UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 25, 1997

Mr. Wayne K. Scharber
Deputy Commissioner
Tennessee Department of Environment
and Conservation
L&C Tower, 21st Floor
401 Church Street
Nashville, TN 37243-1532

Dear Mr. Scharber:

In December 1996, during the Tennessee review, the Integrated Materials Performance Evaluation Program (IMPEP) team found five rules that NRC had not reviewed for compatibility. While some differences exist in the Tennessee regulations that were reviewed, we have reviewed the following rules and find them to be compatible with NRC's requirements.

- Rule 1200-2-11-.03; "Licensing Requirements for Land Disposal of Radioactive Waste," Paragraph (15) and Definition of Land Disposal Facility. This rule is equivalent to NRC's "Definition of Land Disposal and Waste Site QA Program," 10 CFR Part 61 (58 FR 39628) that became effective on July 22, 1993.

- Rule 1200-2-5-.14; "Notification of Incidents" Paragraphs (1) and (2). TN made changes to this regulation to conform with NRC's requirement. This rule is equivalent to NRC's "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, 70 amendments (56 FR 64980) which became effective on October 15, 1991.

- Rule 12-2-8; "Radiation Safety Requirements for Industrial Radiography Operations." TN amended Section 1200-8-.03 to include definitions for radiographer, radiographer's assistant, radiographic exposure device, source changer, storage area, and storage container. These definitions are equivalent to those found at 10 CFR Part 34.2.

- Rule 12-2-8; "Radiation Safety Requirements for Industrial Radiography Operations." TN amended Section 1200-8-.04 "Equipment Control," Paragraphs (1) (a) and (b) to include these requirements. These changes are equivalent to NRC's 10 CFR Part 34.21(a) and (b) amendments (55 FR 843) which became effective on January 10, 1991.

OSP did not review the following rule.

- Rule 1200-2-5-.75; "Quality Management Program for Human Use." TN has completed this rule. The Tennessee Department of Environment and Conservation had not approved it at the time of the IMPEP review. NRC has planned to significantly change NRC's present rule. The outcome of this activity remains uncertain. Therefore, OSP has not reviewed this rule, consistent with the position described for the Commission in SECY-97-054, "Final Recommendations on Policy

Statements and Implementing Procedures for: 'Statement of Principles and Policy for the Agreement State Program' and 'Policy Statement on Adequacy and Compatibility of Agreement State Programs.'" We will conduct a review in accordance with compatibility guidance that will be developed for the revision of Part 35.

If you have any questions, please contact me at 301-415-3340.

Sincerely,

Richard L Bangart

Richard L. Bangart, Director
Office of State Programs

cc: Kenneth W. Bunting, Director
Division of Superfund

Michael H. Mobley, Director
Division of Radiological Health

Lawrence E. Nanney, Deputy Director
Division of Radiological Health

Statements and Implementing Procedures for: 'Statement of Principles and Policy for the Agreement State Program' and 'Policy Statement on Adequacy and Compatibility of Agreement State Programs.'" We will conduct a review in accordance with compatibility guidance that will be developed for the revisions of Part 35.

If you have any questions, please contact me at 301-415-3340.

Sincerely,

Original Signed By
RICHARD L. BANGART

Richard L. Bangart, Director
Office of State Programs

cc: Kenneth W. Bunting, Director
Division of Superfund

Michael H. Mobley, Director
Division of Radiological Health

Lawrence E. Nanney, Deputy Director
Division of Radiological Health

Distribution:
DIR RF
SDroggitis
Tennessee File
HNewsome, OGC
DCD (SP08)
PDR (YES ✓)

DOCUMENT NAME: G:\JHM\TNREGREV.JHM *** See Previous Concurrence.**

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	OSP		OSP		OSP:DD		OGC		OSP:D			
NAME	JHMyers:gd/nb		KSchneider		PHLohaus		FXCameron		RLBangart			
DATE	04/07/97*		04/07/97*		04/08/97*		04/22/97*		04/25/97			

OSP FILE CODE:SP-AG-26

Statements and Implementing Procedures for: 'Statement of Principles and Policy for the Agreement State Program' and 'Policy Statement on Adequacy and Compatibility of Agreement State Programs.'" We will conduct a review in accordance with compatibility guidance that will be developed for the revisions of Part 35.

If you have any questions, please contact me at 301-415-3340.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

cc: Kenneth W. Bunting, Administrator
Land and Radiation Programs

Michael H. Mobley, Director
Division of Radiological Health

Lawrence E. Nanney, Deputy Director
Division of Radiological Health

Distribution:
DIR RF
SDroggitis
Tennessee File
DCD (SP08)
PDR (YES ✓)

DOCUMENT NAME: G:\JHM\TNREGREV.JHM *** See Previous Concurrence.**

*W/O HTN fax

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	OSP		OSP		OSP:DD		OGC		OSP:D			
NAME	JHMyers:gd/nb		KSchneider		PHLohaus		FXCameron		RLBangart			
DATE	04/07/97*		04/07/97*		04/08/97*		04/22/97		04/ /97			

OSP FILE CODE:SP-AG-26

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

Mr. Wayne K. Scharber
Deputy Commissioner
Tennessee Department of Environment
and Conservation
L&C Tower, 21st Floor
401 Church Street
Nashville, TN 37243-1532

Dear Mr. Scharber:

In December 1996, during the Tennessee review, the Integrated Materials Performance Evaluation Program (IMPEP) team found five rules that NRC had not reviewed for compatibility. We have reviewed the following rules and find them to be compatible with NRC's requirements.

- Rule 1200-2-11-.03; "Licensing Requirements for Land Disposal of Radioactive Waste," Paragraph (15) and Definition of Land Disposal Facility. This rule is equivalent to NRC's "Definition of Land Disposal and Waste Site QA Program," 10 CFR Part 61 (58 FR 39628) that became effective on July 22, 1993.

- Rule 1200-2-5-.14; "Notification of Incidents" Paragraphs (1) and (2). TN made changes to this regulation to conform with NRC's requirement. This rule is equivalent to NRC's "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, 70 amendments (56 FR 64980) which became effective on October 15, 1991.

- Rule 12-2-8; "Radiation Safety Requirements for Industrial Radiography Operations." TN amended Section 1200-8-.03 to include definitions for radiographer, radiographer's assistant, radiographic exposure device, source changer, storage area, and storage container. These definitions are equivalent to those found at 10 CFR Part 34.2.

- Rule 12-2-8; "Radiation Safety Requirements for Industrial Radiography Operations." TN amended Section 1200-8-.04 "Equipment Control," Paragraphs (1) (a) and (b) to include these requirements. These changes are equivalent to NRC's 10 CFR Part 34.21(a) and (b) amendments (55 FR 843) which became effective on January 10, 1991.

OSP did not review the following rule.

- Rule 1200-2-5-.75; "Quality Management Program for Human Use." TN has completed this rule. The Tennessee Department of Environment and Conservation had not approved it at the time of the IMPEP review. NRC has planned to significantly change NRC's present rule. The outcome of this activity remains uncertain. Therefore, OSP has not reviewed this rule, consistent with the position described for the Commission in SECY-97-054, "Final Recommendations on Policy

35 is completed and the State has had time to make changes, if required, to the Quality Management Program.

