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# Notice of Rulemaking Hearing

*Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204. For questions and copies of the notice, contact the person listed below.*

**Agency/Board/Commission:** Department of Environment and Conservation  
**Division:** Radiological Health  
**Contact Person:** Beth Murphy  
3<sup>rd</sup> Floor L&C Annex  
401 Church Street  
**Address:** Nashville, Tennessee 37243-1532  
**Phone:** (615) 532-0392  
**Email:** [Beth.Murphy@tn.gov](mailto:Beth.Murphy@tn.gov)

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

**ADA Contact:** ADA Coordinator  
12<sup>th</sup> Floor L&C Tower  
401 Church Street  
**Address:** Nashville, Tennessee 37243  
1-866-253-5827 (toll free) or (615)532-0200  
**Phone:** Hearing impaired callers may use the TN Relay Service at 1-800-848-0298  
**Email:** [Beverly.evans@tn.gov](mailto:Beverly.evans@tn.gov)

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

Address 1:	17 <sup>th</sup> Floor Conference Room, L&C Tower		
Address 2:	401 Church Street		
City:	Nashville, Tennessee		
Zip:	37243-1532		
Hearing Date :	08/08/11		
Hearing Time:	1:00 p.m.	<input checked="" type="checkbox"/> CST	<input type="checkbox"/> EST

**Additional Hearing Information:**

Oral or written comments are invited at the hearing. In addition, written comments may be submitted to Beth Murphy at the Division of Radiological Health, Central Office, address below, prior to or following the public hearing. However, the Division must receive comments in its Central Office by 4:30 p.m. (CST), August 8, 2011, in order to assure consideration.

Copies of draft rules are available for review in the Public Access Areas of the following Department Environmental Field Offices:

Nashville Environmental Field Office  
711 R. S.Gass Boulevard  
Nashville, TN 37243  
(615) 687-7000 / 1-888-891-8332

Knoxville Environmental Field Office  
3711 Middlebrook Pike  
Knoxville, TN 37921  
(865) 594-6035 / 1-888-891-8332

Chattanooga Environmental Field Office  
 State Office Building  
 540 McCallie Avenue, Suite 550  
 Chattanooga, TN 37402-2013  
 (423) 634-5781 / 1-888-891-8332

Memphis Environmental Field Office  
 8383 Wolf Lake Drive  
 Bartlett, TN 38133-4119  
 (901) 371-3000

Copies are available for review also at the Division of Radiological Health, Central Office:

Division of Radiological Health  
 L & C Annex, Third Floor  
 401 Church Street  
 Nashville, TN 37243-1532  
 (615) 532-0364

The "DRAFT" rules may be accessed for review also at the Department's World Wide Web Site located at <http://www.tn.gov/environment/rad>.

**Revision Type (check all that apply):**

- Amendment  
 New  
 Repeal

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

Chapter Number	Chapter Title
0400-20-09	Requirements for Accelerators
Rule Number	Rule Title
0400-20-09-.01	Purpose
0400-20-09-.02	Scope
0400-20-09-.03	Definitions
0400-20-09-.04	Requirements for Registration
0400-20-09-.05	General Requirements for the Issuance of a Certified Registration
0400-20-09-.06	Specific Requirements for the Issuance of a Certified Registration
0400-20-09-.07	Issuance of a Certified Registration
0400-20-09-.08	Specific Terms and Conditions of a Certified Registration
0400-20-09-.09	Expiration of a Certified Registration
0400-20-09-.10	Renewal of a Certified Registration
0400-20-09-.11	Amendment of Certified Registration at Request of Registrant
0400-20-09-.12	Division Action on Request to Renew or Amend
0400-20-09-.13	Inalienability of Certified Registrations
0400-20-09-.14	Reserved
0400-20-09-.15	Modification, Revocation, and Termination of a Certified Registration
0400-20-09-.16	Records
0400-20-09-.17	General Safety Provisions
0400-20-09-.18	Limitations
0400-20-09-.19	Operating and Emergency Procedures
0400-20-09-.20	Tests and Surveys
0400-20-09-.21	Therapeutic Accelerator Installations
0400-20-09-.22	Minimum Subjects to be Covered in Training Accelerator Operators

