (2) devices. | |
| | (g) The use of radioactive material as chromatography sources at temporary job-sites by licensees with licensed authorization for more than two (2) devices. | |
| | (h) The use of gauging and measuring devices at temporary job-sites by licensees with licensed authorization for more than two (2) devices. | |

- (i) The application, use or possession of radioactive material by a medical institution or physicians for the treatment of humans with sealed sources contained in teletherapy devices.
- (j) The application, use or possession of radioactive material by a veterinarian for the treatment of animals using sealed sources, seeds or wires.

Paragraph (12) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$6,000.00" from the paragraph and replacing it with "\$7,800.00" so that, as amended, paragraph (12) shall read as follows:

| | | |
|------|--|------------|
| (12) | CATEGORY 6 ----- | \$7,800.00 |
| | (a) The application, use or possession of radioactive material including source and/or special nuclear material in unsealed form in less than multi-curie quantities for use in the fabrication of sealed sources without regard to amount of contained radioactivity. | |
| | (b) The manufacture of devices and/or sources that require in-depth review before approval by the Division. Each device and/or source reviewed shall be subject to this fee. | |
| | (c) The preparation, use or distribution of radiopharmaceuticals to locations other than the licensee's address for use in medical diagnosis or therapy. | |
| | (d) The use of radiography (the examination of the structure of materials by nondestructive methods using radioactive material) on the licensee's premises in a permanent shielded facility or temporary job-sites. | |
| | (e) The possession and use of radioactive material by academic and medical institutions under a license authorizing all radioisotopes with atomic numbers 3 through 83. | |
| | (f) Reserved. | |
| | (g) The application of radioactive material to soil, water, air, plants and animals, if the application involves an actual or potential release in or to unrestricted areas. | |
| | (h) The possession, use and distribution of radioactive material at one or more satellite facilities, or the possession and use of radioactive material at one or more satellite facilities, by medical institutions. | |
| | (i) The application, use or possession of radioactive material by a medical institution or physicians for research using humans and/or animals. | |

Paragraph (13) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$4,000.00" from the paragraph and replacing it with "\$5,200.00" so that, as amended, paragraph (13) shall read as follows:

| | | |
|------|--|------------|
| (13) | CATEGORY 7 ----- | \$5,200.00 |
| | (a) Reserved. | |
| | (b) Reserved. | |
| | (c) The application, use or possession of radioactive material for well logging, well surveys or tracer studies. | |

Paragraph (14) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$11,250.00" from the paragraph and replacing it with "\$14,625.00" so that, as amended, paragraph (14) shall read as follows:

- (14) CATEGORY 8 ----- \$14,625.00
- (a) The receipt of radioactive material waste from other persons by a nuclear waste handler, for the purpose of packaging or repackaging the material prior to transfer only to persons licensed to receive or dispose of the material.
 - (b) The commercial collection, laundering or dry cleaning of wearing apparel that is contaminated with radioactive material.

Paragraph (15) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$15,000.00" from the paragraph and replacing it with "\$19,500.00" so that, as amended, paragraph (15) shall read as follows:

- (15) CATEGORY 9 ----- \$19,500.00
- (a) The possession of radioactive material or equipment contaminated or potentially contaminated with radioactive material as a result of operations involving the recovery of an element, compound or mixture from ores not subject to licensure because of the radioactive material content of the ore.
 - (b) Facilities that possess radioactive material as a result of operations (not directly involving radioactive decontamination activities) involving recovery of materials or other manufacturing processes (not directly manufacturing radioactive items or products).

Paragraph (16) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$22,500.00" from the paragraph and replacing it with "\$27,000.00" so that, as amended, paragraph (16) shall read as follows:

- (16) CATEGORY 10 ----- \$27,000.00
- (a) Facilities storing radioactive material, contaminated equipment and/or potentially contaminated equipment for transfer to authorized recipients as a service to the nuclear industry.
 - (b) Possession and refurbishment of contaminated equipment and/or potentially contaminated equipment that has been used at nuclear power plants.

Paragraph (17) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$30,000.00" from the paragraph and replacing it with "\$36,000.00" so that, as amended, paragraph (17) shall read as follows:

- (17) CATEGORY 11 ----- \$36,000.00
- (a) The collection, transfer, sorting and/or brokerage of radioactive material as sealed source, residue, product or as material in or on equipment; and/or
 - The decontamination of products and/or equipment containing radioactive material and/or contaminated with radioactive material; and/or
 - The possession, storage and incineration of radioactive material or items contaminated with radioactive materials.
 - (b) On site possession and storage of radioactive material and/or equipment contaminated with radioactive material as a result of operations involving the recovery of an element, compound or mixture from ores subject to licensure because of the radioactive material content of the ore or concentration of the radioactive material during the processing of the ore.

- (c) Facilities involved in the manufacture of product lines containing radioactive material in the manufactured product.
- (d) Possession of radioactive material for processing. This material may exist in ores, concentrates, compounds or metals.
- (e) The possession of multi-curie quantities of unsealed radioactive material either as waste or for further processing and/or conversion into specific marketable products.
- (f) Operations involving the fabrication of sealed sources or manufacture of compounds for distribution to other specific or general licensees.
- (g) The possession and use of radioactive material in a sealed source for irradiation of materials in which the source is exposed for irradiation purposes (non self-contained irradiators).

Paragraph (18) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$375,000.00" from the paragraph and replacing it with "\$450,000.00" so that, as amended, paragraph (18) shall read as follows:

- (18) CATEGORY 12 ----- \$450,000.00
- (a) The application for and/or operation of a low-level radioactive waste disposal facility.
 - (b) The maximum length of reviewing time (the period of time when there are no outstanding unanswered questions) after receipt of a new application and the appropriate fee for a Category 12 specific license and the issuance of a license is 60 months.

Paragraph (19) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$150.00" from the paragraph and replacing it with "\$200.00" so that, as amended, paragraph (19) shall read as follows:

- (19) CATEGORY 13 ----- At least \$200.00 not greater than \$375,000.00
- The application, use or possession of radioactive material for uses or procedures not specifically included in any other category.
- The fee shall be determined on a case-by-case basis.
- The determination shall be based on an analysis of the hazard, the scope of the difficulty encountered in the review process and the specifics of the activity pursuant to the categories established in paragraphs (6) through (18) of this rule.

