

**Department of State  
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Sequence Number: 09-24-14  
Rule ID(s): 5804  
File Date: 9-25-14  
Effective Date: 12-24-14

## 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).*

<b>Agency/Board/Commission:</b>	Environment and Conservation
<b>Division:</b>	Radiological Health
<b>Contact Person:</b>	Roger Fenner
<b>Address:</b>	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 15 <sup>th</sup> Floor Nashville, Tennessee
<b>Zip:</b>	37243
<b>Phone:</b>	(615) 532-0404
<b>Email:</b>	<a href="mailto:Roger.Fenner@tn.gov">Roger.Fenner@tn.gov</a>

**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

(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

Paragraph (2) of Rule 0400-20-10-.24 Registration is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (2) shall read as follows:

- (2) An annual registration fee will be required each year as long as the radiation machine or service is subject to registration. Each registrant shall submit the annual fee payable to, "Treasurer, State of Tennessee," in the appropriate dollar amount in accordance with the Classification and Fee Schedule in paragraph (3) of this rule to the Division of Radiological Health. Payment shall be accompanied by a copy of the fee invoice properly completed. The invoice for the annual fee will be dated May 1<sup>st</sup> and will require payment by June 15<sup>th</sup> of the indicated year. The annual registration fee shall be due within 45 days of issuance of an invoice. At the time of the annual payment, a registrant of only Class II radiation machines may request specific times or list restricted hours during normal work hours for inspections pursuant to Rule 0400-20-10-27 by personnel of the Division of Radiological Health, Tennessee Department of Environment and Conservation.

Part 2 of subparagraph (d) of paragraph (3) of Rule 0400-20-10-.24 Registration is amended by deleting the paragraph and substituting the following so that, as amended, part 2 shall read as follows:

2. Each newly acquired tube subject to registration is inspected within 3 months of ownership or possession.

Authority: T.C.A. §§ 68-202-101 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 08/28/2014 (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: (06/25/14)

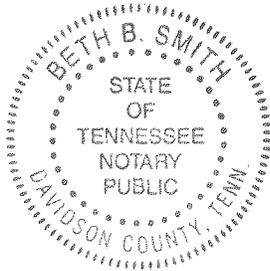
Rulemaking Hearing(s) Conducted on: (add more dates). (08/19/14)

Date: 8/28/14

Signature: Robert J. Martineau

Name of Officer: Robert J. Martineau, Jr.

Title of Officer: Commissioner



My Commission Expires JULY 6, 2015

Subscribed and sworn to before me on: 8.28-14

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

9-23-14  
Date

**Department of State Use Only**

Filed with the Department of State on: 9-25-14

Effective on: 12-24-14

Tre Hargett  
Tre Hargett  
Secretary of State

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2014 SEP 25 PM 3:09  
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: The Tennessee Hospital Association, the Tennessee Medical Association, and the Tennessee Dental Association all responded to the Department's notice of rulemaking that they did not have any concerns regarding the amendments being made to this rule and did not have any formal comments to submit.

Response: Comments so noted.

Comment: The commenter suggested certain changes be made to the computer programs of the Division of Radiological Health and Fiscal Services. He believes these changes would make the process easier without having to make the amendments to the rule that the Department is proposing. His written comments are included below:

### January Bill:

1. Sets "Annual" flag
  - a. R.I. sign up entire year with all of R.I. Program stipulations.
  - b. Sign up for total bill does not allow changing mind "later". (e.g. no funds brought forward)
  - c. Contingency on "failure"
2. Additional machines generate "Date of Possession" flag
  - a. Must pay 18% (but option given to give up 82% for full year)
  - b. Registrant reminded of "6 months" for inspection or "failure" for year

### R.I. Section of DRH:

"Annual" Flag gives prompt 60d from January 31, which initiates OK (clear flag), extension, or failure. Failures go to Fee Section for collection of 82% and cancel 18%

### Additional machines:

"Date of Possession" flag gives prompt 60d from 6 months from "Date of Possession", which initiates OK (clear flag), extension or failure. Failures go to Fee Section for collection of 82% and cancel 18%.

Would deal with "omission" of proper R.I. form on case-by-case basis for changing failure.

- Benefit:
1. Registrant is responsible!
  2. Allows collection of 82% on failure
  3. Doesn't delay 2015 bills to May - \$ lost to State

- Drawbacks:
1. Slightly more computer programming
  2. Keeps 6 months instead of 2 months for additional machines
  3. It is at 1st bill in January that different classes are addressed
  4. Facilities must keep registration up to date, not State
  5. How to address "non-functioning" and "in storage" on initial R.I.