If you have any questions, please contact me at 301-415-3340.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

cc: Kenneth W. Bunting, Administrator
Land and Radiation Programs

Michael H. Mobley, Director
Division of Radiological Health

Lawrence E. Nanney, Deputy Director
Division of Radiological Health

Distribution:
DIR RF
SDroggitis
Tennessee File
DCD (SP08)
PDR (YES ✓)

DOCUMENT NAME: G:\JHM\TNREGREV.JHM

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	OSP	OSP	OSP:DD	OGC	OSP:D	
NAME	JHMyers:gd	KSchneider	PHLohaus	FXCameron	RLBangart	
DATE	04/7 /97	04/7 /97	04/8 /97	04/ /97	04/ /97	

OSP FILE CODE:SP-AG-26

FAX INFORMATION

U. S. NUCLEAR REGULATORY COMMISSION
OFFICE OF STATE PROGRAMS

OFFICE OF STATE PROGRAMS FAX: (301) 415-3502

NUMBER OF PAGES: 3 including this page

DATE: APRIL 28, 1997

TO: MICHAEL H. MOBLEY

FROM: RICHARD L. BANGART, DIRECTOR
OFFICE OF STATE PROGRAMS
(301) 415-3340

SUBJECT: TENNESSEE REGULATIONS

VERIFICATION - 415-3340

< TRANSACTION REPORT >

04-28-1997(MON) 16:30

[TRANSMIT]

NO.	DATE	TIME	DESTINATION STATION	PG.	DURATION	MODE	RESULT
31836	4-28	16:28	615 532 7938	3	0°01'32"	NORM.E	OK
			Schanbel to M. Mobley	3	0°01'32"		

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 10, 1997

MEMORANDUM TO: Francis X. Cameron, Special Counsel for Public Liaison and Agreement State Programs
Office of General Counsel

FROM: Richard L. Bangart, Director
Office of State Programs

Richard L Bangart

SUBJECT: REVIEW OF TENNESSEE REGULATIONS FOR COMPATIBILITY

In December 1996, the Tennessee (TN) IMPEP team discovered five regulations had not been reviewed by NRC for compatibility. OSP has reviewed these regulations and have found them to be compatible with NRC requirements. We are submitting them to you for a final compatibility determination.

OSP provides comments on the regulations in question below:

- **Rule 1200-2-11-.03; "Licensing Requirements for Land Disposal of Radioactive Waste," Paragraph (15)** and **Definition of Land Disposal Facility** (Attachment 1). The equivalent NRC requirement is found at 10 CFR Part 61.2 and is a Division 1 matter of compatibility. The TN definition is identical to NRC's.

- **Rule 1200-2-5-.14; "Notification of Incidents," Paragraphs (1) and (2)** (Attachment 2). TN made changes to this regulation to conform with NRC's requirement. NRC's equivalent rule is found at 10 CFR Part 20.2202, **Notification of Incidents**. NRC requires immediate notification about certain incidents and the rule is a Division 2 matter of compatibility.

  The paragraph (1) of the TN rule states that licensees "shall notify the Division as soon as possible but not later than four (4) hours after discovery. . . ." Although they word this requirement differently, the intent of the TN requirement is the same or more restrictive than NRC's requirement.

  The paragraph (2) of the TN rule does not contain some wording found in NRC's requirement. TN did not include the phrase "involving loss of control of licensed material" in their regulation. TN's regulations refer to a "source of radiation." This substitution makes the TN rule consistent with Suggested State Regulations that apply to non-AEA material and other radiation producing devices.

- **Rule 12-2-8; "Radiation Safety Requirements for Industrial Radiography Operations"** (Attachment 3). TN made several modifications to the regulations governing radiography operations.

OGC-97- 001311

9704880256

TN amended Section 1200-8-.03 Definitions to include definitions for radiographer, radiographer's assistant, radiographic exposure device, source changer, storage area, and storage container. The definitions are a matter of Division 1 compatibility are found in 10 CFR Part 34.2. The State's definitions are similar to those adopted by NRC. — Chip - I went over this w/ Jim - differences reflect State authority

TN also amended **Section 1200-8-.04 "Equipment Control,"** Paragraphs (1) (a) and (b). These sections are Division 2 level of compatibility. The TN equivalent rules are identical to the requirements found in NRC's 10 CFR Part 34.21(a) and (b).

- **Rule 1200-2-5-.75; "Quality Management Program for Human Use"** (Attachment 4). TN completed this rule but it was not approved by the Tennessee Department of Environment and Conservation. NRC has planned to significantly change NRC's present rule. The outcome of this activity remains uncertain. Therefore, OSP has not reviewed this rule, consistent with the position described for the Commission in SECY-97-054. We will conduct a review in accordance with compatibility guidance that will be developed for the revision of Part 35.

Also for your comment and concurrence is a letter we propose to send to the State of Tennessee reporting NRC's findings on their rules.

If you have questions about the regulation review or this correspondence please contact me or Jim Myers at 415-2328 or JHM.

Attachments:
As stated

LAND Disposal

Proposed Rules
of
Tennessee Department of Environment and Conservation
Division of Radiological Health

Chapter 1200–2–11
Licensing Requirements for Land Disposal of Radioactive Waste

Presented herein are proposed amendments of the Department of Environment and Conservation, submitted pursuant to T.C.A. Section 4–5–202 in lieu of a rulemaking hearing. It is the intent of the Department of Environment and Conservation to promulgate these amendments without a rulemaking hearing unless a petition requesting such hearing is filed within thirty (30) days of the publication date of the issue of the *Tennessee Administrative Register* in which the proposed amendments are published. Such petition to be effective must be filed at the Division of Radiological Health, Third Floor of the L & C Annex Building located at 401 Church Street, Nashville, TN 37243–1532, and in the Department of State, Fifth Floor, James K. Polk State Office Building, Sixth and Deaderick, Nashville, TN 37243–0310, and must be signed by twenty–five (25) persons who will be affected by the rule, or submitted by a municipality which will be affected by the rule, or an association of twenty–five (25) or more members, or any standing committee of the General Assembly.

For a copy of this proposed rule contact: Barbara A. Davis, Division of Radiological Health, Third Floor, L & C Annex, 401 Church Street, Nashville, TN 37243–1532, and 615 532–0364.

The text of the proposed amendments is as follows:

Amendments

Paragraph (15) of Rule 1200–2–11–.03 Definitions is amended by adding the word "structures, " and substituting the word "are" for "is", so that as amended the paragraph shall read:

(15) *Land disposal facility* – Means the land, buildings, structures, and equipment which are intended to be used for the disposal of radioactive wastes.

Part 10 of Subparagraph (a) of Paragraph (3) of Rule 1200–2–11–.08 Content of Application is amended by substituting the word "assurance" for "control", by adding the words ", developed and applied by the applicant", by deleting the words "for the determination of natural disposal site characteristics" and substituting the words "to the determination of the natural characteristics of the disposal site", and by deleting the words "for quality assurance during", so that as amended the part shall read:

10. A description of the quality assurance program, developed and applied by the applicant to:

(i) The determination of the natural characteristics of the disposal site,

(ii) The design, construction, operation and closure of the land disposal facility, and

(iii) The receipt, handling, and emplacement of waste.

Audits and managerial controls must be included.

Authority: T.C.A. §68-202-206 and 4-5-202.

ATTACHMENT 1

Legal Contact:
Greer C. Tidwell, Jr.
TDEC Office of General Counsel
20th Floor, L & C Tower
401 Church Street
Nashville, TN 37243–1548
(615) 532–0131

Party who will approve final copy for publication and contact for disk acquisition:
Barbara A. Davis
TDEC Division of Radiological Health
3rd Floor, L & C Annex
401 Church Street
Nashville, TN 37243–1532
(615) 532–0364

Signature of the agency officer or officers directly responsible for proposing and/or drafting these rules.

Michael H. Mobley, Director
Division of Radiological Health

Barbara A. Davis
Division of Radiological Health

I certify that this is an accurate and complete copy of proposed rules lawfully promulgated and adopted by the Tennessee Department of Environment and Conservation on the _____ day of _____, 19____.