Rule 0400-20-10-.31 Fees for Licenses is amended by adding paragraph (20) so that, as amended, paragraph (20) shall read as follows:

- (20) CATEGORY NUCLEAR POWER PLANTS AND OTHER FUEL FACILITIES ----- Actual cost of program
- The Department may set and collect an annual fee from persons engaged in the business of producing electricity by utilizing nuclear energy and persons operating facilities for the fabrication of nuclear fuel. The amount of fees collected may not exceed the actual expenses that arise from emergency planning and implementation and environmental surveillance activities.

Chapter 0400-20-10
Licensing and Registration

New Rules

Chapter 0400-20-10 Licensing and Registration is amended by adding 0400-20-10-.34 that shall have the title Supplemental Fees for the Calendar year 2013 and contains the following:

0400-20-10-.34 Supplemental Fees for Calendar Year 2013

(1) Purpose

Adequate funds are required to facilitate the proper administration of The Radiological Health Service Act and The Medical Radiation Inspection Safety Act. Failure to properly administer these acts threatens the health and safety of the citizens of the state. Operating revenue for the administration of these acts is collected on a calendar year basis. Projected revenue needs of the Division in 2013 cannot be met by current registration and licensing fees. Rulemaking to increase 2013 fees cannot be completed prior to the first assessment date, January 1, 2013. Therefore, one time supplemental fees are hereby established to provide the Division with additional revenue during Calendar Year 2013. Division invoices will establish due dates for payment of these supplemental fees.

(2) Supplemental Fees Schedules

(a) In addition to the fees established in paragraph (3) of Rule 0400-20-10-.24 Registration, persons subject to registration anytime during Calendar Year 2013 shall pay a supplemental fee to be determined according to Schedule I of this paragraph:

SCHEDULE I

| | |
|---|-------------------|
| Class I Equipment | \$20.00 per tube |
| Class II Equipment | \$45.00 per tube |
| Class III Equipment | \$86.00 per tube |
| Class IV Equipment | \$90.00 per tube |
| Class V Equipment | \$180.00 per tube |
| Class VI Equipment | \$270.00 per tube |
| Class VII Equipment | \$600.00 per tube |
| A person providing inspection services under paragraph (4) of Rule 0400-20-10-.27 | \$250.00 |
| A person providing assembly/installation/servicing | \$250.00 |

(b) In addition to the fees established in paragraphs (6) through (19) of Rule 0400-20-10-.31 Fees for Licenses, persons subject to licensure anytime during Calendar Year 2013 shall pay a supplemental fee to be determined according to Schedule II of this paragraph:

SCHEDULE II

| | |
|-------------|----------|
| Category GL | \$200.00 |
|-------------|----------|

| | |
|-------------|--|
| Category 1 | \$125.00 |
| Category 2 | \$250.00 |
| Category 3 | \$270.00 |
| Category 4 | \$450.00 |
| Category 5 | \$630.00 |
| Category 6 | \$1,800.00 |
| Category 7 | \$1,200.00 |
| Category 8 | \$3,375.00 |
| Category 9 | \$4,500.00 |
| Category 10 | \$4,500.00 |
| Category 11 | \$6,000.00 |
| Category 12 | \$75,000.00 |
| Category 13 | At least \$50.00 and not greater than \$125,000.00 |

The Category 13 supplemental fee shall be determined on a case-by-case basis. The determination shall be based on an analysis of the hazard, the scope of the difficulty encountered in the review process and the specifics of the activity, following the categories established in paragraphs (6) through (19) of Rule 0400-20-10-.31.

| | |
|---|---|
| Category Nuclear Power Plants and Other Fuel Facilities | Actual expenses that arise from emergency planning and implementation and environmental surveillance activities |
|---|---|

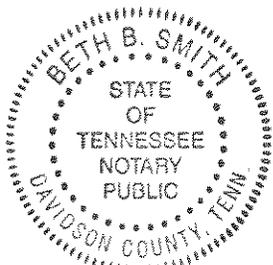
Authority: T.C.A. §§ 68-202-201 et seq. and 4-5-201 et seq.

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner of the Tennessee Department of Environment and Conservation on 01/31/2013 (mm/dd/yyyy), 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: 11/26/12

Rulemaking Hearing(s) Conducted on: (add more dates). 01/23/13



Date: 1-31-13

Signature: Robert J. Martineau, Jr.

Name of Officer: Robert J. Martineau, Jr.

Title of Officer: Commissioner

My Commission Expires JULY 6, 2015 Subscribed and sworn to before me on: 1-31-13

Notary Public Signature: Beth B. Smith

My commission expires on: July 6, 2015

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.

Robert E. Cooper, Jr.
Robert E. Cooper, Jr.
Attorney General and Reporter
2-11-13 Date

Department of State Use Only

Filed with the Department of State on: 2/13/13

Effective on: 5/14/13

Tre Hargett
Tre Hargett
Secretary of State

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Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

Comment: Wording for 0400-20-10-.31(20) does not clearly state the type of facilities included in this fee category.

Response: The Department agrees. Wording for 0400-20-10-.31(20) will be changed to:

(20) CATEGORY ----- Actual cost of program
NUCLEAR POWER PLANTS AND OTHER FUEL FACILITIES

The Department may set and collect an annual fee from persons engaged in the business of producing electricity by utilizing nuclear energy and persons operating facilities for the fabrication of nuclear fuel. The amount of fees collected may not exceed the actual expenses that arise from emergency planning and implementation and environmental surveillance activities.

Comment: Wording for 0400-20-10-.34(2)(b) does not clearly state the type of facilities included in this fee category.

Response: The Department agrees. The wording will be changed to:

Category Nuclear Power Plants and Other Fuel Facilities Actual expenses that arise from emergency planning and implementation and environmental surveillance activities

Comment: 0400-20-10-.34(2)(a) class III equipment should be \$86.00 per tube.

Response: The Department agrees.

Comment: 0400-20-10-.34(2)(b) category 1 should be \$125 instead of \$75 and category 12 should be \$75,000 instead of \$125,000.

Response: The Department agrees.

Comment: Rule 0400-20-10-.34 proposes supplemental fees for 2013 to x-ray registrants and license holders. The fees per tube should be adjusted to just 18% of the total for x-ray registrants who meet the requirements for reduced fees as outlined in 0400-20-10-.24(3)(d).

Response: Subparagraph (3)(d) of Rule 0400-20-10-.24 will apply to the comparable fees of Rule 0400-20-10-.34 for qualified registrants.

Comment: Would the fees associated with staff inspectors/installers/assemblers be per person or per facility? We would like the Division to consider allowing institutions to pay one fee per institution.