Response: These suggestions are not compatible with the Division of Radiological Health's DRH track computer program and Fiscal Services' GIA computer program and would be difficult to implement. To make these types of changes to these computer programs, much additional work on the part of Information Systems, Fiscal Services, and the Division would be required. These amendments to the rules will not affect the Division's budget. Fees will be collected within the same fiscal year, therefore there will not be a loss of money to the state.

Comment: Two Commenters suggested amendments to Rule 0400-20-10-.24(3)(d). A written comment concerning this rule was submitted:

My name is Ben Edwards. I am the Radiation Safety Officer for Vanderbilt University and the Vanderbilt University Medical Center.

I first want to acknowledge the critical importance of the Division of Radiological Health. The Division's duty of protecting Tennesseans and the environment from the hazards associated with ionizing radiation is an essential function that must be adequately supported.

With regard to the proposed rule changes, I have the following comment:

The proposed changes to Chapter 0400-20-10 do not address the most problematic item in that chapter. Rule 0400-20-10-.24 paragraph (3) subparagraph (d) allows registrants to pay 18% of the full registration fee only if ALL of the x-ray tubes on the registration have been inspected on time. However, if any x-ray tube is inspected late, regardless of the reason, the full fee is assessed for not only the late tube but for ALL tubes on the registration. As written, this rule:

- penalizes registrations with large number of tubes
- creates a penalty that is disproportionate to the infraction, and
- establishes a regulation that is arcane, difficult for new program managers and radiation safety officers to understand, and inconsistent with the corresponding regulations in other states.

The Division has demonstrated a willingness to consider written appeals of full registration fees imposed under this rule. However, pursuing the appeals process creates additional administrative work for both the registrant and the Division, diverting time and resources away from the more important business of ensuring safety and regulatory compliance. Similarly, this Rule encourages institutions to split their x-ray tubes into as many registrations as possible simply to reduce their vulnerability, again creating additional administrative work for the registrant and the Division with no safety or compliance benefit. To address this problem, I propose the amendment of Rules 0400-20-10-.24(3)(d) and 0400-20-10-.24(3)(d)1 to read **[changes in bold]**:

0400-20-10-.24(3)(d) A registrant may qualify to pay a registration fee equal to 18 percent of that listed in this paragraph **for any tube that meets** the following conditions:

1. **Any** tube subject to registration **is** inspected in accordance with paragraphs (3), (4), and (5) of Rule 0400-20-10-.27.

Response: These comments suggest modifications to rules that are beyond the scope of these amendments. The Department plans to explore how these suggested amendments would affect the Division and will consider these suggestions for a future rulemaking.

Comment: The proposed time frame to have newly purchased x-ray tubes inspected is not enough time for the facilities to have the inspection completed. The current time frame is six months. The proposed rule decreases this to two months. This could create a burden on the medical physicist as they still have to complete their inspections of the regular x-ray tubes. Changing the proposed time frame to three months would provide a more ideal amount of time. If this proposal is necessary from a billing perspective, it is suggested that rule 0400-20-10-.24(3)(d) be amended to charge full fee on only the x ray units that are not in compliance with reduced fee rules.

Response: This comment covers two separate components. The portion of this comment that suggests amendments to 0400-20-10-.24(3)(d) is beyond the scope of these amendments; however, the

Department plans to explore how this suggested amendment would affect the Division and will consider the changes for a future rulemaking. The other portion of this comment suggests that the time frame for inspection of new x-ray tubes be changed from 2 months as proposed to 3 months. The Division agrees with this comment and will incorporate it into the proposed rules.

Comment: Registrants have a requirement to register their x-ray units within ten days of getting the x-ray unit. Previously had a requirement to get them inspected within six months. Now the Division is proposing two months. In the past, registrants have had trouble receiving their registration back from the state within the six month time frame. We realize that the Division has had staffing issues but if you move it to two months, since they are required to have the registration in hand during the inspection, the Division needs to ensure that registrants receive their registration back within a timely manner (e.g. two weeks).

Response: Inspections may be performed by a Registered Inspector prior to the registrant receiving the registration form from the Department. The Registered Inspector may note on the inspection form that the registration is pending.

Comment: I believe 90 to 120 day post install time frame would be better served. The March 17th date is feasible. I believe most facilities schedule inspections around their patient/personnel schedules. Not opposed to changes but don't see that they would improve anything. Sites should be able to utilize the discounts as this can be large expense for small businesses.