Chapter Number	Chapter Title
1200-02-09	Requirements for Accelerators
Rule Number	Rule Title
1200-02-09-.01	Purpose
1200-02-09-.02	Scope
1200-02-09-.03	Definitions
1200-02-09-.04	Requirements for Registration

1200-02-09-.05	General Requirements for the Issuance of a Certified Registration
1200-02-09-.06	Specific Requirements for the Issuance of a Certified Registration
1200-02-09-.07	Issuance of a Certified Registration
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1200-02-09-.22	Minimum Subjects to be Covered in Training Accelerator Operators

(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://tn.gov/sos/rules/1360/1360.htm>)

## Repeal

Chapter 1200-02-09 Requirements for Accelerators is repealed.

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

## New Rules

### Chapter 0400-20-09 Requirements for Accelerators

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#### 0400-20-09-.01 Purpose.

This Chapter establishes requirements for all accelerators and facilities. The provisions of this Chapter are in addition to and not in substitution for other applicable provisions of these regulations.

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

#### 0400-20-09-.02 Scope.

Except as otherwise provided, this Chapter applies to all persons who possess or use accelerators.

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

#### 0400-20-09-.03 Definitions.

- (1) "Accelerator" means any device used to impart kinetic energy to electrically charged particles including but not limited to electrons, protons, deuterons, and helium ions. For the purpose of this chapter "accelerator" includes equipment designed for and used only for the production of x-rays of 0.9 MeV or greater and equipment capable of discharging nuclear particles into a medium external to the accelerating device.
- (2) "Misadministration" means an event that meets the criteria in Rule 0400-20-05-.145.
- (3) "Operator" means a person who manipulates the controls of an accelerator and who is responsible to the registrant for assuring compliance with the requirements of these regulations and all Certified Registration Conditions during operation of the accelerator.

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

#### 0400-20-09-.04 Requirements for Registration.

- (1) No person shall activate an accelerator, until the registration has been certified pursuant to the information supplied by the applicant and Rule 0400-20-09-.05.
- (2) Application for a Certified Registration shall be made to the Division as follows:
  - (a) Application for a Certified Registration shall be filed on a form prescribed by the Division.
  - (b) The Division may at any time after the filing of the original application or before the expiration of the Certified Registration require further statements in order to enable the Division to determine whether certification should be granted or denied or whether the Certified Registration should be modified or revoked.
  - (c) Each application shall be signed by a person authorized to act for and on behalf of the applicant.
- (3) Possession of a Certified Registration is not required in order to transfer, own, receive, acquire, or possess an accelerator when such devices are in storage or disassembled or otherwise incapable of operation. However, each person receiving such accelerator shall within 10 days after the receipt of the accelerator submit an application for Certified Registration pursuant to Rule 0400-20-10-.24.

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

#### 0400-20-09-.05 General Requirements for the Issuance of a Certified Registration.

A registration will be certified if the Division determines that:

- (1) The applicant has personnel to use the accelerator for purposes requested and to handle any associated radioactive material in such a manner as to protect public health and safety or property;
- (2) The applicant's proposed equipment, facilities, and procedures will protect the public health and safety or property;
- (3) The applicant has a method of retraining and testing of operators and all other associated personnel at least annually to assure continued competency; and
- (4) The applicant satisfies all applicable requirements of these regulations.

