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Sequence Number: 04-16-18
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File Date: 4/18/18

Notice of Rulemaking Hearing

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

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

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

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

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

Address 1:	Conference Room B, 3rd Floor		
Address 2:	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue		
City:	Nashville, Tennessee		
Zip:	37243		
Hearing Date :	06/19/18		
Hearing Time:	9:00 A.M.	_X_CST/CDT ___EST/EDT	

Additional Hearing Information:

The proposed rulemaking includes the following amendments:

- Hand-held x-ray equipment is defined.
- Corrections to the Chapter 0400-20-06 Table of Contents are made.
- Language pertaining to medical, dental, and analytical hand-held x-ray equipment is added; this language includes guidance on personnel dosimetry monitoring, unauthorized usage, and training.
- Language that addresses personnel security screening that is used to identify contraband items and weapons that would present a security threat within a secured facility perimeter is added.

Oral or written comments are invited at the hearing. In addition, written comments may be submitted to Andrew Holcomb at the Division of Radiological Health, 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/CDT), June 19, 2018, in order to assure consideration.

Copies of draft rules are available for review in the Public Access Areas of the following Departmental Environmental Assistance Centers:

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

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

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

Memphis Field Office
8383 Wolf Lake Drive
Bartlett, TN 38133-4119
(901) 368-7939 / 1-888-891-8332

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

Division of Radiological Health
William R. Snodgrass Tennessee Tower
312 Rosa L. Parks Avenue, 15th Floor
Nashville, Tennessee 37243
(615) 532-0364

The "DRAFT" rules may be accessed for review also at the Department's World Wide Web Site located at http://tn.gov/environment/topic/ppo-radiation.

Revision Type (check all that apply):

X Amendment
X 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**
0400-20-06	Use of X-ray Apparatus
Rule Number	**Rule Title**
0400-20-06-.03	Definitions
0400-20-06-.04	General Safety Precautions
0400-20-06-.05	Medical X-ray Installations
0400-20-06-.06	Veterinary X-ray Installations
0400-20-06-.07	Analytical X-ray Installations
0400-20-06-.10	Personnel Security Screening Systems Using X-ray Radiation

(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 0400-20-06
Use of X-ray Apparatus

Amendments

The table of contents to Chapter 0400-20-06 is amended by adding: 0400-20-06-.10 Personnel Security Screening Systems Using X-ray Radiation.

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

Paragraph (68) of Rule 0400-20-06-.03 Definitions is amended by adding subparagraph (e) to read as follows:

(e) Hand-held means portable x-ray equipment that is specifically designed to operate when held in a person's hand.

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

Paragraph (9) of Rule 0400-20-06-.04 General Safety Precautions is amended by deleting it in its entirety and substituting instead the following:

(9) The Division may waive compliance with the specific requirements of this rule for an existing x-ray apparatus or installation if:

(a) Such compliance would require replacement or substantial modification of the x-ray apparatus or installation; and,

(b) The registrant demonstrates, to the Division's satisfaction, achievement through other means, of radiation protection equivalent to that required by these rules.

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

Subparagraph (d) of paragraph (3) of Rule 0400-20-06-.05 Medical X-ray Installations is amended by deleting it in its entirety and substituting instead the following:

(d) Unless operating intraoral dental radiographic equipment designed to be operated as a hand-held device pursuant to subparagraph (3)(r) of this rule, no one except the patient should be in the room when x-ray exposures are made. If for some reason it is necessary for operating personnel to be in the room with the patient during exposures, an exposure cord shall be provided that is sufficiently long to permit operating personnel to stand at least 2 meters from the patient and the tube head and in an area of minimal exposure to scattered and leakage radiation and outside of the primary beam.

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

Subparagraph (g) of paragraph (3) of Rule 0400-20-06-.05 Medical X-ray Installations is amended by deleting it in its entirety and substituting instead the following:

(g) Unless operating intraoral dental radiographic equipment designed to be operated as a hand-held device pursuant to subparagraph (3)(r) of this rule, neither the tube housing nor the Position Indicating Device may be hand held during an exposure.

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

Paragraph (3) of Rule 0400-20-06-.05 Medical X-ray Installations is amended by adding subparagraph (r) to read as follows:

(r) For any intraoral dental radiographic equipment designed to be operated as a hand-held device:

1. The following requirements apply to any intraoral dental radiographic equipment designed to be operated as a hand-held device:

(i) The registrant shall provide and require individual personnel monitoring of external occupational dose via a whole body dosimeter and extremity dosimeters for both the right and left hands to all persons who may operate the hand-held device. The registrant may be relieved of the requirement of this subpart after one (1) year of personnel monitoring if the results of the personnel monitoring demonstrate that the operator of the hand-held device is not likely receive a dose in excess of 10 percent of the limits in Rule 0400-20-05-.50, as outlined in Rule 0400-20-05-.71. The registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Rule 0400-20-05-.71.