The Secretary of State is hereby instructed that, in the absence of a petition for rulemaking hearing being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of thirty (30) days after the publication date of the issue of the Tennessee Administrative Register in which these proposed rules are published.

Justin P. Wilson, Commissioner
Tennessee Department of Environment and Conservation

Subscribed and sworn to before me this the _____ day of _____, 19____.

Notary Public

My commission expires on the _____ day of _____, 19____.

All proposed 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.

Charles W. Burson
Attorney General and Reporter

The proposed rules set out herein were properly filed in the Department of State on the _____ day of _____, 19____, and pursuant to the instructions set out above, and in the absence of the filing of an appropriate petition calling for a rulemaking hearing, will become effective on the _____ day of _____, 19____.

_____

Riley C. Darnell
Secretary of State

By _____

TN UNIQUE DIFFERENCE MISSING

Rulemaking Hearing Rules
of
Tennessee Department of Environment and Conservation
Division of Radiological Health

Chapter 1200–2–5
Standards for Protection Against Radiation

Amendments

Rule 1200–2–5–.141 Notification of Incidents is amended by deleting the Rule and substituting new wording, so that as amended Rule 1200–2–5–.141 shall read:

1200–2–5–.141 Notification of Incidents

(1) Immediate notification. Notwithstanding other requirements for notification the requirements of this Rule are controlling. Licensees and registrants shall notify the Division as soon as possible but not later than four (4) hours after discovery that a source of radiation possessed by the licensee or registrant has caused, may have caused or threatens to cause any of the following:

(a) An individual to receive:

1. A total effective dose equivalent of 25 rems (0.25 Sv) or more,

2. An eye dose equivalent of 75 rems (0.75 Sv) or more, or

3. A shallow–dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more;

(b) The release of radioactive material that could cause an individual present for 24 hours to receive five times or more the annual occupational limit on intake. This does not apply to locations where personnel are not normally stationed during routine operations, such as hot–cells or specific process enclosures; or

(c) Prevention of immediate protective actions necessary to avoid exposure to radiation or releases that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(2) Twenty–four hour notification. Licensees and registrants shall notify the Division within 24 hours after discovery that a source of radiation possessed by the licensee or registrant may have caused or threatens to cause any of the following:

INVOLVING LOSS OF CONTROL OF LICENSED MATERIAL

(a) An individual to receive, in a period of 24 hours:

1. A total effective dose equivalent exceeding 5 rems (0.05 Sv),

2. An eye dose equivalent exceeding 15 rems (0.15 Sv), or

3. A shallow–dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv);

(b) The release of radioactive material that could cause an individual present for 24 hours to receive an intake exceeding one annual occupational limit on intake. This does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or specific process enclosures; or

(c) Any of the following events involving licensable material:

1. An unplanned contamination event that:

   (i) Requires restricted access to the contaminated area for more than 24 hours. Restriction may be by imposing additional radiological controls or by prohibiting entry into the area,

   (ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified for the material in Schedule RHS 8-30 of 1200-2-5, and

   (iii) Restricts access to the area for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed when:

   (i) The equipment is required by regulation or license condition to:

      (I) Prevent releases exceeding regulatory limits,

      (II) Prevent exposures to radiation exceeding regulatory limits, or

      (III) Mitigate the consequences of an accident;

   (ii) The equipment is required to be available and operable when it is disabled or fails to function; and

   (iii) No equipment meeting the same performance standards is immediately available, operable and capable of performing the required safety function.

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

4. An unplanned fire or explosion damaging any licensable material or any device, container or equipment containing licensable material when:

   (i) The quantity of material involved exceeds five times the lowest annual limit on intake specified for the material in Schedule RHS 8-30 of 1200-2-5, and

(ii) The damage affects the integrity of the licensable material or any device, container or equipment containing licensable material.

(3) Preparation and submission of reports. Licensees and registrants shall make reports in response to the requirements of this section as follows:

(a) Licensees and registrants shall make reports required by paragraphs (1) and (2) of this Rule by telephone to the Division.

1. The telephone number for the Division is:

(615) 532–0364 7:00 a.m. Central Time to 4:30 p.m. Central Time except weekends and holidays

(615) 741–0001 Tennessee Emergency Management Agency at all other times.

2. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

(i) The caller's name and call back telephone number;

(ii) A description of the event, including date and time;

(iii) The exact location of the event;

(iv) The isotopes, quantities, and chemical and physical form of the licensable material involved; and

(v) Any personnel radiation exposure data available.

(b) Written report. Licensees and registrants who make a report required by paragraph (1) or (2) of this Rule shall submit a written follow–up report within 30 days of the initial report. This requirement may be satisfied by submitting written reports prepared under other regulations that contain all necessary information and are appropriately distributed. Licensees and registrants shall send these written reports to the Division at the address given in 1200–2–4–.07. The reports shall include the following:

1. A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

2. The exact location of the event;

3. The isotopes, quantities, and chemical and physical forms of the licensable material involved;

4. Date and time of the event;

5. Corrective actions taken or planned and the results of any evaluations or assessments; and

6. For each individual exposed:

(i) The name, Social Security number and date of birth. The report shall be prepared so that this information is stated in a separate and detachable part, and

(ii) The extent of exposure of each individual without identification of individuals by name.

(4) This Rule does not include doses that result from, and are within the limits for, planned special exposures reported under 12–2–5–.144.

Authority: T.C.A. 4–5–201 *et seq.*; T.C.A. 68–202–203 and 206.

Legal Contact:
Greer C. Tidwell, Jr.
TDEC Office of General Counsel
20th Floor, L & C Tower
401 Church Street
Nashville, TN 37243–1548
(615) 532–0131

Party who will approve final copy/
Contact for disk acquisition:
Barbara A. Davis
TDEC Division of Radiological Health
3rd Floor, L & C Annex
401 Church Street
Nashville, TN 37243–1532
(615) 532–0364

Signature of the agency officer or officers directly responsible for proposing and/or drafting these rules:

Michael H. Mobley, Director
Division of Radiological Health

Barbara A. Davis
Division of Radiological Health

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Department of Environment and Conservation on the _____ day of _____, 19____.

Further, I certify that the provisions of T.C.A. §4–5–222 have been fully complied with, that these rules are properly presented for filing, a notice of rulemaking hearing has been filed in the Department of State on the _____ day of _____, 19____, and such notice of rulemaking hearing having been published in the _____ 19___, issue of the *Tennessee Administrative Register*, and such rulemaking hearing having been conducted pursuant thereto on the _____ day of _____, 19____.

Justin P. Wilson, Commissioner
Tennessee Department of Environment and Conservation

Subscribed and sworn to before me the _____ day of _____, 19____.

Notary Public

My commission expires on the _____ day of _____, 19____.

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.

Charles W. Burson
Attorney General and Reporter

The rulemaking hearing rules set out herein were properly filed in the Department of State on the _____ day of _____, 19____, and will become effective on the _____ day of _____, 19____.

Riley C. Darnell
Secretary of State

By_____

34.20 OK

RULES
OF
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

34.20

CHAPTER 1200-2-8
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY OPERATIONS

TABLE OF CONTENTS

1200-2-8-.01 Purpose

This Chapter establishes requirements for the use of sources of radiation for industrial radiography operations. Except for the requirements of this Chapter clearly applicable only to devices employing sealed radioactive sources, e.g., 1200-2-8-.04(1) and (5), both radiation machines and sealed radioactive sources are covered by this Chapter. The provisions of this Chapter are in addition to and not in substitution for other applicable provisions of these regulations.