- Response: Currently, the fees associated with inspections will be one per person and the fees associated with assembly/installation/servicing will be one per registered entity.
- Comment: Please also consider making changes to 0400-20-10-.27(5)(f). We recognize that this rule has been recently amended. However, we feel the Division's policy regarding penalties and fees for registrants who miss the inspection deadline for an x-ray tube is much more punitive to multi-tube registrants as opposed to single tube registrants in the State. If a single tube registrant misses the inspection deadline, the regulations describe that the 18% discount will not be applicable for that registrant. For multi-tube registrants, we lose the 18% discount for all tubes. Currently, the process allows us to submit a formal appeal to the Division to request that the discount be applied to all other tubes. The appeal process is timely; meanwhile, penalties and fees are compounding on all the tubes possessed by the registrant. The penalties for this rule violation associated with a registrant like the University of Tennessee that possesses approximately 50 tubes is far greater than a veterinary practice with one x-ray tube. We both violated the same rule; however, the disciplinary actions for the multi-tube registrant are much more detrimental. We fully understand and respect the Division's prerogative to assess swift penalties for this rule violation. Our request is if a tube is inspected late, the 18% discount would still automatically apply to all other tubes possessed by the registrant if their inspections are satisfactory to the Division. We also request that the penalties and fees be described to the registrant in the regulations if the inspection does not meet the Division's terms. We understand the Division's need for economic deterrent from future violations. But the civil and criminal penalties described in T.C.A. 68-202-212 are not clear for this situation. Rules similar to those described under T.C.A. 68-202-506(c) for registration violations would be helpful to limit the number of days between the notification of violation and the settlement.
- Response: These comments suggest modifications to rules that are beyond the scope of these amendments. The Department will consider these suggestions for a future rulemaking.
- Comment: Paragraphs (6-20) of Rule 0400-20-10-.31 address fees for licenses, into different categories – both general licenses and then tiered specific licenses. Currently, license fees for general licenses are not assessed for certain institutions possessing a specific license. Your rules do not state any differentiation from current practice, but can you provide assurance that this will still be the case?
- Response: Currently, the Division will not be assessing a general license fee for certain institutions that possess a specific license.
- Comment: Will general license fees be assessed in the same manner as x-ray fees, whereby institutions will be assessed the fee for each registered usage of a general license subject to leak testing or will institutions be assessed one fee for use of any combination of General Licenses?
- Response: Institutions will be assessed one fee for use of any combination of General Licenses.
- Comment: The proposed change to paragraph 0400-20-10-.24(3) eliminates the exemption for registered inspectors and registered assemblers/installers/servicers who are also employees of the registrant for who they are providing the inspection or assembly/installation work therefore subparagraph 0400-20-10-.24(3)(f) should be deleted.
- Response: The Department agrees and will delete subparagraph 0400-20-10-.24(3)(f) and amend 0400-20-10-.24(3)(b) and (c) to delete references to 0400-20-10-.24(3)(f). References to 0400-20-10-.24(3)(f) in 0400-20-10-.34(2)(a) will also be deleted.
- Comment: The proposed new rule 0400-20-10-.34 establishes one-time supplemental fees for calendar year 2013. While the urgent need for additional financial support for the Division to maintain operations is apparent, this approach is impractical in that it creates a new section of regulations

that will only apply for a few months but will linger on in the regulations for far longer, creating confusion and thereby increasing the administrative workload of both the regulated community and the Division. Also, the regulated community will already face considerable difficulty in absorbing the unbudgeted increase in operating expenses represented by these rule changes. Adding these additional one-time fees will make that task more difficult, again diverting time and resources away from the business of maintaining safety and compliance.

Response: The Division of Radiological Health (DRH) has not raised fees since 2001. Every effort has been made to reduce cost before seeking the fee increase. The State General Fund dollars that DRH receives are not adequate to support the services that the Division is obligated to provide by law. DRH must add the supplemental fees in order to maintain these services.

Comment: While the need for these fee increases to maintain the Division's operations is apparent, it must also be acknowledged that societally, these higher fees will increase the costs of health care, and thereby reduce access to health care for uninsured, underinsured, and other members of our community who are facing financial hardships.

Response: The Division of Radiological Health (DRH) has not raised fees since 2001. Every effort has been made to reduce cost before seeking the fee increase. The State General Fund dollars that DRH receives are not adequate to support the services that the Division is obligated to provide by law. DRH must increase fees in order to maintain these services.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

- (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 amended rules will affect small businesses with possession of radioactive material, x-ray equipment, and persons that inspect/assemble/install/service x-ray equipment. The estimated number of small businesses included under these rules is approximately 5,400 facilities.

- (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.

There are no projected additional reporting, recordkeeping or administrative costs as a result of the amendments to the current fee categories. A new fee category has been proposed for programs related to nuclear fuel fabrication and for persons engaged in the business of producing electricity by utilizing nuclear energy. There will be minimal reporting, recordkeeping, and other administrative costs as a result of this fee category.

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

The annual projected revenue increase is approximately \$1,288,000 for all facilities affected by these amendments. The probable effect on small businesses is an increase of approximately \$325,000 which will be divided among approximately 5,400 facilities. For most small businesses, this rule will increase the annual fee amount by \$20 to \$250 per tube for x-ray registrants or per category for radioactive material licensees.

- (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 unaware of alternatives to the proposed rules. The Division has done many things to be fiscally responsible and save money. There are expenses the Division has no control over such as increases in salaries and benefits, rent, the cost of state and leased cars, equipment needed to perform our job duties (e.g., survey instruments, PPE, sample containers, x-ray film). Costs associated with these items have increased since the last time fees were increased, 12 years ago.

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

This fee increase will make the State of Tennessee's fees comparable to other states that have agreement state programs. DRH fees are much lower than the NRC's fees. If the Division does not get this additional revenue, we will not be able to continue this level of oversight and run a significant risk of losing our radiation regulatory program back to the federal government. Since the federal agency's (the NRC) fees are much higher, Tennessee's businesses would be impacted by the increase in fees.

- (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 from regulatory requirements could compromise the Department's oversight ability to protect public health and the environment at these facilities.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The Department anticipates that these amended rules will 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;

This rulemaking affects Chapter 0400-20-10. Its various additions and modifications will incorporate:

- Increasing existing fees listed in Rules 0400-20-10-.24 titled REGISTRATION and 0400-20-10-.31 titled FEES FOR LICENSES.
- Adding a fee for a staff member of a registered facility who performs inspection services or who assembles, installs, or services equipment only for that registrant.
- Adding a fee category for persons operating facilities for the fabrication of nuclear fuel and for persons engaged in the business of producing electricity by utilizing nuclear energy.
- Adding Rule 0400-20-10-.34 to establish a one time supplemental fee assessment for calendar year 2013. Adequate funds are required to facilitate the proper administration of The Radiological Health Service Act and The Medical Radiation Inspection Safety Act. Failure to properly administer these acts threatens the health and safety of the citizens of the state. Operating revenue for the administration of these acts is collected on a calendar year basis. Projected revenue needs of the Division in 2013 cannot be met by current registration and licensing fees. Since a rulemaking to increase 2013 fees could not be completed prior to the first assessment date, January 1, 2013, it was necessary to add this new rule to collect a supplemental fee for calendar year 2013 only.