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

#### 0400-20-09-.06 Specific Requirements for the Issuance of a Certified Registration.

- (1) In addition to the requirements of Rule 0400-20-09-.05, a Certified Registration for human use of an accelerator in medical institutions will be issued only if:
  - (a) The applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of an accelerator within that institution. Membership of the committee shall include physicians expert in internal medicine, hematology, therapeutic radiology and a person experienced in particle depth dose calculations, and protection against radiation;
  - (b) The applicant possesses facilities for the clinical care of patients; and
  - (c) The physician designated on the application as the responsible individual shall be a radiologist or therapeutic radiologist certified by the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology and has experience in the use of accelerators to treat humans.<sup>1</sup>

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<sup>1</sup> Certified registrants that desire to utilize physician(s) who do not meet these criteria for minimum training and experience may request a variance exempting the physician from the requirements for a limited time period. The variance request should include:

1. The name of the proposed individual,

- (2) In addition to the requirements of Rule 0400-20-09-.05, a Certified Registration for an accelerator which is to be used in research and development will be issued only if:
  - (a) The applicant has appointed a radiological safety officer who will advise and assist on radiological safety problems; and
  - (b) The applicant has established a radiation safety committee (composed of the radiological safety officer and one or more individuals trained or experienced in the safe use of accelerators) which will review and approve, in advance, proposals for such use.
- (3) In addition to the requirements of Rule 0400-20-09-.05, a Certified Registration for use of an accelerator in industrial radiography will be issued only if the requirements of Chapter 0400-20-08 are satisfied.
- (4) In addition to the requirements of Rule 0400-20-09-.05, a Certified Registration for the production of radioactive materials by an accelerator will be issued only if:
  - (a) The applicant's staff has experience in the use of accelerators in the production of radioactive materials; and
  - (b) The applicant has appointed a radiological safety officer who will advise and assist on radiological safety problems.
- (5) In addition to the requirements of Rule 0400-20-09-.05, a Certified Registration for the modification of the structure, chemical composition, bacterial composition of materials, etc. by an accelerator will be issued only if:
  - (a) The applicant's staff has experience in the modification of materials; and
  - (b) The applicant has appointed a radiological safety officer who will advise and assist on the radiological safety problems.

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

0400-20-09-.07 Issuance of a Certified Registration.

- (1) Upon a determination that an application meets the requirements of these rules, the Division will issue a Certified Registration authorizing the proposed activity.
- (2) The Division may incorporate in any Certified Registration at the time of issuance, or thereafter by such additional provisions with respect to the registrant's accelerator as it deems appropriate or necessary in order to:
  - (a) Protect the public health and safety or property; and
  - (b) Require reports and the keeping of records, as may be necessary to evaluate activities conducted under the Certified Registration.

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2. A description of his or her training and experience including information similar to that specified in subparagraph (1)(c) of Rule 0400-20-09-.06,

3. Information to substantiate that the physician is currently engaged in the certification process,

4. Written endorsement of the technical qualifications of the proposed physician from personal knowledge by a physician certified by the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology. This should be a letter from the proposed physician's Residency Director where the physician in question completed the Residency program in radiology or therapeutic radiology.

Upon receipt of acceptable information, the Division will grant a specific variance to subparagraph (1)(c) of Rule 0400-20-09-.06. This variance will be for a time period not to exceed 1 year. The Division will entertain a request to extend this variance for no more than a 2 additional 1 year time periods provided the certified registrant can support that the physician remains currently engaged in the certification process.

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

0400-20-09-.08 Specific Terms and Conditions of a Certified Registration.

- (1) Certified Registrations issued pursuant to this Chapter shall be subject to all rules, regulations, and orders of the Division.
- (2) Neither the Certified Registration nor any right under the Certified Registration shall be assigned or otherwise transferred.
- (3) Each person registered by the Division pursuant to this Chapter shall confine his use and possession of the accelerator to the locations and purposes authorized in the Certified Registration.

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

0400-20-09-.09 Expiration of a Certified Registration.

Except as provided in Rule 0400-20-09-.10 each Certified Registration shall expire at the end of the day in the month and year stated therein.