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. Administrative History: Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.02 Scope

The regulations in this Chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. Nothing in this Chapter shall apply to the use of sources of radiation in the healing arts.

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. Administrative History: Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.03 Definitions

(1) *Cabinet radiography* means industrial radiography using radiation machines in an enclosed interlocked cabinet in which:

ATTACHMENT 3

(a) The radiation machine will not operate unless all openings are closed with interlocks activated;

(b) The cabinet is so shielded that every location on the exterior meets the conditions for an unrestricted area as defined in Chapter 1200–2–5; and

(c) The cabinet is so constructed or arranged as to exclude the entrance of any part of the body of an individual during irradiation.

(d) Baggage entrance and exit openings of airport baggage systems need not be interlocked. All other openings in these systems shall be interlocked. The operator shall be present during operation to ensure no individual enters the device through the baggage entrance or exit opening(s).

(2) *Direct Surveillance* means direct physical observation of a source of radiation, source changer or storage container.

(3) *Permanent radiographic installation* means a shielded installation or structure designed or intended for radiography and in which radiography is regularly performed.

(4) *Personal supervision* means supervision with the radiographer:

(a) Physically present at the site where sources of radiation and associated equipment are being used;

(b) Observing the radiographer's assistant's performance; and

(c) In such proximity that immediate assistance can be given if required.

(5) *Radiographer* means any individual who performs or personally supervises industrial radiographic operations and is responsible to the licensee or registrant for assuring compliance with these regulations and all license or registration conditions.

(6) *Radiographer's assistant* means any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools or radiation survey instruments in industrial radiography.

(7) *Radiographic exposure device* means:

(a) Any instrument having a sealed source in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position; or

(b) Any apparatus that may produce, when the associated controls are operated, one or more forms of radiation

used for making a radiographic exposure.

(8) *Shielded room x-ray radiography* means industrial radiography utilizing radiation machines that is conducted in an enclosed room:

(a) Which is not occupied during radiographic operations;

(b) Which is shielded so that every location on the exterior meets the conditions for an unrestricted area as defined in Chapter 1200–2–5; and

(c) The only access to which is through openings that are interlocked so that the radiation machine will not operate unless all openings are closed with interlocks activated.

(9) *Source changer* means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transportation and storage of sealed sources.

(10) *Storage area* means any location, facility or vehicle that is used to store, to transport or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and that is locked or has a physical barrier to prevent accidental exposure, tampering with or unauthorized removal of the device, container or source.

(11) *Storage container* means a device in which sealed sources are transported or stored.

(12) *Temporary job site* means any location where industrial radiography is performed other than the location(s) listed in the specific license or registration.

Authority: T.C.A. §§4–5–201 et seq., 68–202–203 and 68–202–206. Administrative History: Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed June 19, 1989; effective September 27, 1989. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200–2–8–.04 Equipment Control

(1) Limits on levels of radiation for radiographic exposure devices and storage containers:

(a) Radiographic exposure devices measuring less than 4 inches (10 centimeters) from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens per hour at 6 inches (15 centimeters) from any exterior surface of the device. Radiographic exposure devices measuring a minimum of 4 inches (10 centimeters) from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, and 10 milliroentgens per hour at 1 meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.

(b) Subparagraph (1)(a) of this Rule applies to all equipment manufactured prior to January 10, 1992. After January 10, 1996, radiographic equipment other than storage containers and source changers shall meet the requirements of 1200–2–8–.04(10), and paragraph (1) of this Rule applies only to storage containers and source changers.

(2) Locking of sources of radiation and storage containers:

(a) Each source of radiation shall have a lock or outer locked container designed to prevent unauthorized or accidental production of radiation, or removal or exposure of a sealed source. Each source of radiation shall be kept locked at all times except when under the direct surveillance of a radiographer or a radiographer's assistant who is under the personal supervision of a radiographer, or as may be otherwise authorized pursuant to Chapter 1200–2–5. Each source changer and storage container shall have a lock and be kept locked when containing sealed sources except when the container or source changer is under the direct surveillance of a radiographer or a radiographer's assistant under the personal supervision of a radiographer.

(b) Radiographic exposure devices, source changers, and storage containers, shall be locked and surveyed to assure that the sealed source is in the shielded position:

1. Before being moved from one location to another; and

2. Before being secured at a given location.

(3) Storage precautions: Locked radiographic exposure devices, source changers and storage containers shall be physically secured to prevent tampering with or removal by unauthorized persons.

(4) Radistion survey instruments:

(a) The licensee or registrant shall maintain calibrated and operable radiation survey instruments to make physical radiation surveys as required by this Chapter and Chapter 1200–2–5 of these regulations. Instrumentation required by this paragraph shall have a range such that 2 milliroentgens per hour through 1 roentgen per hour can be measured.

(b) Each radiation survey instrument shall be calibrated:

1. At energies appropriate for use and at intervals not to exceed three (3) months and after each instrument servicing;

2. Such that accuracy within plus or minus 20 percent can be demonstrated; and

3. At two or more widely separated points, other than zero, on each scale.

(c) Records of calibrations, dates and results thereof shall be maintained for inspection by the Division for three (3) years after the date of calibration.

(5) Leak testing, repairing, tagging, opening, modifying and replacing of sealed sources:

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the Division, the U.S. Nuclear Regulatory Commission, or any Agreement State.

(b) Each sealed source shall be tested for leakage at intervals not to exceed six

(6) months. In the absence of a certificate from a transferor that a test has been made within the six (6) months prior to the transfer, the sealed source shall not be put into use until tested.

(c) The leak test shall be capable of detecting the presence of 0.005 microcurie of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to 1200–2–10–.13(6)(e). Records of leak test results shall identify each sealed source and its container by serial number and shall be kept in units of microcuries or disintegrations per minute (dpm) and maintained for inspection by the Division for three years after the test is made.

(d) Any test conducted pursuant to (b) and (c) of this paragraph that reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Division regulations. Two copies of a report shall be filed within five (5) days after obtaining results of the test with the Division at its office located at L & C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243–1532, describing the equipment involved, the test results and the corrective action taken.

(e) A sealed source that is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least one (1) inch (2.54 centimeters) square bearing the conventional radiation caution symbol, as described in Chapter 1200–2–5, and at least the instructions:

"DANGER – RADIOACTIVE MATERIAL – DO NOT HANDLE – NOTIFY CIVIL AUTHORITIES IF FOUND"

(6) Quarterly inventory. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation received and possessed by him. The records of the inventories shall be maintained for three (3) years from the date of the inventory for inspection by the Division. The records shall include the quantities and kinds of radioactive material, location of all sources of radiation, and the date of inventory. Each sealed source and its radiographic exposure device shall be identified by serial number.

(7) Utilization logs. Each licensee or registrant shall maintain current logs at the address specified in the license or registration. These logs shall be kept available for three (3) years from the date of the recorded event for inspection by the Division. The logs shall show for each source of radiation the following information:

(a) A description (make, model and serial number) of each radiographic exposure device and, if appropriate, sealed source(s) contained therein;

(b) The identity of the radiographer to whom assigned; and

(c) Locations (plant or site) where used and dates of use.

(8) Inspection and maintenance of radiographic exposure devices, source changers, and storage containers.

(a) The licensee shall check for obvious defects in radiographic exposure devices, storage containers and source changers prior to use each day the equipment is used.

(b) The licensee shall conduct a program of inspection and maintenance of radiographic exposure devices, source changers, and storage containers at intervals not to exceed three (3) months, or prior to the first use thereafter, to assure proper functioning of components important to safety. Records of these inspections and maintenance shall be retained for three (3) years for inspection by the Division.