Response: The January 17th invoicing date does not give Department staff enough time to review and process inspection reports received late in the year. By adopting the May 1<sup>st</sup> invoicing date, the Department staff should have ample time to review inspection reports and enter the information into the database that Fiscal Services uses to invoice. This will allow Fiscal Services to send an accurate invoice to the registrants who qualify for a reduction in fees. Billing would be improved for customers because it would allow most customers invoiced for correct fee. The number of customers receiving invoices will be substantially reduced. The Division has decided to extend the proposed time frame for a new x-ray tube to be inspected from 2 months to 3 months.

### **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 rule will affect small businesses with possession of x-ray producing equipment, and persons that inspect x-ray equipment. The estimated number of small businesses included under these rules is approximately 5,000 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.

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

These amendments are being made in response to feedback from internal and external stakeholders. Many of these stakeholders are small businesses. These amendments will provide a better invoicing process affecting these businesses in a positive manner.

- (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. These amendments are being made in response to feedback from internal and external stakeholders.

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

There are no federal or state counterpart rules to compare.

- (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.

Exempting small businesses from this proposed rule would result in denying them of the benefits it offers.

## **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 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;

Two subdivisions of Rule 0400-20-10-.24 regarding registration of radiation machines and services and inspection of newly acquired x-ray tubes are amended in order to increase the accuracy of registration fee invoicing and reduce the number of refunds issued by the Department of Environment and Conservation. Registrants of radiation machines can qualify to pay a reduced registration fee if a private individual approved by the Department performs required inspections (and the registrants meet other requirements.) Rule 0400-20-10-.24(2) currently requires invoices to be dated January 17th and to be paid by March 17th. The Division of Radiological Health is not able to process all inspection reports received for inspections conducted during the previous year in time to determine whether the registrant qualifies for the discounted rate because the current rule requires invoices to be sent in January prior to issuance of registration fee invoices. The amended rule will require invoices to be dated May 1st and to be paid by June 15th so that the reports can be processed prior to invoicing. Rule 0400-20-10-.24(3)(d)2 is amended to require newly acquired x-ray tubes to be inspected within 3 months of ownership or possession instead of 6 months. Initial registration fees are invoiced on a quarterly basis. Due to this change, more inspection reports will be received and processed by the Division prior to issuance of the initial registration fee invoice.

- (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. 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 registrants of radiation machines (x-ray producing machines) and providers of radiation machine inspection services will be affected by these rule amendments. Comments received from the public included suggested changes and sought additional clarification. Some suggestions were beyond the scope of the proposed rulemaking but will be considered in the future. One suggestion was not feasible due to current technology and procedures. Two commenters suggested the same change (from 2 months to 3 months) which was incorporated into the rule amendments. The Tennessee Hospital Association, the Tennessee Medical Association, and the Tennessee Dental Association responded to the Department's notice of rulemaking that they did not have concerns or formal comments to submit.

- (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;

This rulemaking will not impact state or local government revenues or expenditures.

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

Emily Urban  
Office of General Counsel  
Department of Environment and Conservation  
(615) 532-0138

[Emily.Urban@tn.gov](mailto:Emily.Urban@tn.gov)

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

Emily Urban  
Assistant General Counsel  
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  
William R. Snodgrass Tennessee Tower  
312 Rosa L. Parks Avenue, 2nd Floor  
Nashville, Tennessee 37243  
(615) 532-8685  
[Emily.Urban@tn.gov](mailto:Emily.Urban@tn.gov)

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

The Department is not aware of any additional relevant information.

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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 (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).*

<b>Agency/Board/Commission:</b>	Environment and Conservation
<b>Division:</b>	Radiological Health
<b>Contact Person:</b>	Roger Fenner
<b>Address:</b>	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 15 <sup>th</sup> Floor Nashville, Tennessee
<b>Zip:</b>	37243
<b>Phone:</b>	(615) 532-0404
<b>Email:</b>	<a href="mailto:Roger.Fenner@tn.gov">Roger.Fenner@tn.gov</a>

**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

(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

Paragraph (2) of Rule 0400-20-10-.24 Registration is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (2) shall read as follows:

- (2) An annual registration fee will be due ~~the first working day following January 1 of~~ required each year as long as the radiation machine or service is subject to registration. Each registrant shall submit the annual fee payable to, "Treasurer, State of Tennessee," in the appropriate dollar amount in accordance with the Classification and Fee Schedule in paragraph (3) of this rule to the Division of Radiological Health. Payment shall be accompanied by a copy of the fee invoice properly completed. The invoice for the annual fee will be dated ~~January 17~~ May 1<sup>st</sup> and will require payment by ~~March 17~~ June 15<sup>th</sup> of the indicated year. The annual registration fee shall be due within 45 days of issuance of an invoice. At the time of the annual payment, a registrant of only Class II radiation machines may request specific times or list restricted hours during normal work hours for inspections pursuant to Rule 0400-20-10-.27 by personnel of the Division of Radiological Health, Tennessee Department of Environment and Conservation.