- (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;

These rules are promulgated under the authorities of T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., 68-203-101 et seq. and 4-5-201 et seq.

- (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;

All licensees and registrants will be affected by these amendments. Comments from these entities did not contain any major rejection of the proposed rules but did contain suggested changes in the proposed language or sought additional clarification.

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

The Department is not aware of any.

- (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;

The annual projected revenue increase is approximately \$1,288,000 for all facilities affected by these amendments. The Division of Radiological Health (DRH) has not raised fees since 2001. Every effort has been made to reduce cost before seeking the fee increase. The State General Fund dollars that DRH receives are not adequate to support the services that the Division is obligated to provide by law. Also, several years ago, the Nuclear Regulatory Commission (the NRC) decided to abolish an environmental monitoring contract between the NRC and state agencies. This contract had previously reimbursed the Division for routine environmental monitoring around the TVA nuclear power plants and Nuclear Fuel Services in Erwin, TN. Therefore, the Division had to come up with ways to cover the costs of this program, such as cutting back on other routine sampling relative to radioactive material licensee sites not related to the original NRC contract.

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

Beth Shelton
Division of Radiological Health
3rd Floor L & C Tower 401 Church Street
Nashville, Tennessee 37243-1532

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

Alan M. Leiserson
Legal Services Director
Office of General Counsel

- (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

Office of General Counsel
Tennessee Department of Environment and Conservation
20th Floor L & C Tower
Nashville, Tennessee 37243-1548
(615) 532-0131
Alan.Leiserson@tn.gov

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

The Department is not aware of any.

Department of State
Division of Publications
 312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower
 Nashville, TN 37243
 Phone: 615-741-2650
 Fax: 615-741-5133
 Email: register.information@tn.gov

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Sequence Number: _____
 Rule ID(s): _____
 File Date: _____
 Effective Date: _____

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

| | |
|---------------------------------|--|
| Agency/Board/Commission: | Environment and Conservation |
| Division: | Radiological Health |
| Contact Person: | Beth Shelton |
| Address: | 3 rd Floor L & C Annex 401 Church Street Nashville, Tennessee |
| Zip: | 37243-1532 |
| Phone: | (615) 532-0364 |
| Email: | beth.shelton@tn.gov |

Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. 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-.24 | Registration |
| 0400-20-10-.31 | Fees for Licenses |
| 0400-20-10-.34 | Supplemental Fees For Calendar Year 2013 |

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

Chapter 0400-20-10
Licensing and Registration

Amendments

Subparagraph (a) of paragraph (3) of Rule 0400-20-10-.24 Registration is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (a) shall read as follows:

(a) Radiation Machines

CLASS I

Dental Radiation Machines: ~~\$ 65.00~~ \$85.00 per tube

All diagnostic equipment used exclusively for dental diagnostic procedures.

CLASS II

Priority Two Medical Radiation Machines: ~~\$450.00~~ \$195.00 per tube

All medical diagnostic x-ray equipment, not in Class III, used exclusively for medical or veterinary diagnostic procedures.

CLASS III

Priority One Medical Radiation Machines: ~~\$200.00~~ \$286.00 per tube

All diagnostic x-ray equipment used in radiologists' offices, orthopedic surgeon's offices or hospitals exclusively for medical diagnostic procedures.

CLASS IV

Therapy Medical Radiation Machines: ~~\$300.00~~ \$390.00 per tube

All x-ray equipment with energies less than 0.9 MeV used for the purpose of medical or veterinary radiation therapy.

CLASS V

Priority Two Industrial and Educational Radiation Machines: ~~\$600.00~~ \$780.00 per tube

Closed-beam analytical radiation machines, gauges or industrial radiation machines used in shielded room or cabinet radiography.

CLASS VI

Priority One Industrial and Educational Radiation Machines: ~~\$900.00~~ \$1,170.00 per tube

All x-ray machines used for industrial radiography and all open-beam analytical x-ray machines and all radiation machines not specifically included in Class I, II, III, IV, V, VII.

CLASS VII

Accelerators: ~~\$2,000.00~~ \$2,600.00 annual fee, plus an initial fee of \$375.00 per maximum nominal rated MeV for initial certified registration review (initial review fee not to exceed \$150,000.00)

All devices defined as accelerators as per "State Regulations for Protection Against Radiation."

Subparagraph (b) of paragraph (3) of Rule 0400-20-10-.24 Registration is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (b) shall read as follows:

(b) ~~A person providing assembly/installation/servicing, except as provided by subparagraph (3)(f) of Rule 0400-20-10-.24, shall pay an annual registration fee of six hundred dollars.~~ ~~\$600.00~~ \$850.00 A person providing inspection services as permitted by paragraph (4) of Rule 0400-20-10-.27 shall pay an annual registration fee of eight hundred fifty dollars.

Subparagraph (c) of paragraph (3) of Rule 0400-20-10-.24 Registration is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (c) shall read as follows:

(c) ~~A person providing assembly/installation/servicing, except as provided by subparagraph (3)(f) of Rule 0400-20-10-.24, shall pay an annual registration fee of six hundred fifty dollars.~~ ~~\$600.00~~ \$850.00 A person providing assembly/installation/servicing, except as provided by subparagraph (3)(f) of Rule 0400-20-10-.24, shall pay an annual registration fee of eight hundred fifty dollars.

Subparagraph (f) of paragraph (3) of Rule 0400-20-10-.24 Registration is amended by deleting it in its entirety.

~~(f) A person providing inspection services, as permitted by paragraph (4) of Rule 0400-20-10-.27, or a person providing assembly/installation/servicing, who is a staff member of the facility registered pursuant to Tennessee Code Annotated (T.C.A.) § 68-202-101 et seq. and these Regulations, and who performs such inspection services or assembly/installation/servicing only for that registrant, shall not be subject to subparagraphs (b) and (c) above.~~

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

Paragraph (6) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$150.00" from the paragraph and replacing it with "\$350.00" so that, as amended, paragraph (6) shall read as follows:

(6) CATEGORY GL -----~~\$150.00~~ \$350.00

Any person possessing radioactive material, under the terms of any general license issued these regulations, in a form or device on which a test for leakage of radioactive material is required.