(9) Permanent radiographic installations.

(a) Permanent radiographic installations having high radiation area entrance controls of the types described in Chapter 1200-2-5 shall also meet the special requirements in (b) and (c) of this paragraph.

(b) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be actuated by radiation whenever the source is exposed or a radiation area is generated. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed or a radiation area is generated.

(c) The alarm system shall be tested at intervals not to exceed three (3) months, or prior to the first use thereafter of the source of radiation in the installation. The licensee or registrant shall retain records of these tests for three (3) years for inspection by the Division.

34.20 = (10) Performance requirements for radiography equipment. Equipment utilizing radioactive material used in industrial radiographic operations shall meet the following minimum criteria:

(a) Each radiographic exposure device and all associated equipment shall meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981) American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018 (ANSI N432).

(b) In addition to the requirements specified in subparagraph (a) of this paragraph, the following requirements apply to radiographic exposure devices and associated equipment:

1. Each radiographic exposure device shall have attached to it by the user a durable, legible, clearly visible label bearing the:

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Radioactivity and the date on which this radioactivity was last measured;

(iii) Model number and serial number of the sealed source;

(iv) Manufacturer of the sealed source; and

(v) Licensee's name, address and telephone number.

2. Any radiographic exposure device intended for use as a Type B transport container shall be currently approved by the U.S. Nuclear Regulatory Commission as a Type B package according to the requirements of 10 CFR Part 71.

3. Modification of any exposure devices and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(c) In addition to the requirements specified in subparagraphs (a) and (b) of this paragraph, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine operation:

1. The coupling between the source assembly and the source control cable shall be designed in such a manner that the source assembly shall not become disconnected if cranked outside the guide tube. The coupling shall be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

2. The device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system shall only be released by means of a deliberate operation on the exposure device.

3. The outlet fittings, lock box and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers that shall be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

4. Each sealed source or source assembly shall have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER – RADIOACTIVE." The label shall not interfere with the safe operation of the exposure device or associated equipment.

5. The guide tube shall have passed the crushing tests for the control tube as specified in ANSI N432 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

6. Guide tubes shall be used when moving the source out of the device.

7. An exposure head or similar device designed to prevent the source

assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.

8. The guide tube exposure head connection shall be able to withstand the tensile test for control units specified in ANSI N432.

9. Source changers shall provide a system for assuring that the source shall not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992, shall comply with the requirements of this paragraph (10).

(e) All radiographic exposure devices and associated equipment in use after January 10, 1996, shall comply with the requirements of this paragraph (10).

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. Administrative History: Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.05 Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants

(1) Training.

(a) The licensee or registrant shall not permit any individual to act as a radiographer as defined in this Chapter until such individual:

1. Has been instructed in the subjects outlined in 1200-2-8-.07 and has demonstrated understanding thereof by successful completion of a written test and a field examination on the subjects covered that has been approved by the Division;

2. Has received copies of and instruction in:

(i) The regulations contained in this Chapter;

(ii) The applicable rules of Chapters 1200-2-5 and 1200-2-9;

(iii) License or registration conditions; and

(iv) The licensee's or registrant's operating and emergency procedures

and shall have been tested in a manner approved by the Division to demonstrate understanding thereof; and

3. Has physically demonstrated competence to use the sources of

radiation, related handling tools, and survey instruments that will be employed in his assignment.

(b) The licensee or registrant shall not permit any individual to act as a radiographer's assistant as defined in this Chapter until such individual:

1. Has received copies of and instruction in the licensee's or registrant's operating and emergency procedures and shall have been tested in a manner approved by the Division to demonstrate understanding thereof; and

2. Has physically demonstrated competence to use, under the personal supervision of the radiographer, the sources of radiation, related handling tools, and survey instruments that will be employed in his assignment.

(c) Records of the above training and testing, including copies of the written tests and dates of oral tests and field examinations, shall be maintained for three (3) years for inspection by the Division.

(d) Whenever a radiographer's assistant uses sources of radiation or related handling tools or conducts radiation surveys required by 1200-2-8-.06(3)(b) to determine that the sealed source has returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer.

(2) Operating and emergency procedures. The licensee or registrant shall submit to the Division a copy of current operating and emergency procedures prior to the issuance or renewal of a license or registration. The licensee or registrant shall retain a copy of the operating and emergency procedures until the Division terminates the license or registration that authorizes the activity for which the procedures were developed. If the operating and emergency procedures are superseded, the superseded procedures shall be retained by the licensee or registrant for three (3) years after each change. These procedures shall include specific instructions in at least the following:

(a) The handling and use of sources of radiation to be employed such that no individual shall be exposed to radiation doses in excess of the limits established in Chapter 1200-2-5 of these regulations;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to radiographic areas;

(d) Methods and occasions for locking and securing sources of radiation;

(e) Personnel monitoring and the use of personnel monitoring equipment;

(f) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles and control of sources of radiation during transportation;

(g) Minimizing exposure of individuals in the event of an accident;

(h) The procedure for notifying proper persons in the event of an accident;

(i) Maintenance of records;

(j) The inspection and maintenance of radiographic exposure devices and storage containers; and

(k) Steps that shall be taken immediately by radiographic personnel in the event a pocket dosimeter is found to be off-scale.

(3) Personnel monitoring control.

(a) The licensee or registrant shall not permit any individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each such individual wears a direct-reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD). An alarm ratemeter is not required to be worn in permanent radiography facilities where other appropriate alarming or warning devices are in routine use. Pocket dosimeters shall have a range from zero to at least 200 milliroentgens but not greater than 1 roentgen and shall be recharged at the start of each shift. Each film badge and TLD shall be assigned to and worn by only one individual.

(b) Pocket dosimeters shall be read and exposures recorded daily. The licensee or registrant shall retain each record of these exposures for three (3) years after the record is made.

(c) Pocket dosimeters shall be checked at periods not to exceed one (1) year for correct response to radiation. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure.

(d) If an individual's pocket dosimeter is discharged beyond its range, industrial radiographic operations by that individual shall cease. The individual's film badge or TLD shall be sent for processing immediately. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made. Radiation exposures shall be maintained below the dose limits in Chapter 1200-2-5.

(e) Reports received from the film badge or TLD processor shall be kept for inspection by the Division until the Division authorizes disposition.

(f) If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD.

(g) Each alarm ratemeter shall:

1. Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;

2. Be set to give an alarm signal at a preset dose rate of 500 mR/hr;

3. Require special means to change the preset alarm function; and

4. Be calibrated at periods not to exceed one year for correct response to radiation. Acceptable ratemeters shall alarm within plus or minus 20 percent of the true radiation dose rate.

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. Administrative History: Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.06 Precautionary Procedures in Radiographic Operations

(1) Security. During each radiographic operation the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area as defined in Chapter 1200-2-5 except:

(a) Where the high radiation area is equipped with a control device or alarm system as required in Chapter 1200-2-5 of these regulations; or

(b) Where the high radiation area is locked to protect against unauthorized or accidental entry.

(2) Posting. Areas in which radiography is being performed shall be conspicuously posted according to the standards set out in Chapter 1200-2-5, without exceptions.

(3) Radiation surveys and survey records.

(a) The licensee or registrant shall ensure that at least one calibrated and operable radiation survey instrument is available:

1. At the location of its radiographic operations; and

2. At the storage area, as defined in 1200-2-8-.03, whenever a radiographic exposure device, a storage container or source is being placed in storage.

(b) After each exposure, the licensee or registrant shall ensure that a survey with a calibrated and operable radiation survey instrument is made to determine that the sealed source has been returned to its shielded position or that the radiation from the radiation machine has been terminated. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall include the guide tube.