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

0400-20-09-.10 Renewal of a Certified Registration.

- (1) Request for renewal of a Certified Registration shall be filed in accordance with paragraph (2) of Rule 0400-20-09-.04.
- (2) In any case in which a registrant, not less than 30 days prior to expiration of his existing Certified Registration, has filed a request in proper form for renewal or for a new Certified Registration authorizing the same activities, such existing Certified Registration shall not expire until the request has been finally determined by the Division.

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

0400-20-09-.11 Amendment of Certified Registration at Request of Registrant.

Requests for amendment of a Certified Registration shall be filed in accordance with paragraph (2) of Rule 0400-20-09-.04 and shall specify the manner in which the registrant desires his Certified Registration to be amended and the grounds for such amendment.

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

0400-20-09-.12 Division Action on Request to Renew or Amend.

In considering a request by a registrant to renew or amend his Certified Registration, the Division will apply the criteria set forth in Rules 0400-20-09-.05 and 0400-20-09-.06 as applicable.

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

0400-20-09-.13 Inalienability of Certified Registrations.

No Certified Registration issued or granted under this Chapter and no right to utilize an accelerator granted by any Certified Registration issued pursuant to this Chapter shall be transferred, assigned, or in any manner disposed of, either voluntarily, or involuntarily, directly, or indirectly, through transfer of control of any Certified Registration to any persons unless the Division shall find that the transfer, assignment or disposal is in accordance with the provisions of the regulations and shall give its consent in writing.

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

0400-20-09-.14 Reserved.

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

#### 0400-20-09-.15 Modification, Revocation, and Termination of a Certified Registration.

- (1) A Certified Registration shall be subject to amendment, revision or modification or may be suspended or revoked by reason of amendments to the Act, or by reason of rules or regulations issued by the Division.
- (2) Any Certified Registration may be revoked, suspended, or modified, in whole or part, for any material false statement in the application or in any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact of any report, records, or inspection or other means which would warrant the Division to refuse to grant a Certified Registration on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act or of the Certified Registration or of any rule or regulation of the Division. This action will be taken pursuant to Tennessee Code Annotated, Chapter 23.
- (3) The Division may terminate a Certified Registration upon written request submitted by the registrant to the Division.

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

#### 0400-20-09-.16 Records.

In addition to the records required elsewhere in these rules, each registrant shall maintain records of any tests or surveys required by this Chapter.

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

#### 0400-20-09-.17 General Safety Provisions.

- (1) The Division may waive compliance with the specific requirements of this Chapter if the applicant or registrant demonstrates, to the Division's satisfaction, achievement of radiation protection, through other means, equivalent to that required by these rules.
- (2) Each registrant shall provide personnel monitoring devices that shall be calibrated for the radiations and energies of radiation produced by the accelerator and shall be used as required by Rules 0400-20-05-.70 and 0400-20-05-.71.
- (3) Each installation shall be provided with such primary barriers and/or secondary barriers as are necessary to assure compliance with Rules 0400-20-05-.50, 0400-20-05-.55, 0400-20-05-.56 and 0400-20-05-.60.
- (4) Controls and Safety Devices:
  - (a) Only the operator at the control panel shall be able to activate an accelerator to create a radiation field in any area in which an individual could receive a dose in excess of 2 millirems per hour.
  - (b) All entrances into a target room or other high radiation areas shall be provided with interlocks.
  - (c) The interlock system and the emergency cut-off shall be separate electrical circuits and/or mechanical systems.
  - (d) When any interlock is interrupted, broken, or tripped, either the accelerator will shut off automatically or the radiation level within the room will be reduced to an average of not more than 2 millirems per hour and a maximum of 10 millirems per hour at a distance of 1 meter in any direction from any accessible surface of the accelerator system. After shut-off or reduction in output, it shall be possible to restore the accelerator to full operation only from the control panel. Radiation levels produced by radioactive materials shall not be considered as the radiation levels to be reduced by such controls.
  - (e) Interlocks shall not be used to shut off the accelerator except in an emergency or during testing.