Part 2 of subparagraph (d) of paragraph (3) of Rule 0400-20-10-.24 Registration is amended by deleting the paragraph and substituting the following so that, as amended, part 2 shall read as follows:

2. Each newly acquired tube subject to registration is inspected within ~~6~~ 3 months of ownership or possession.

Authority: T.C.A. §§ 68-202-101 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 08/28/2014, 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: (06/25/14)

Rulemaking Hearing(s) Conducted on: (add more dates). (08/19/14)

Date: August 28, 2014

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

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Comment: The Tennessee Hospital Association, the Tennessee Medical Association, and the Tennessee Dental Association all responded to the Department's notice of rulemaking that they did not have any concerns regarding the amendments being made to this rule and did not have any formal comments to submit.

Response: Comments so noted.

Comment: The commenter suggested certain changes be made to the computer programs of the Division of Radiological Health and Fiscal Services. He believes these changes would make the process easier without having to make the amendments to the rule that the Department is proposing. His written comments are included below:

### January Bill:

1. Sets "Annual" flag
  - a. R.I. sign up entire year with all of R.I. Program stipulations.
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"Annual" Flag gives prompt 60d from January 31, which initiates OK (clear flag), extension, or failure. Failures go to Fee Section for collection of 82% and cancel 18%

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- Benefit:
1. Registrant is responsible!
  2. Allows collection of 82% on failure
  3. Doesn't delay 2015 bills to May - \$ lost to State

- Drawbacks:
1. Slightly more computer programming
  2. Keeps 6 months instead of 2 months for additional machines
  3. It is at 1st bill in January that different classes are addressed
  4. Facilities must keep registration up to date, not State
  5. How to address "non-functioning" and "in storage" on initial R.I.

Response: These suggestions are not compatible with the Division of Radiological Health's DRH track computer program and Fiscal Services' GIA computer program and would be difficult to implement. To make these types of changes to these computer programs, much additional work on the part of Information Systems, Fiscal Services, and the Division would be required. These amendments to the rules will not affect the Division's budget. Fees will be collected within the same fiscal year, therefore there will not be a loss of money to the state.

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My name is Ben Edwards. I am the Radiation Safety Officer for Vanderbilt University and the Vanderbilt University Medical Center.

I first want to acknowledge the critical importance of the Division of Radiological Health. The Division's duty of protecting Tennesseans and the environment from the hazards associated with ionizing radiation is an essential function that must be adequately supported.

With regard to the proposed rule changes, I have the following comment:

The proposed changes to Chapter 0400-20-10 do not address the most problematic item in that chapter. Rule 0400-20-10-.24 paragraph (3) subparagraph (d) allows registrants to pay 18% of the full registration fee only if ALL of the x-ray tubes on the registration have been inspected on time. However, if any x-ray tube is inspected late, regardless of the reason, the full fee is assessed for not only the late tube but for ALL tubes on the registration. As written, this rule:

- penalizes registrations with large number of tubes
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The Division has demonstrated a willingness to consider written appeals of full registration fees imposed under this rule. However, pursuing the appeals process creates additional administrative work for both the registrant and the Division, diverting time and resources away from the more important business of ensuring safety and regulatory compliance. Similarly, this Rule encourages institutions to split their x-ray tubes into as many registrations as possible simply to reduce their vulnerability, again creating additional administrative work for the registrant and the Division with no safety or compliance benefit. To address this problem, I propose the amendment of Rules 0400-20-10-.24(3)(d) and 0400-20-10-.24(3)(d)1 to read **[changes in bold]**:

0400-20-10-.24(3)(d) A registrant may qualify to pay a registration fee equal to 18 percent of that listed in this paragraph **for any tube that meets** the following conditions:

1. **Any** tube subject to registration **is** inspected in accordance with paragraphs (3), (4), and (5) of Rule 0400-20-10-.27.

Response: These comments suggest modifications to rules that are beyond the scope of these amendments. The Department plans to explore how these suggested amendments would affect the Division and will consider these suggestions for a future rulemaking.

Comment: The proposed time frame to have newly purchased x-ray tubes inspected is not enough time for the facilities to have the inspection completed. The current time frame is six months. The proposed rule decreases this to two months. This could create a burden on the medical physicist as they still have to complete their inspections of the regular x-ray tubes. Changing the proposed time frame to three months would provide a more ideal amount of time. If this proposal is necessary from a billing perspective, it is suggested that rule 0400-20-10-.24(3)(d) be amended to charge full fee on only the x ray units that are not in compliance with reduced fee rules.