Paragraph (7) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$300.00" from the paragraph and replacing it with "\$425.00" so that, as amended, paragraph (7) shall read as follows:

(7) CATEGORY 1 -----~~\$300.00~~ \$425.00

A specific license for source material used exclusively for shielding radiation.

Paragraph (8) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$600.00" from the paragraph and replacing it with "\$850.00" so that, as amended, paragraph (8) shall read as follows:

(8) CATEGORY 2 -----~~\$600.00~~ \$850.00

(a) Reserved.

- (b) The application, use or possession of radioactive material as chromatography sources or gauges not requiring assignment to another category.
- (c) The application, use or possession of radioactive material for in vitro use only, total quantity not to exceed 200 microcuries.
- (d) Any person who packages or containerizes, loads transport vehicles or ships radioactive materials to a licensed disposal/processing facility in Tennessee. In addition to application and annual maintenance fees, there is also a levied fee of two cents per pound (\$0.02/lb) on all items contaminated or potentially contaminated with radioactive material or on low-level radioactive waste received at a processing, storage, disposal or refurbishing facility in Tennessee.

Notwithstanding the requirements of this paragraph and Rule 0400-20-10-.32, licensees with multiple sites within the state will be levied only one fee if items are moved directly from one site to another.

The operator of the disposal/processing facility shall collect the fee of two cents per pound (\$0.02/lb). For each calendar month, he shall remit the total of fees collected for the month to the Division of Radiological Health by the 25th day of the following month.

- (e) The application, use or possession of radioactive material for the calibration for hire of radiation detection, monitoring and measuring instruments.
- (f) The performance for hire of leak tests on sealed sources of radioactive material.

Paragraph (9) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$900.00" from the paragraph and replacing it with "\$1170.00" so that, as amended, paragraph (9) shall read as follows:

(9) CATEGORY 3 -----~~\$900.00~~ \$1,170.00

- (a) The application, use or possession of radioactive material, unless specific to a higher numbered category, by an academic institution, but does not include licenses authorizing all radioisotopes with atomic number 3 through 83.
- (b) The possession and use of radioactive material for civil defense activities.
- (c) The application, use or possession of radioactive material by a medical, institution or physicians for use in radiopharmaceuticals for the diagnosis or therapy of humans.
- (d) Reserved.
- (e) Reserved.
- (f) Reserved.
- (g) The application, use or possession of radioactive material for demonstration or training purposes.
- (h) The application, use or possession of radioactive material for in vitro use only, total quantity exceeding 200 microcuries.

- (i) The use of sealed sources for soil and/or construction materials testing at temporary job-sites by licensees with licensed authorization for no more than two (2) devices.
- (j) The use of radioactive material as chromatography sources at temporary job-sites by licensees with licensed authorization for no more than two (2) devices.
- (k) The use of gauging and measuring devices at temporary job-sites by licensees with licensed authorization for no more than two (2) devices.

Paragraph (10) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$1500.00" from the paragraph and replacing it with "\$1950.00" so that, as amended, paragraph (10) shall read as follows:

- (10) CATEGORY 4 ----- ~~\$1,500.00~~ \$1,950.00
- (a) The application, use or possession of radioactive material by a medical institution or physicians for interstitial, intracavitary or superficial treatment of humans using sealed sources, seeds or wires.
 - (b) The application, use or possession of radioactive material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-contained irradiators).
 - (c) The application, use or possession of radioactive material for analytical testing purposes.

Paragraph (11) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$2100.00" from the paragraph and replacing it with "\$2730.00" so that, as amended, paragraph (11) shall read as follows:

- (11) CATEGORY 5 ----- ~~\$2,100.00~~ \$2,730.00
- (a) The use of radioactive material in research and development, manufacturing, testing, processing and assembling of products. This group includes the use of source material in the manufacture of items such as mantles, alloys, gases, liquids, metals, ceramics, glass or photographic products.
 - (b) The use of radioactive material in a process that incorporates that material into a product in exempt concentrations.
 - (c) The possession and use of radioactive material in curie quantities in a number of sources in gauges and gauging applications that require frequent changes and therefore frequent review of the program to ensure that the hazard potential does not exceed the scope of the radiation safety program.
 - (d) The use of a single radioactive material in the fabrication of sealed sources or ampoules.
 - (e) The receipt of prepackaged radioactive material waste from other persons by a nuclear waste handler for storage for less than three (3) months before, transfer only to persons licensed to receive or dispose of the material.
 - (f) The use of sealed sources for soil and/or construction materials testing at temporary job-sites by licensees with licensed authorization for more than two (2) devices.

- (g) The use of radioactive material as chromatography sources at temporary job-sites by licensees with licensed authorization for more than two (2) devices.
- (h) The use of gauging and measuring devices at temporary job-sites by licensees with licensed authorization for more than two (2) devices.
- (i) The application, use or possession of radioactive material by a medical institution or physicians for the treatment of humans with sealed sources contained in teletherapy devices.
- (j) The application, use or possession of radioactive material by a veterinarian for the treatment of animals using sealed sources, seeds or wires.

Paragraph (12) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$6,000.00" from the paragraph and replacing it with "\$7,800.00" so that, as amended, paragraph (12) shall read as follows:

(12) CATEGORY 6 -----~~\$6,000.00~~ \$7,800.00

- (a) The application, use or possession of radioactive material including source and/or special nuclear material in unsealed form in less than multi-curie quantities for use in the fabrication of sealed sources without regard to amount of contained radioactivity.
- (b) The manufacture of devices and/or sources that require in-depth review before approval by the Division. Each device and/or source reviewed shall be subject to this fee.
- (c) The preparation, use or distribution of radiopharmaceuticals to locations other than the licensee's address for use in medical diagnosis or therapy.
- (d) The use of radiography (the examination of the structure of materials by nondestructive methods using radioactive material) on the licensee's premises in a permanent shielded facility or temporary job-sites.
- (e) The possession and use of radioactive material by academic and medical institutions under a license authorizing all radioisotopes with atomic numbers 3 through 83.
- (f) Reserved.
- (g) The application of radioactive material to soil, water, air, plants and animals, if the application involves an actual or potential release in or to unrestricted areas.
- (h) The possession, use and distribution of radioactive material at one or more satellite facilities, or the possession and use of radioactive material at one or more satellite facilities, by medical institutions.
- (i) The application, use or possession of radioactive material by a medical institution or physicians for research using humans and/or animals.