(c) Any time a radiographic exposure device is placed in a storage area, the licensee shall ensure that a survey with a calibrated and operable radiation survey instrument is made to determine that the sealed source is in its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. The results of the last storage survey of the workday, required by this subparagraph (c), shall be recorded and retained for three (3) years.

(d) Records shall be kept of the duration of each radiographic exposure and the number of exposures made. In addition, for each radiographic exposure employing a radiation machine the voltage and current used shall be noted. These records shall be maintained for three (3) years for inspection by the Division and for field work may be kept on the area survey form.

(e) Each licensee or registrant conducting industrial radiography at a temporary jobsite shall have the following documents available at that site for inspection by the Division:

1. Appropriate license or registration;

2. Operating and emergency procedures;

3. Applicable regulations;

4. Survey records required pursuant to 1200-2-8-.06 and Chapter 1200-2-5 for the period of operation at the site;

5. Daily pocket dosimeter records for the period of operation at the site; and

6. The latest instrument calibration and leak test records for specific devices in use at the site. Acceptable records include tags or labels that are affixed to the device or survey meter.

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. Administrative History: Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed June 19, 1989; effective September 27, 1989. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.07 Minimum Subjects To Be Covered in Training Radiographers

(1) Fundamentals of radiation safety.

(a) Characteristics of [illegible] and gamma radiation.

(b) Units of radiation dose and quantity of radioactivity.

(c) Hazards of exposure to radiation.

(d) Levels of radiation from sources of radiation to be used.

(e) 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.

(c) Use of personnel monitoring equipment.

1. Film badges and thermoluminescent dosimeters (TLDs).

2. Pocket dosimeters.

3. Alarm ratemeters.

(3) Radiographic equipment to be used.

(a) Remote handling equipment.

(b) Radiographic exposure devices and sealed sources.

(c) Storage containers.

(4) The requirements of pertinent state regulations.

(5) The licensee's or registrant's written operating and emergency procedures.

(6) Case histories of radiography accidents.

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Repeal and new rule filed October 27, 1993; effective January 10, 1994.*

1200-2-8-.08 Cabinet Radiography

The only requirement of this Chapter which applies to cabinet radiography as defined in this Chapter is that no registrant shall permit any individual to operate a cabinet radiography unit until such individual has:

(1) Received a copy of the operating procedures for the unit;

(2) Received instruction in the operating procedures;

(3) Demonstrated an understanding of the operating procedures; and

(4) Demonstrated competence in the use of the unit.

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. Administrative History: Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.09 Fluoroscopic Radiography

Radiography utilizing fluoroscopy should be done only by remote observation; however, if direct viewing of the screen by personnel is used, the registrant shall demonstrate that radiation exposure limits are not exceeded.

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. Administrative History: Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.10 Required Administrative Procedures for Industrial Radiography Program

(1) Licensees and registrants shall have a program for training radiographers and radiographer's assistants and submit to the Division for approval a schedule or description of such program that includes the:

(a) Initial training:

1. This initial training shall consist of a complete training program as outlined in 1200-2-8-.07 or

2. Resumes of prior training and experience of individuals that show fulfillment of the requirements of 1200-2-8-.07(1) and (2) and the initial training of such individuals in the licensee's or registrant's specific radiography program as outlined in 1200-2-8-.07(3), (4) and (5);

(b) Periodic training (shall be at least annual);

(c) On-the-job training;

(d) Means to be used by the licensee or registrant to determine the radiographer's knowledge and understanding of and ability to comply with:

1. Division regulations and licensing or registration requirements; and

2. The licensee's or registrant's operating and emergency procedures; and

(e) Means to be used by the licensee or registrant to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the licensee's or registrant's operating and emergency procedures;

(2) The licensee or registrant shall establish and submit to the Division for approval written operating and emergency procedures as described in 1200-2-8-.05(2);

(3) The licensee or registrant shall establish and submit to the Division a description of its inspection program adequate to ensure that its radiographers and radiographer's assistants follow the Division's regulatory requirements and the licensee's or registrant's operating and emergency procedures. The inspection program shall:

(a) Include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three (3) months;

(b) Provide that if a radiographer or a radiographer's assistant has not participated in a radiographic operation for more than three (3) months since the last inspection, that individual's performance shall be observed and recorded the next time the individual participates in a radiographic operation; and

(c) Include the retention of inspection records on the performance of radiographers or radiographer's assistants for three (3) years;

(4) The licensee or registrant shall submit to the Division a description of his overall organizational structure pertaining to the radiography program, including specified delegations of authority and responsibility for operation of the program; and

(5) The licensee who desires to conduct his own leak tests shall establish procedures to be followed in testing sealed sources for possible leakage and/or contamination and shall submit to the Division for approval a description of such procedures including:

(a) Instrumentation to be used;

(b) Method of performing tests, e.g., points on equipment to be smeared and method of taking the smear; and

(c) Pertinent experience of the person who will perform the test.

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. Administrative History: Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed June 19, 1989; effective September 27, 1989. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.11 Shielded Room X-Ray Radiography

The only requirements of this Chapter applying to shielded room x-ray radiography are as follows:

(1) All entrances into the shielded room shall be provided with interlocks. After an interlock has been interrupted, broken, or tripped, it shall be possible to cause x-rays to be produced again only from the control panel. Interlocks shall not be used to shut off the x-ray equipment except in an emergency or during testing.

(2) Emergency shut–off switches shall be located within the high radiation areas so as to be accessible to individuals therein within the warning period in subparagraph (1)(e). These switches and their mode of operation shall be identified by a conspicuously posted sign adjacent to the switch. The emergency shut–off switches shall include a manual reset that must be reset at the switch before x–rays can again be produced from the control panel. After an emergency shut–off switch has been activated, it shall be possible to produce x–rays again only from the control panel.

(3) The interlock system and the emergency shut–off system shall be separate electrical and/or mechanical systems.

(4) The interior of the shielded room shall be provided with flashing or rotating warning lights that operate when, and only when, radiation is being produced. These lights shall be so positioned that they can be observed from any position or orientation within the room.

(5) An audible warning signal within the room shall be actuated for at least ten (10) seconds immediately prior to the first initiation of radiation after the closing of any opening that can admit personnel.

(6) The x–ray equipment control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, prevent the production of x–ray radiation by the equipment.

(7) All entrances into the shielded room shall be provided with a conspicuously visible warning device, which need not be flashing or rotating but which operates only when radiation is being produced.

(8) Surveys shall be made as required in 1200–2–8–.06(3)(b). Personnel devices providing an audible signal when activated by radiation will be acceptable for this survey. Proper operation of this device shall be checked daily and a record maintained of this check. All personnel working with the x–ray equipment shall be provided with such a device. This device shall be designed so as to clearly indicate entry into a 2 milliroentgen per hour x–ray radiation field.

(9) All personnel associated with the x–ray equipment shall be provided with personnel monitoring devices that shall be calibrated for the x–ray energies being utilized. Records of personnel exposure shall be maintained as required in Chapter 1200–2–5.

(10) No registrant shall permit any individual to operate a radiation machine for shielded room x–ray radiography until such individual has received a copy of, instruction in, and demonstrated an understanding of operating and emergency procedures for the unit, and competence in its use. (See 1200–2–8–.05(2)(a), (c), (d), (e), (g), (h), (i), (j) and (k)). These operating and emergency procedures shall be submitted to the Division for approval prior to their adoption.

(11) All safety and warning devices, including interlocks and emergency shut–off switches, shall be tested at intervals not to exceed three (3) months to determine that they are functioning properly. Records shall be maintained of all tests.