- (f) Emergency shut-off switches shall be located within the high radiation areas so as to be accessible to individuals therein within the warning period. These switches and their mode of operation shall be identified by a conspicuously posted sign adjacent to the switch. These switches shall be capable of automatically causing the accelerator to either shut off or reduce the radiation level to an average of not more than 2 millirems per hour and a maximum of 10 millirems per hour at a distance of 1 meter in any direction from any accessible surface of the accelerator system. Such shut-off switches shall include a manual reset at each such switch which must be reset at the switch before the accelerator may be restarted by the operator at the control panel. Radiation levels produced by radioactive material shall not be considered as the radiation levels to be reduced by such control.
  - (g) All locations designated as high radiation areas, except those exempted in subparagraph (3)(c) of Rule 0400-20-09-.21, shall be equipped with visual flashing or rotating warning lights that operate when, and only when, radiation is being produced. Each entrance to such area shall have a visual warning device, which need not be flashing or rotating, but operates when, and only when radiation is being produced.
  - (h) Each high radiation area except those exempted in subparagraph (3)(b) of Rule 0400-20-09-.21 shall have an audible warning device which shall be activated for at least 5 seconds prior to the possible creation of such high radiation area. Following the activation of the audible warning device, there shall be a delay of not less than 30 seconds before the high radiation area may be produced. Such warning device shall be discernible in all high radiation and radiation areas.
  - (i) All meters and controls on the accelerator control console shall be identified and discernible.
  - (j) The accelerator control panel shall be provided with a locking device to prevent use by unauthorized individuals. Such locking device shall, when locked, make the accelerator incapable of creating a radiation field in any areas in which an individual could receive a dose in excess of 2 millirems per hour.
  - (k) There shall be available at each facility portable radiation monitoring equipment which is operable and has been calibrated for the radiations being produced by the facility. Such equipment shall be tested for operation and calibrated at intervals not to exceed 3 months and after each instrument servicing and repair. A note shall be attached to each instrument showing the latest calibration date. Records of calibration shall be maintained for inspection by the Division.
  - (l) There shall be present at the control panel and at entrances to all high radiation areas a device which shall give a continuous indication of the radiation levels present in the target or areas.
  - (m) Electrical circuit diagrams of the accelerator and the associated interlock systems shall be kept current and on file at each accelerator facility.
  - (n) All high radiation areas shall be so constructed that persons within the area may at all times be able to escape.
- (5) Operation.
- (a) Only operators qualified as required under Rule 0400-20-09-.18 shall be allowed to unlock and operate the control panel of an accelerator.
  - (b) Interlocks may be bypassed only to test, adjust, maintain, and/or rearrange equipment provided a conspicuous indication of such condition is made at the control panel. This subparagraph does not authorize the operation of an accelerator with the high radiation area warning devices or emergency shut off switches incapable of proper operation.
  - (c) Activities in which interlocks are bypassed as permitted under subparagraph (5)(b) of Rule 0400-20-09-.17.
    1. Shall only be authorized by the radiation safety officer;
    2. Shall only be performed for a specified time;

3. Shall be recorded showing the date, length of time bypassed, reason for bypassing, and signed by the individual installing and removing the bypass. These records shall be maintained for inspection by the Division; and
  4. Shall be performed at low power and current, if possible.
- (d) No individual shall be permitted to enter an area, the access of which is controlled by interlocks, while such interlocks are bypassed, as permitted in subparagraph (5)(b) of Rule 0400-20-09-.17, unless such individual is utilizing personnel monitoring equipment which will give an audible indication when a dose rate of 15 millirems per hour is exceeded. The personnel monitoring equipment referred to in this paragraph is in addition to that required elsewhere in these rules. Calibration requirements of subparagraph (4)(k) of Rule 0400-20-09-.17 shall also apply to such personnel monitoring equipment.
- (e) The operator shall have at the control panel a copy of the operating and emergency procedures.