Response: This comment covers two separate components. The portion of this comment that suggests amendments to 0400-20-10-.24(3)(d) is beyond the scope of these amendments; however, the

Department plans to explore how this suggested amendment would affect the Division and will consider the changes for a future rulemaking. The other portion of this comment suggests that the time frame for inspection of new x-ray tubes be changed from 2 months as proposed to 3 months. The Division agrees with this comment and will incorporate it into the proposed rules.

Comment: Registrants have a requirement to register their x-ray units within ten days of getting the x-ray unit. Previously had a requirement to get them inspected within six months. Now the Division is proposing two months. In the past, registrants have had trouble receiving their registration back from the state within the six month time frame. We realize that the Division has had staffing issues but if you move it to two months, since they are required to have the registration in hand during the inspection, the Division needs to ensure that registrants receive their registration back within a timely manner (e.g. two weeks).

Response: Inspections may be performed by a Registered Inspector prior to the registrant receiving the registration form from the Department. The Registered Inspector may note on the inspection form that the registration is pending.

Comment: I believe 90 to 120 day post install time frame would be better served. The March 17th date is feasible. I believe most facilities schedule inspections around their patient/personnel schedules. Not opposed to changes but don't see that they would improve anything. Sites should be able to utilize the discounts as this can be large expense for small businesses.

Response: The January 17th invoicing date does not give Department staff enough time to review and process inspection reports received late in the year. By adopting the May 1<sup>st</sup> invoicing date, the Department staff should have ample time to review inspection reports and enter the information into the database that Fiscal Services uses to invoice. This will allow Fiscal Services to send an accurate invoice to the registrants who qualify for a reduction in fees. Billing would be improved for customers because it would allow most customers invoiced for correct fee. The number of customers receiving invoices will be substantially reduced. The Division has decided to extend the proposed time frame for a new x-ray tube to be inspected from 2 months to 3 months.

### **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 rule will affect small businesses with possession of x-ray producing equipment, and persons that inspect x-ray equipment. The estimated number of small businesses included under these rules is approximately 5,000 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.

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

These amendments are being made in response to feedback from internal and external stakeholders. Many of these stakeholders are small businesses. These amendments will provide a better invoicing process affecting these businesses in a positive manner.

- (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. These amendments are being made in response to feedback from internal and external stakeholders.

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

There are no federal or state counterpart rules to compare.

- (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.

Exempting small businesses from this proposed rule would result in denying them of the benefits it offers.

## **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 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;

Two subdivisions of Rule 0400-20-10-.24 regarding registration of radiation machines and services and inspection of newly acquired x-ray tubes are amended in order to increase the accuracy of registration fee invoicing and reduce the number of refunds issued by the Department of Environment and Conservation. Registrants of radiation machines can qualify to pay a reduced registration fee if a private individual approved by the Department performs required inspections (and the registrants meet other requirements.) Rule 0400-20-10-.24(2) currently requires invoices to be dated January 17th and to be paid by March 17th. The Division of Radiological Health is not able to process all inspection reports received for inspections conducted during the previous year in time to determine whether the registrant qualifies for the discounted rate because the current rule requires invoices to be sent in January prior to issuance of registration fee invoices. The amended rule will require invoices to be dated May 1st and to be paid by June 15th so that the reports can be processed prior to invoicing. Rule 0400-20-10-.24(3)(d)2 is amended to require newly acquired x-ray tubes to be inspected within 3 months of ownership or possession instead of 6 months. Initial registration fees are invoiced on a quarterly basis. Due to this change, more inspection reports will be received and processed by the Division prior to issuance of the initial registration fee invoice.

- (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. 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 registrants of radiation machines (x-ray producing machines) and providers of radiation machine inspection services will be affected by these rule amendments. Comments received from the public included suggested changes and sought additional clarification. Some suggestions were beyond the scope of the proposed rulemaking but will be considered in the future. One suggestion was not feasible due to current technology and procedures. Two commenters suggested the same change (from 2 months to 3 months) which was incorporated into the rule amendments. The Tennessee Hospital Association, the Tennessee Medical Association, and the Tennessee Dental Association responded to the Department's notice of rulemaking that they did not have concerns or formal comments to submit.

- (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;

This rulemaking will not impact state or local government revenues or expenditures.

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

Emily Urban  
Office of General Counsel  
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;

Emily Urban  
Assistant General Counsel  
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

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

The Department is not aware of any additional relevant information.

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