(12) If a safety or warning device malfunctions, the x–ray control panel shall be locked in the "off" position. It shall not be used, except as may be necessary for repair or replacement of the malfunctioning safety or warning device, until the safety or

warning device is functioning properly.

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. Administrative History: Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.12 Reporting Requirements

(1) In addition to the reporting requirements specified in other chapters of these regulations, each licensee or registrant shall provide a written report to the Division of Radiological Health, L & C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1532, within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

(a) Unintentional disconnection of the source assembly from the control cable.

(b) Inability to retract the source assembly to its fully shielded position and secure it in this position.

(c) Failure of any component (critical to safe operation of the device) to properly perform its intended function.

(2) The licensee or registrant shall include the following information in each report submitted under (1) of this Rule:

(a) A description of the equipment problem.

(b) Cause of each incident, if known.

(c) Manufacturer and model number of equipment involved in the incident.

(d) Place, time and date of the incident.

(e) Actions taken to establish normal operations.

(f) Corrective actions taken or planned to prevent recurrence.

(g) Qualifications of personnel involved in the incident.

(3) Reports of overexposure submitted under Chapter 1200-2-5 that involve failure of safety components of radiography equipment shall also include the information specified in (2) of this Rule.

Not implemented

QM

RULEMAKING HEARING RULES
OF
TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

CHAPTER 1200-2-5
STANDARDS FOR PROTECTION AGAINST RADIATION

AMENDMENTS

Rule 1200-2-5-.32 DEFINITIONS is amended by adding the following definitions in alphabetical order:

(1) *Auditable form* of records means records that comply with the forms described in 1200-2-5-.139 and that are maintained accessible for review by the Division's inspectors.

(2) *Authorized user* means:

(a) A licensed physician, dentist, or podiatrist who is identified as an authorized user for human use on:

1. A Nuclear Regulatory Commission or Agreement State license, or

2. A permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope; or

(b) A licensed physician who is authorized to administer therapeutic radiation machine therapy.

(3) *Diagnostic clinical procedures manual* means a collection of written radiopharmaceutical diagnostic procedures approved by the authorized user that:

(a) Describes each method (and other instructions and precautions) by which the licensee performs radiopharmaceutical diagnostic clinical procedures; and

(b) Includes the radiopharmaceutical, dosage, and route of administration.

(4) *Misadministration* means the administration of:

(a) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:

1. Involving the wrong patient, wrong human research subject, or wrong radiopharmaceutical, or

2. When both:

(i) The administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage, and

(ii) The administered dosage differs from the prescribed dosage

by more than 30 microcuries;

(b) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

1. Involving the wrong patient, wrong human research subject, wrong radiopharmaceutical, or wrong route of administration, or

2. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage;

(c) A stereotactic radiosurgery radiation dose:

1. Involving the wrong patient, wrong human research subject, or wrong treatment site, or

2. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(d) A teletherapy radiation dose:

1. Involving the wrong patient, wrong human research subject, wrong mode of treatment, or wrong treatment site,

2. When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose,

3. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose, or

4. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

(e) A brachytherapy radiation dose:

1. Involving the wrong patient, wrong human research subject, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site),

2. Involving a sealed source that is leaking,

3. When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure, or

4. When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose;

(f) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:

1. Involving the wrong patient, wrong human research subject, wrong

radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

2. When the dose to the patient exceeds 5 rems (50 millisieverts) effective dose equivalent or 50 rem (500 millisieverts) dose equivalent to any individual organ; or

(g) A therapeutic radiation machine dose:

1. Involving the wrong patient, wrong human research subject, wrong mode of treatment, or wrong treatment site,

2. When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose,

3. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose, or

4. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(5) *Prescribed dosage* means the quantity of radiopharmaceutical activity as documented in:

(a) A written directive; or

(b) The diagnostic clinical procedures manual.

(6) *Prescribed dose* means:

(a) For stereotactic radiosurgery, the total dose as documented in the written directive;

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(c) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(d) For therapeutic radiation machine therapy, the total dose and dose per fraction as documented in the written directive.

(7) *Recordable event* means the administration of:

(a) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(b) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(c) A radiopharmaceutical dosage greater than 30 microcuries of either sodium

iodide I–125 or I–131 when both:

1. The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

2. The administered dosage differs from the prescribed dosage by more than 15 microcuries;

(d) A therapeutic radiopharmaceutical dosage, other than sodium iodide I–125 or I–131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(e) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose;

(f) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose; or

(g) A therapeutic radiation machine dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose.

(8) *Therapeutic radiation machine* means x–ray or electron–producing equipment designed and used for external beam radiation therapy.

(9) *Written directive* means an order in writing for the administration of radiation to a specific patient or human research subject, dated and signed by an authorized user. Specific requirements for written directives are covered in 1200–2–5–.75.

Statutory Authority: T.C.A. 4–5–201 *et seq.*; T.C.A. 68–202–203 and 206.

Rule 1200–2–5–.75 RESERVED is amended by deleting the word "RESERVED" and adding the following language so that, as amended, Rule 1200–2–5–.75 shall read:

1200–2–5–.75 Quality Management Program for Human Use

(1) Licensees and applicants for licensure involving human use, and registrants and applicants for registration involving human use for therapy or research, shall establish and maintain a written quality management program. The purpose of the quality management program is to assure that radioactive material or radiation shall be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

(a) That, prior to the administration of a radiopharmaceutical or radiation, except as specified in subparagraph (1)(b)6 of this Rule, a written directive is prepared containing information as follows:

1. For any administration of quantities greater than 30 microcuries of either sodium iodide I–125 or I–131: the dosage,

2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I–125 or I–131: the radiopharmaceutical, dosage, and route of administration,

3. For stereotactic radiosurgery: target coordinates, collimator size, total dose, and, if appropriate, plug pattern,

4. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period,

5. For high–dose–rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose,

6. For all other brachytherapy:

   (i) Prior to implantation: the radioisotope, number of sources, and source strengths, and

   (ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose), or

7. For therapeutic radiation machine therapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(b) That oral directives or revisions to written directives may be made as follows:

1. If a written revision to an existing written directive would delay administration and thereby jeopardize the patient's health, an oral revision to an existing written directive is acceptable, provided:

   (i) The oral revision is documented immediately in the patient's record, and

   (ii) The authorized user issues a revised written directive within 24 hours of the oral revision.

2. A written revision to a written directive may be made if the revision is signed and dated by an authorized user prior to the administration.

(c) That each facility that performs radiopharmaceutical diagnostic procedures shall have a diagnostic clinical procedures manual;

(d) That, prior to each administration, the patient's or human research subject's identity is verified by two or more independent methods or persons as the individual named in the written directive;

(e) That final treatment plans and related calculations for brachytherapy, teletherapy, stereotactic radiosurgery, and therapeutic radiation machine

therapy agree with the respective written directives;

(f) That each administration is in accordance with the written directive or the diagnostic clinical procedures manual; and

(g) That any unintended deviation from the written directive or the diagnostic clinical procedures manual is identified and evaluated, and appropriate action is taken pursuant to these rules.

(2) Licensees and registrants shall:

(a) Develop procedures for and conduct a review of the quality management program. These reviews shall:

1. Include, since the last review, an evaluation of:

(i) A representative sample of patient and human research subject administrations,

(ii) All recordable events, and

(iii) All misadministrations; and

2. Be conducted at intervals no greater than 12 months to verify compliance with all aspects of the quality management program;

(b) Evaluate each review to determine the effectiveness of the quality management program in meeting the objectives of paragraph (1) of this Rule. The quality management program shall be modified if needed to assure the objectives are met; and

(c) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three (3) years.