(ii) Registrants shall implement security and accountability procedures to prevent unauthorized use, misuse, or unauthorized removal of the hand-held device from its storage location. Immediately after learning of an incidence of unauthorized use, misuse, or unauthorized removal from its storage location, a registrant shall report the incident to the Division at the contact point identified in part (3)(a)1 of Rule 0400-20-05-.141. The registrant shall maintain records of the security and accountability procedures described in this subpart. Said records shall be made available for review by the Division.

(iii) The registrant shall incorporate specific information regarding hand-held devices into any initial and recurring training provided to the facility staff. The registrant shall maintain records of the initial and recurring training provided to the facility staff described in this subpart. Said records shall be made available for review by the Division. The training shall contain, at a minimum, the following:

(I) Training on the proper operation of the hand-held device;

(II) The operator shall ensure that there are no bystanders within a radius of at least six (6) feet from the patient being examined with the hand-held device;

(III) Hand-held intraoral dental radiographic devices shall not be used for patient examinations in hallways or waiting rooms;

(IV) The requirements listed in subparts (i) and (ii) of this part; and

(V) Instructions provided by the manufacturer in regard to equipment with unique features as required under 21 CFR 1020.30(h)(1)(i).[1]

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

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[1] "A unit that is hand-held constitutes a unique feature that requires manufacturers to describe any safety procedures and precautions necessary to reduce operator exposure." (See Guidance for Industry and FDA Staff – Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use, December 24, 2008, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Diagnostic Devices Branch, Division of Mammography Quality and Radiation Programs, Office of Communication, Education, and Radiation Programs)

Subparagraph (a) of paragraph (2) of Rule 0400-20-06-.06 Veterinary X-ray Installations is amended by deleting it in its entirety and substituting instead the following:

(a) For any veterinary intraoral dental radiographic equipment designed to be operated as a hand-held device:

1. The following requirements apply to any veterinary intraoral dental radiographic equipment designed to be operated as a hand-held device: [2]

(i) The registrant shall provide and require individual personnel monitoring of external occupational dose via a whole body dosimeter and extremity dosimeters for both the right and left hands to all persons who may operate the hand-held device. The registrant may be relieved of the requirement of this subpart after one (1) year of personnel monitoring if the results of the personnel monitoring demonstrate that the operator of the hand-held device is not likely to receive a dose in excess of 10 percent of the limits in Rule 0400-20-05-.50, as outlined in Rule 0400-20-05-.71. The registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Rule 0400-20-05-.71.

(ii) Registrants shall implement security and accountability procedures to prevent unauthorized use, misuse, or unauthorized removal of the hand-held device from its storage location. Immediately after learning of an incidence of unauthorized use, misuse, or unauthorized removal from its storage location, a registrant shall report the incident to the Division at the contact point identified in part (3)(a)1 of Rule 0400-20-05-.141. The registrant shall maintain records of the security and accountability procedures described in this subpart. Said records shall be made available for review by the Division.

(iii) The registrant shall incorporate specific information regarding hand-held devices into any initial and recurring training provided to the facility staff. The registrant shall maintain records of the initial and recurring training provided to the facility staff described in this subpart. Said records shall be made available for review by the Division. The training shall contain, at a minimum, the following:

(I) Training on the proper operation of the hand-held device;

(II) The operator shall ensure that there are no bystanders within a radius of at least six (6) feet from the patient being examined with the hand-held device;

(III) Hand-held intraoral dental radiographic devices shall not be used for patient examinations in hallways or waiting rooms;

(IV) The requirements listed in subparts (i) and (ii) of this part; and

(V) Instructions provided by the manufacturer in regard to equipment with unique features as required under 21 CFR 1020.30(h)(1)(i).[3]

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[2] This is intended to apply to intraoral radiographic units that are hand-held. Any unit designed to be hand-held but operated as a fixed unit shall be subject to the requirements outlined in paragraph (3) of Rule 0400-20-06-.05.

[3] "A unit that is hand-held constitutes a unique feature that requires manufacturers to describe any safety procedures and precautions necessary to reduce operator exposure." (See Guidance for Industry and FDA Staff – Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use, December 24, 2008, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Diagnostic Devices Branch, Division of Mammography Quality and Radiation Programs, Office of Communication, Education, and Radiation Programs)

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

Rule 0400-20-06-.07 Analytical X-ray Installations is amended by adding a new paragraph to read as follows:

(3) Additional requirements for open-beam, hand-held analytical devices.

In addition to the requirements of paragraphs (1) and (2) of this rule, the following requirements apply to open-beam, hand-held, analytical x-ray devices:

(a) Procedures.