Paragraph (13) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$4,000.00" from the paragraph and replacing it with "\$5,200.00" so that, as amended, paragraph (13) shall read as follows:

(13) CATEGORY 7 -----~~\$4,000.00~~ \$5,200.00

- (a) Reserved.
- (b) Reserved.

- (c) The application, use or possession of radioactive material for well logging, well surveys or tracer studies.

Paragraph (14) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$11,250.00" from the paragraph and replacing it with "\$14,625.00" so that, as amended, paragraph (14) shall read as follows:

- (14) CATEGORY 8 -----~~\$11,250.00~~ \$14,625.00
 - (a) The receipt of radioactive material waste from other persons by a nuclear waste handler, for the purpose of packaging or repackaging the material prior to transfer only to persons licensed to receive or dispose of the material.
 - (b) The commercial collection, laundering or dry cleaning of wearing apparel that is contaminated with radioactive material.

Paragraph (15) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$15,000.00" from the paragraph and replacing it with "\$19,500.00" so that, as amended, paragraph (15) shall read as follows:

- (15) CATEGORY 9 -----~~\$15,000.00~~ \$19,500.00
 - (a) The possession of radioactive material or equipment contaminated or potentially contaminated with radioactive material as a result of operations involving the recovery of an element, compound or mixture from ores not subject to licensure because of the radioactive material content of the ore.
 - (b) Facilities that possess radioactive material as a result of operations (not directly involving radioactive decontamination activities) involving recovery of materials or other manufacturing processes (not directly manufacturing radioactive items or products).

Paragraph (16) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$22,500.00" from the paragraph and replacing it with "\$27,000.00" so that, as amended, paragraph (16) shall read as follows:

- (16) CATEGORY 10 -----~~\$22,500.00~~ \$27,000.00
 - (a) Facilities storing radioactive material, contaminated equipment and/or potentially contaminated equipment for transfer to authorized recipients as a service to the nuclear industry.
 - (b) Possession and refurbishment of contaminated equipment and/or potentially contaminated equipment that has been used at nuclear power plants.

Paragraph (17) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$30,000.00" from the paragraph and replacing it with "\$36,000.00" so that, as amended, paragraph (17) shall read as follows:

- (17) CATEGORY 11 -----~~\$30,000.00~~ \$36,000.00
 - (a) The collection, transfer, sorting and/or brokerage of radioactive material as sealed source, residue, product or as material in or on equipment; and/or

The decontamination of products and/or equipment containing radioactive material and/or contaminated with radioactive material; and/or

The possession, storage and incineration of radioactive material or items contaminated with radioactive materials.

- (b) On site possession and storage of radioactive material and/or equipment contaminated with radioactive material as a result of operations involving the recovery of an element, compound or mixture from ores subject to licensure because of the radioactive material content of the ore or concentration of the radioactive material during the processing of the ore.
- (c) Facilities involved in the manufacture of product lines containing radioactive material in the manufactured product.
- (d) Possession of radioactive material for processing. This material may exist in ores, concentrates, compounds or metals.
- (e) The possession of multi-curie quantities of unsealed radioactive material either as waste or for further processing and/or conversion into specific marketable products.
- (f) Operations involving the fabrication of sealed sources or manufacture of compounds for distribution to other specific or general licensees.
- (g) The possession and use of radioactive material in a sealed source for irradiation of materials in which the source is exposed for irradiation purposes (non self-contained irradiators).

Paragraph (18) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$375,000.00" from the paragraph and replacing it with "\$450,000.00" so that, as amended, paragraph (18) shall read as follows:

- (18) CATEGORY 12 ----- ~~\$375,000.00~~ \$450,000.00
- (a) The application for and/or operation of a low-level radioactive waste disposal facility.
 - (b) The maximum length of reviewing time (the period of time when there are no outstanding unanswered questions) after receipt of a new application and the appropriate fee for a Category 12 specific license and the issuance of a license is 60 months.

Paragraph (19) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting "\$150.00" from the paragraph and replacing it with "\$200.00" so that, as amended, paragraph (19) shall read as follows:

- (19) CATEGORY 13 ----- At least
~~\$150.00~~ \$200.00 not
greater than
\$375,000.00
- The application, use or possession of radioactive material for uses or procedures not specifically included in any other category.
- The fee shall be determined on a case-by-case basis.
- The determination shall be based on an analysis of the hazard, the scope of the difficulty encountered in the review process and the specifics of the activity pursuant to the categories established above in paragraphs (6) through (18) of this rule.

Rule 0400-20-10-.31 Fees for Licenses is amended by adding paragraph (20) so that, as amended, paragraph (20) shall read as follows:

- (20) CATEGORY NUCLEAR POWER PLANTS AND OTHER FUEL FACILITIES ----- Actual cost of program

The Department may set and collect an annual fee from persons engaged in the business of producing electricity by utilizing nuclear energy and persons operating facilities for the fabrication of nuclear fuel. The amount of fees collected may not exceed the actual expenses that arise from emergency planning and implementation and environmental surveillance activities.

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

Chapter 0400-20-10
Licensing and Registration

New Rules

Chapter 0400-20-10 Licensing and Registration is amended by adding 0400-20-10-.34 that shall have the title Supplemental Fees for the Calendar year 2013 and contains the following:

0400-20-10-.34 Supplemental Fees for Calendar Year 2013

(1) Purpose

Adequate funds are required to facilitate the proper administration of The Radiological Health Service Act and The Medical Radiation Inspection Safety Act. Failure to properly administer these acts threatens the health and safety of the citizens of the state. Operating revenue for the administration of these acts is collected on a calendar year basis. Projected revenue needs of the Division in 2013 cannot be met by current registration and licensing fees. Rulemaking to increase 2013 fees cannot be completed prior to the first assessment date, January 1, 2013. Therefore, one time supplemental fees are hereby established to provide the Division with additional revenue during Calendar Year 2013. Division invoices will establish due dates for payment of these supplemental fees.