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

#### 0400-20-09-.18 Limitations.

No registrant shall permit any person to act as an operator as defined in Rule 0400-20-09-.03 until such person:

- (1) Has been instructed in the subjects outlined in Rule 0400-20-09-.22;
- (2) Has received copies of and instruction in the applicable parts of these regulations, a copy of the facility's Certified Registration and the registrant's operating and emergency procedures; and
- (3) Has physically demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in his assignment.

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

#### 0400-20-09-.19 Operating and Emergency Procedures.

The registrant's operating and emergency procedures shall include instructions in at least the following:

- (1) The use of the accelerator in such a manner that no person will be exposed to radiation doses in excess of the limits established in Chapter 0400-20-05;
- (2) Methods and occasions for conducting surveys;
- (3) Methods for controlling access to high radiation areas;
- (4) Methods and occasions for locking the control panel of the accelerator;
- (5) Personnel monitoring and the use of personnel monitoring equipment;
- (6) Methods for minimizing exposure of individuals in the event of an accident;
- (7) Notification procedures in the event of an accident; and
- (8) The maintenance of records.

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

#### 0400-20-09-.20 Tests and Surveys.

Each registrant shall:

- (1) Test all safety and warning devices including interlocks at intervals not to exceed 3 months to determine that they are functioning properly;
- (2) In conjunction with initial operation and after changes have been made in shielding, operating parameters, equipment, or occupancy of adjacent areas, make a survey as required in Rule 0400-20-05-.70;
- (3) Test any interlock which has been bypassed or otherwise prevented from operation, when such interlock is returned to use, to determine if it is functioning properly; and
- (4) Have a survey made of each radiation area upon the initial entry by personnel into these areas following the operation of accelerator. The registrant shall not be required to make a record of the survey required by this paragraph.

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

0400-20-09-.21 Therapeutic Accelerator Installations.

- (1) Operation.
  - (a) No individual except the patient shall be in the treatment room during irradiation.
  - (b) The emergency procedures shall include instructions for:
    1. Minimizing exposure of individuals in the event of an accident, e.g., alternate means of terminating the accelerator beam.
    2. Removing the patient from the treatment room.
    3. Preventing the entrance of individuals into the treatment room.
    4. Notifying the responsible physician or radiation protection officer.
  - (c) During patient irradiation, both the patient and the control panel shall at all times be kept under observation by the operator.
- (2) Equipment.
  - (a) A therapeutic-type protective tube housing shall be utilized for x-ray therapy devices.
  - (b) Diaphragms or cones shall be used to collimate the useful beam of radiation to those portions of the body undergoing treatment. Such diaphragms or cone shall transmit not more than 5 percent of the maximum useful beam.
  - (c) A timer shall be provided to terminate the exposure after a preset time regardless of what other exposure limiting devices are present. Where the timing device is utilized as a backup device, the time preset shall not be greater than that necessary to provide the required dose with allowance for equipment variability.
  - (d) Full calibration measurements shall be performed on each therapeutic accelerator:
    1. Prior to the first use of the unit for treating humans;
    2. Prior to treating humans;
      - (i) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration;
      - (ii) Following reinstallation of the unit in a new location;