All registrants possessing open-beam, hand-held, analytical devices shall have available for review by the Division operating policies and procedures that contain measures to insure that:

1. Radiation protection is provided equivalent to that afforded in subparagraph (1)(d) of this rule. This shall be in the form of an operating procedure that contains, at a minimum:

(i) The operator's hands will not approach the primary beam;

(ii) The operator will not hold the sample during operation of the hand-held x-ray device;

(iii) The operator will not aim the primary beam at him/herself or at any individual during operation of the device; and

(iv) Before energizing the device, the operator will ensure that no person is within 2 meters of the device or sample being tested.[4]

2. If the safety devices, which are known as the "X-ray On" warning light and the tube housing "X-ray On" indicator light, as outlined in subparagraphs (1)(c) and (1)(e) of this rule, are not of a fail-safe design, administrative controls shall be put in place in the form of an operating procedure that shall include, at a minimum:

(i) Discussion of the warning light(s) safety mechanism on the analyzer, the rationale behind subparagraphs (1)(c) and (1)(e) of this rule, the absence of the fail-safe design on the analyzer, and the potential risks to the operator should the warning light(s) fail;

(ii) Training the operator to visually verify that the warning light(s) is correctly working when the analyzer is known to be generating x-rays;

(iii) Training the operator to recognize warning light failure. For example: warning light(s) not functioning when the device is known to be generating x-rays, or if one of several warning lights is not operating;

(iv) Proper procedures for reporting an actual or suspected warning light failure; and

(v) If failure of the warning light, or any one of the warning lights or if there are multiple warning lights, is confirmed, the analyzer will immediately be removed from service and returned to the manufacturer for repair. Return to service will not be permitted until necessary repair has been performed, and the maintenance record for the analyzer updated. Such maintenance records shall be made available upon request by the Division.

3. Operator radiation exposure is as low as reasonably achievable. For example, use of ancillary equipment when possible, such as a sample holder.

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[4] This part is intended to apply to units that are hand-held. Analytical units designed to be hand-held but operated in a fixed configuration and not hand-held shall be subject to the requirements of subparagraph (1)(d) of this rule.

(b) Extremity Monitoring.

The registrant shall provide and require individual personnel monitoring with extremity dosimeters for all operators of the hand-held device. Extremity monitoring may be discontinued after one year if the results of the personnel monitoring demonstrate that the operator of the hand-held device is not likely to receive a dose in excess of 10 percent of the limits in Rule 0400-20-05-.50, as outlined in Rule 0400-20-05-.71. The registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Rule 0400-20-05-.71.

(c) Training.

In addition to the training requirements of subparagraph (2)(a) of this rule, the registrant shall provide training for all users and operators on the requirements of subparagraph (a) and (b) of paragraph. Records of all user and operator training shall be maintained and made available for review by the Division. Training records shall include:

1. The date the training was provided;

2. The name of each individual trained (printed) and their signature;

3. The name and dated signature of the individual providing the training;

4. The topics covered in the training (or an attachment of the training material); and

5. The duration of the training.

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

Chapter 0400-20-06
Use of X-ray Apparatus

New Rules

Add the following to the table of contents to Chapter 0400-20-06 Use of X-ray Apparatus:

0400-20-03-.10 Personnel Security Screening Systems Using X-ray Radiation

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

A new rule is added to Chapter 0400-20-06 to read as follows:

0400-20-06-.10 Personnel Security Screening Systems Using X-ray Radiation.

(1) "Personnel security screening system" means radiation-generating equipment used for the sole purpose of screening an individual who is in custody of a law enforcement agency or persons accessing or in a vehicle accessing the secured facility perimeter in order to identify contraband items and weapons that would present a security threat within a secured facility perimeter.

(2) X-ray devices used for personnel security screening shall be used only by law enforcement agencies at city, county, or state correctional detention facilities. No individual shall be exposed to the useful beam unless authorized by a law enforcement agency for security benefit. No individual shall be exposed to the useful beam for demonstration or frivolous purposes.

(3) The x-ray system is manufactured, maintained, and operated solely for security screening purposes in strict compliance with, and fully according to, the most restrictive standards found in ANSI/HPS N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation," which is herein incorporated by reference. This ANSI publication may be examined and inspected at the TDEC Division of Radiological Health, WRS Tennessee Tower 15th Floor, 312 Rosa L. Parks Ave, Nashville TN 37243, and is available from the American National Standards Institute, Inc., at http://www.hps.org/#. The agency has determined that posting the publication on the internet for purposes of public inspection and examination would constitute a violation of federal copyright law.

(4) The institution tracks radiation dose for each individual, as specified by ANSI/HPS N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation," to ensure the individual does not exceed the recommended dose limit.

Authority: T.C.A. §§ 68-202-101 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.

KATI HICKS
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY

Date: 4-17-18

Signature: Debra G. Shults

Name of Officer: Debra G. Shults

Title of Officer: Director of the Division of Radiological Health

Subscribed and sworn to before me on: 4/17/18

Notary Public Signature: Kati Hicks

My commission expires on: 11/5/18

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Filed with the Department of State on: 4/18/18

Tre Hargett
Secretary of State

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