(3) Licensees and registrants shall evaluate and respond to each recordable event within 30 days after discovery by:

(a) Assembling the relevant facts including the cause;

(b) Identifying what, if any, corrective action is required to prevent recurrence; and

(c) Retaining a record, in an auditable form, for three (3) years, of the relevant facts and what corrective action, if any, was taken.

(4) Licensees and registrants shall evaluate and respond to each misadministration in accordance with Rule 1200-2-5-.146.

(5) Licensees and registrants shall retain in an auditable form for three (3) years:

(a) Each written directive; and

(b) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph (1)(a) above.

(6) Licensees or registrants may modify the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. Licensees or registrants shall furnish modifications to the Division within 30 days after modifications have been made.

(8) Implementation of the quality management program:

(a) Each applicant for a new license involving human use shall submit to the Division a quality management program as part of the application for a license. Applicants shall implement the program upon issuance of the license by the Division.

(b) Each applicant for a new registration involving human use for therapy or research shall submit to the Division a quality management program as part of the application for a registration. Applicants shall implement the program upon issuance of the registration by the Division.

(c) On or before October 1, 1996, any licensee authorized for human use and any registrant authorized for human use for therapy or research, shall submit to the Division, a copy of the quality management program and a written certification that it has been implemented.

Statutory Authority: T.C.A. 4–5–201 *et seq.*; T.C.A. 68–202–203 and 206.

Rule 1200–2–5–.76 RESERVED is amended by deleting the word "RESERVED" and adding the following language so that, as amended, Rule 1200–2–5–.76 shall read:

1200–2–5–.76 Supervision Required by Licenses and Registrations Involving Human Use

(1) Licensees and registrants authorized for human use who permit an individual supervised by an authorized user to receive, possess, prepare, use, or transfer sources of radiation shall:

(a) Require an authorized user to be immediately available to communicate with the supervised individual;

(b) Allow human use only by specifically trained individuals, permitted under state and local regulations, and designated by the authorized user;

(c) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of sources of radiation and in the licensee's or registrant's written quality management program; and

(d) At intervals not greater than 12 months:

1. Review the supervised individual's use of sources of radiation,

2. Provide re–instruction as needed, and

8. Review the records kept to reflect this use.

(2) Licensees or registrants shall require the supervised individual to:

(a) Follow the instructions of the supervising authorized user;

(b) Follow the written radiation safety and quality management procedures established by the licensee or registrant; and

(c) Comply with these regulations and the license or registration conditions governing the use of sources of radiation.

(3) Licensees and registrants authorized for human use that supervise an individual are responsible for the acts and omissions of the supervised individual.

Statutory Authority: T.C.A. 4–5–201 *et seq.*; T.C.A. 68–202–203 and 206.

Rule 1200–2–5–.146 RESERVED is amended by deleting the word "RESERVED" and adding the following language so that, as amended, Rule 1200–2–5–.146 shall read:

1200–2–5–.146 Notifications, Records, and Reports Specific to Misadministrations

(1) The licensee or registrant shall notify the Division by telephone no later than the next working day after discovery of a misadministration. The telephone number of the Division is (615) 532–0364.

(2) The licensee or registrant shall submit a written report to the Division at the address given in Rule 1200–2–4–.07 within 15 days after discovery of a misadministration.

(a) The written report shall include:

1. The licensee's or registrant's name;

2. The prescribing physician's name;

3. A brief description of the event; including the prescribed dose or dosage and the administered dose or dosage;

4. Why the event occurred;

5. Corrective actions taken;

6. The effect or possible effect on the patient or human research subject;

7. What improvements are needed to prevent recurrence;

8. Actions taken to prevent recurrence; and

9. Whether the licensee or registrant notified the patient or human research subject, or the person having lawful authority to make medical decisions for the patient or human research subject. [Unless otherwise indicated, the patient or human research subject or the person having lawful authority to make medical decisions for the patient or human research subject, shall be subsequently referred to as the human subject in this Rule.]

(i) If the human subject was not notified, indicate why not, or

(ii) If the human subject was notified, indicate what information was provided to that individual.

(b) The report shall not include the human subject's name or other information that could lead to identification of the patient or human research subject.

(3) The licensee or registrant shall notify the referring physician and the human subject of the misadministration within 24 hours after discovery.

(a) Notification to the human subject is not required if the referring physician personally informs the licensee or registrant either that:

1. The referring physician will inform the human subject, or

2. Based on his medical judgment, telling the human subject would be harmful to the human subject.

(b) The licensee or registrant is not required to notify the human subject without first consulting the referring physician. If the referring physician or the human subject cannot be reached within 24 hours, the licensee or registrant shall notify the human subject as soon as possible thereafter.

(c) The licensee or registrant may not delay any appropriate medical care for the patient or human research subject because of any delay in notification. S[illegible]re includes care necessitated by the misadministration.

(4) If the human subject was notified, the licensee or registrant shall furnish, within 15 days after discovery of the misadministration, a written report to the human subject. This shall be done by sending either:

(a) A copy of the report that was submitted to the Division; or

(b) A brief description of the event and the consequences to the patient or human research subject, provided a statement is included that the report submitted to the Division can be obtained from the licensee or registrant.

(5) Licensees and registrants shall retain a record of each misadministration in an auditable form for five (5) years. The record shall contain:

(a) The names of all individuals involved in the misadministration (including the prescribing physician, allied health personnel, the patient or human research subject, and the patient's or human research subject's referring physician);

(b) The patient's or human research subject's social security number, or other identification number if one has been assigned by the licensee or registrant; and

(c) A brief description of the misadministration, including:

1. The prescribed dose or dosage and the administered dose or dosage,

2. Why it occurred,

3. The effect or possible effect on the patient or human research subject,

4. Corrective actions taken,

5. What improvements are needed to prevent recurrence, and

6. The actions taken to prevent recurrence.

(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees, registrants and physicians in relation to each other or human subjects.

Statutory Authority: T.C.A. 4–5–201 *et seq.*; T.C.A. 68–202–203 and 206.

Legal Contact:
Greer C. Tidwell, Jr.
TDEC Office of General Counsel
20th floor L&C Tower
401 Church Street
Nashville, TN 37243–1548
(615) 532–0131

Party who will approve final copy:
Barbara A. Davis
TDEC Division of Radiological Health
3rd floor L&C Annex
401 Church Street
Nashville, TN 37243–1532
(615) 532–0364

Signature of the agency officer or officers directly responsible for proposing and/or drafting these rules:

Michael H. Mobley, Director
Division of Radiological Health

Barbara A. Davis
Division of Radiological Health

I certify that this is an accurate and complete copy of rulemaking hearing rules lawfully promulgated and adopted by the Department of Environment and Conservation, Division of Radiological Health, on the _____ day of _____, 19____.

Further, I certify that these rules are properly presented for filing, a notice of rulemaking hearing has been filed in the Department of State on the _____ day of _____, 19____, and such notice of rulemaking hearing having been published in the _____ 19___, issue of the *Tennessee Administrative Register*, and such rulemaking hearing having been conducted pursuant thereto on the _____ day of _____, 19____.

Justin P. Wilson, Commissioner
Tennessee Department of Environment and Conservation

Subscribed and sworn to before me the _____ day of _____, 19____.

Notary Public

My commission expires on the _____ day of _____, 19____.

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.

Charles W. Burson
Attorney General and Reporter

The rulemaking hearing rules set out herein were properly filed in the Department of State on the _____ day of _____, 19____, and will become effective on the _____ day of _____, 19____.

Riley C. Darnell
Secretary of State

By _____