(2) Supplemental Fees Schedules

(a) In addition to the fees established in paragraph (3) of Rule 0400-20-10-.24 Registration, persons subject to registration anytime during Calendar Year 2013 shall pay a supplemental fee to be determined according to Schedule I of this paragraph:

SCHEDULE I

| | |
|--|--------------------------|
| <u>Class I Equipment</u> | <u>\$20.00 per tube</u> |
| <u>Class II Equipment</u> | <u>\$45.00 per tube</u> |
| <u>Class III Equipment</u> | <u>\$86.00 per tube</u> |
| <u>Class IV Equipment</u> | <u>\$90.00 per tube</u> |
| <u>Class V Equipment</u> | <u>\$180.00 per tube</u> |
| <u>Class VI Equipment</u> | <u>\$270.00 per tube</u> |
| <u>Class VII Equipment</u> | <u>\$600.00 per tube</u> |
| <u>A person providing inspection services under paragraph (4) of Rule 0400-20-10-.27</u> | <u>\$250.00</u> |
| <u>A person providing assembly/installation/servicing</u> | <u>\$250.00</u> |

(b) In addition to the fees established in paragraphs (6) through (19) of Rule 0400-20-10-.31 Fees for Licenses, persons subject to licensure anytime during Calendar Year 2013 shall pay a supplemental fee to be determined according to Schedule II of this paragraph:

SCHEDULE II

| | |
|--------------------|---|
| <u>Category G1</u> | <u>\$200.00</u> |
| <u>Category 1</u> | <u>\$125.00</u> |
| <u>Category 2</u> | <u>\$250.00</u> |
| <u>Category 3</u> | <u>\$270.00</u> |
| <u>Category 4</u> | <u>\$450.00</u> |
| <u>Category 5</u> | <u>\$630.00</u> |
| <u>Category 6</u> | <u>\$1,800.00</u> |
| <u>Category 7</u> | <u>\$1,200.00</u> |
| <u>Category 8</u> | <u>\$3,375.00</u> |
| <u>Category 9</u> | <u>\$4,500.00</u> |
| <u>Category 10</u> | <u>\$4,500.00</u> |
| <u>Category 11</u> | <u>\$6,000.00</u> |
| <u>Category 12</u> | <u>\$75,000.00</u> |
| <u>Category 13</u> | <u>At least \$50.00 and not greater than \$125,000.00</u> |

The Category 13 supplemental fee shall be determined on a case-by-case basis. The determination shall be based on an analysis of the hazard, the scope of the difficulty encountered in the review process and the specifics of the activity, following the categories established in paragraphs (6) through (19) of Rule 0400-20-10-.31.

Category Nuclear Power Plants and Other Fuel Facilities Actual expenses that arise from emergency planning and implementation and environmental surveillance activities

Authority: T.C.A. §§ 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 of the Tennessee Department of Environment and Conservation on 01/31/2013, 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: 11/26/12

Rulemaking Hearing(s) Conducted on: (add more dates). 01/23/13

Date: _____

Signature: _____

Name of Officer: Robert J. Martineau, Jr.

Title of Officer: Commissioner

Subscribed and sworn to before me on: _____

Notary Public Signature: _____

My commission expires on: _____

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.

Robert E. Cooper, Jr.
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 containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

Comment: Wording for 0400-20-10-.31(20) does not clearly state the type of facilities included in this fee category.

Response: The Department agrees. Wording for 0400-20-10-.31(20) will be changed to:

(20) CATEGORY ----- Actual cost of program
NUCLEAR POWER PLANTS AND OTHER FUEL FACILITIES

The Department may set and collect an annual fee from persons engaged in the business of producing electricity by utilizing nuclear energy and persons operating facilities for the fabrication of nuclear fuel. The amount of fees collected may not exceed the actual expenses that arise from emergency planning and implementation and environmental surveillance activities.

Comment: Wording for 0400-20-10-.34(2)(b) does not clearly state the type of facilities included in this fee category.

Response: The Department agrees. The wording will be changed to:

Category Nuclear Power Plants and Other Fuel Facilities Actual expenses that arise from emergency planning and implementation and environmental surveillance activities

Comment: 0400-20-10-.34(2)(a) class III equipment should be \$86.00 per tube.

Response: The Department agrees.

Comment: 0400-20-10-.34(2)(b) category 1 should be \$125 instead of \$75 and category 12 should be \$75,000 instead of \$125,000.

Response: The Department agrees.

Comment: Rule 0400-20-10-.34 proposes supplemental fees for 2013 to x-ray registrants and license holders. The fees per tube should be adjusted to just 18% of the total for x-ray registrants who meet the requirements for reduced fees as outlined in 0400-20-10-.24(3)(d).

Response: Subparagraph (3)(d) of Rule 0400-20-10-.24 will apply to the comparable fees of Rule 0400-20-10-.34 for qualified registrants.

Comment: Would the fees associated with staff inspectors/installers/assemblers be per person or per facility? We would like the Division to consider allowing institutions to pay one fee per institution.

- Response: Currently, the fees associated with inspections will be one per person and the fees associated with assembly/installation/servicing will be one per registered entity.
- Comment: Please also consider making changes to 0400-20-10-.27(5)(f). We recognize that this rule has been recently amended. However, we feel the Division's policy regarding penalties and fees for registrants who miss the inspection deadline for an x-ray tube is much more punitive to multi-tube registrants as opposed to single tube registrants in the State. If a single tube registrant misses the inspection deadline, the regulations describe that the 18% discount will not be applicable for that registrant. For multi-tube registrants, we lose the 18% discount for all tubes. Currently, the process allows us to submit a formal appeal to the Division to request that the discount be applied to all other tubes. The appeal process is timely; meanwhile, penalties and fees are compounding on all the tubes possessed by the registrant. The penalties for this rule violation associated with a registrant like the University of Tennessee that possesses approximately 50 tubes is far greater than a veterinary practice with one x-ray tube. We both violated the same rule; however, the disciplinary actions for the multi-tube registrant are much more detrimental. We fully understand and respect the Division's prerogative to assess swift penalties for this rule violation. Our request is if a tube is inspected late, the 18% discount would still automatically apply to all other tubes possessed by the registrant if their inspections are satisfactory to the Division. We also request that the penalties and fees be described to the registrant in the regulations if the inspection does not meet the Division's terms. We understand the Division's need for economic deterrent from future violations. But the civil and criminal penalties described in T.C.A. 68-202-212 are not clear for this situation. Rules similar to those described under T.C.A. 68-202-506(c) for registration violations would be helpful to limit the number of days between the notification of violation and the settlement.
- Response: These comments suggest modifications to rules that are beyond the scope of these amendments. The Department will consider these suggestions for a future rulemaking.
- Comment: Paragraphs (6-20) of Rule 0400-20-10-.31 address fees for licenses, into different categories – both general licenses and then tiered specific licenses. Currently, license fees for general licenses are not assessed for certain institutions possessing a specific license. Your rules do not state any differentiation from current practice, but can you provide assurance that this will still be the case?
- Response: Currently, the Division will not be assessing a general license fee for certain institutions that possess a specific license.
- Comment: Will general license fees be assessed in the same manner as x-ray fees, whereby institutions will be assessed the fee for each registered usage of a general license subject to leak testing or will institutions be assessed one fee for use of any combination of General Licenses?
- Response: Institutions will be assessed one fee for use of any combination of General Licenses.
- Comment: The proposed change to paragraph 0400-20-10-.24(3) eliminates the exemption for registered inspectors and registered assemblers/installers/servicers who are also employees of the registrant for who they are providing the inspection or assembly/installation work therefore subparagraph 0400-20-10-.24(3)(f) should be deleted.
- Response: The Department agrees and will delete subparagraph 0400-20-10-.24(3)(f) and amend 0400-20-10-.24(3)(b) and (c) to delete references to 0400-20-10-.24(3)(f). References to 0400-20-10-.24(3)(f) in 0400-20-10-.34(2)(a) will also be deleted.
- Comment: The proposed new rule 0400-20-10-.34 establishes one-time supplemental fees for calendar year 2013. While the urgent need for additional financial support for the Division to maintain operations is apparent, this approach is impractical in that it creates a new section of regulations