- (iii) Following any repair of the unit that includes repair of the components associated with radiation exposure; and
- 3. At intervals not exceeding 1 year.
- (e) Full calibration measurements required by subparagraph (d) of this paragraph shall include determination of:
  - 1. The exposure rate or dose rate to an accuracy within  $\pm 3$  percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;
  - 2. The congruence between the radiation field and the field indicated by the light beam localizing device;
  - 3. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
  - 4. Timer accuracy; and
  - 5. The accuracy of all distance measuring devices used for treating humans.
- (f) Full calibration measurements shall be made in accordance with the procedure recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine (Physics in Medicine and Biology, Vol. 16, No. 3, 1971, pp. 379-396).
- (g) Full calibration measurements required by subparagraph (d) of this paragraph shall be performed by a qualified expert as defined in Rule 0400-20-04-.04.
- (h) Spot-check measurements shall be performed on each therapeutic accelerator at intervals not exceeding 1 month.
- (i) Spot-check measurements required by subparagraph (h) of this paragraph shall include determination of:
  - 1. Timer accuracy;
  - 2. The congruence between the radiation field and the field indicated by the light beam localizing device;
  - 3. The accuracy of all distance measuring devices used for treating humans; and
  - 4. The exposure rate, dose rate or a quantity related in a known manner to those rates for one typical set of operating conditions.
- (j) Spot-check measurements required by subparagraph (h) of this paragraph shall be performed in accordance with procedures established by a qualified expert as defined in Rule 0400-20-04-.04. (A qualified expert need not actually perform the spot-check measurements.) If a qualified expert does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified expert within 15 days.
- (k) Full calibration measurements required in subparagraph (d) of this paragraph shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous 2 years and after any servicing that may have affected system calibration.
- (l) Spot-check measurements required by subparagraph (h) of this paragraph shall be performed using a dosimetry system that has been calibrated in accordance with subparagraph (k) of this paragraph. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with subparagraph (k) of this paragraph. This alternative calibration method shall have been

performed within the previous 1 year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

- (m) Records of the measurements, tests, corrective actions and instrument calibration made under subparagraphs (d) through (f) and (h) through (l) of this paragraph and the registrants evaluation of the Qualified Expert's training and experience shall be maintained for inspection by the Division.
- (3) Facility.
- (a) Provisions shall be made to permit continuous observation of the patients during irradiation. Windows, mirror systems, or closed-circuit television viewing screens used for observing the patient shall be so located that the operator may see the patient from his position at the control panel.
  - (b) An accelerator used only for the treatment of humans shall not be required to have an audible warning device within the treatment room as required by subparagraph (4)(h) of Rule 0400-20-09-.17.
  - (c) An accelerator used only for the treatment of humans shall not be required to have a flashing or rotating warning light in the treatment room but shall have therein a readily observable warning light or lights that operate when and only when radiation is being produced.

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

0400-20-09-.22 Minimum Subjects To Be Covered in Training Accelerator Operators.

- (1) Fundamentals of radiation safety.
  - (a) Characteristics of radiation.
  - (b) Units of radiation dose and exposure and quantity of radioactivity.
  - (c) Biological effects of radiation.
  - (d) Methods of controlling radiation dose and exposure.
    - 1. Working time
    - 2. Working distance
    - 3. Shielding
- (2) Radiation detection instrumentation to be used.
  - (a) Use of radiation survey instruments.
    - 1. Operation
    - 2. Calibration
    - 3. Limitations
  - (b) Survey techniques.
    - 1. Methods of surveys
    - 2. Records which must be made and retained.
  - (c) Use of personnel monitoring equipment.

- (3) Operation and control of accelerators.
- (4) The requirements of state regulations.
- (5) The registrant's written operating and emergency procedures.

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

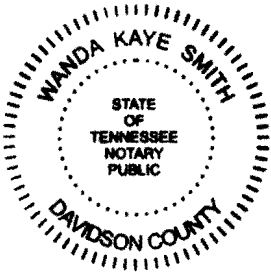
I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: June 2, 2011

Signature: *Debra G. Shults*

Name of Officer: Debra G. Shults

Title of Officer: Director, Division of Radiological Health



Subscribed and sworn to before me on: June 2, 2011

Notary Public Signature: *Wanda K Smith*

My commission expires on: My Commission Expires November 7, 2012

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*Tre Hargett*  
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Secretary of State

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