that will only apply for a few months but will linger on in the regulations for far longer, creating confusion and thereby increasing the administrative workload of both the regulated community and the Division. Also, the regulated community will already face considerable difficulty in absorbing the unbudgeted increase in operating expenses represented by these rule changes. Adding these additional one-time fees will make that task more difficult, again diverting time and resources away from the business of maintaining safety and compliance.

Response: The Division of Radiological Health (DRH) has not raised fees since 2001. Every effort has been made to reduce cost before seeking the fee increase. The State General Fund dollars that DRH receives are not adequate to support the services that the Division is obligated to provide by law. DRH must add the supplemental fees in order to maintain these services.

Comment: While the need for these fee increases to maintain the Division's operations is apparent, it must also be acknowledged that societally, these higher fees will increase the costs of health care, and thereby reduce access to health care for uninsured, underinsured, and other members of our community who are facing financial hardships.

Response: The Division of Radiological Health (DRH) has not raised fees since 2001. Every effort has been made to reduce cost before seeking the fee increase. The State General Fund dollars that DRH receives are not adequate to support the services that the Division is obligated to provide by law. DRH must increase fees in order to maintain these services.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

- (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 amended rules will affect small businesses with possession of radioactive material, x-ray equipment, and persons that inspect/assemble/install/service x-ray equipment. The estimated number of small businesses included under these rules is approximately 5,400 facilities.

- (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.

There are no projected additional reporting, recordkeeping or administrative costs as a result of the amendments to the current fee categories. A new fee category has been proposed for programs related to nuclear fuel fabrication and for persons engaged in the business of producing electricity by utilizing nuclear energy. There will be minimal reporting, recordkeeping, and other administrative costs as a result of this fee category.

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

The annual projected revenue increase is approximately \$1,288,000 for all facilities affected by these amendments. The probable effect on small businesses is an increase of approximately \$325,000 which will be divided among approximately 5,400 facilities. For most small businesses, this rule will increase the annual fee amount by \$20 to \$250 per tube for x-ray registrants or per category for radioactive material licensees.

- (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 unaware of alternatives to the proposed rules. The Division has done many things to be fiscally responsible and save money. There are expenses the Division has no control over such as increases in salaries and benefits, rent, the cost of state and leased cars, equipment needed to perform our job duties (e.g., survey instruments, PPE, sample containers, x-ray film). Costs associated with these items have increased since the last time fees were increased, 12 years ago.

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

This fee increase will make the State of Tennessee's fees comparable to other states that have agreement state programs. DRH fees are much lower than the NRC's fees. If the Division does not get this additional revenue, we will not be able to continue this level of oversight and run a significant risk of losing our radiation regulatory program back to the federal government. Since the federal agency's (the NRC) fees are much higher, Tennessee's businesses would be impacted by the increase in fees.

- (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 from regulatory requirements could compromise the Department's oversight ability to protect public health and the environment at these facilities.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The Department anticipates that these amended rules will 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;

This rulemaking affects Chapter 0400-20-10. Its various additions and modifications will incorporate:

- Increasing existing fees listed in Rules 0400-20-10-.24 titled REGISTRATION and 0400-20-10-.31 titled FEES FOR LICENSES.
- Adding a fee for a staff member of a registered facility who performs inspection services or who assembles, installs, or services equipment only for that registrant.
- Adding a fee category for persons operating facilities for the fabrication of nuclear fuel and for persons engaged in the business of producing electricity by utilizing nuclear energy.
- Adding Rule 0400-20-10-.34 to establish a one time supplemental fee assessment for calendar year 2013. Adequate funds are required to facilitate the proper administration of The Radiological Health Service Act and The Medical Radiation Inspection Safety Act. Failure to properly administer these acts threatens the health and safety of the citizens of the state. Operating revenue for the administration of these acts is collected on a calendar year basis. Projected revenue needs of the Division in 2013 cannot be met by current registration and licensing fees. Since a rulemaking to increase 2013 fees could not be completed prior to the first assessment date, January 1, 2013, it was necessary to add this new rule to collect a supplemental fee for calendar year 2013 only.

- (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;

These rules are promulgated under the authorities of T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., 68-203-101 et seq. and 4-5-201 et seq.

- (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;

All licensees and registrants will be affected by these amendments. Comments from these entities did not contain any major rejection of the proposed rules but did contain suggested changes in the proposed language or sought additional clarification.

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

The Department is not aware of any.

- (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;

The annual projected revenue increase is approximately \$1,288,000 for all facilities affected by these amendments. The Division of Radiological Health (DRH) has not raised fees since 2001. Every effort has been made to reduce cost before seeking the fee increase. The State General Fund dollars that DRH receives are not adequate to support the services that the Division is obligated to provide by law. Also, several years ago, the Nuclear Regulatory Commission (the NRC) decided to abolish an environmental monitoring contract between the NRC and state agencies. This contract had previously reimbursed the Division for routine environmental monitoring around the TVA nuclear power plants and Nuclear Fuel Services in Erwin, TN. Therefore, the Division had to come up with ways to cover the costs of this program, such as cutting back on other routine sampling relative to radioactive material licensee sites not related to the original NRC contract.

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

Beth Shelton
Division of Radiological Health
3rd Floor L & C Tower 401 Church Street
Nashville, Tennessee 37243-1532

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

Alan M. Leiserson
Legal Services Director
Office of General Counsel

- (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

Office of General Counsel
Tennessee Department of Environment and Conservation
20th Floor L & C Tower
Nashville, Tennessee 37243-1548
(615) 532-0131
Alan.Leiserson@tn.gov

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

The Department is not aware of any.