

December 8, 2008

Lawrence E. Nanney, Director
Division of Radiological Health
401 Church Street
Nashville, TN 37243

Dear Mr. Nanney:

We have reviewed the proposed changes to the Tennessee regulations, "State Regulations for Protection Against Radiation," received by our office on October 13, 2008. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 32, 35, 40, and 70 and the requirements of the five amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Beth Murphy on December 5, 2008.

As a result of our review, we have 13 comments that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that the Tennessee regulations meet the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final Tennessee regulations. However, we have determined that if your proposed regulations were adopted, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure [SA-200](#).

We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in FSME Procedure [SA-201](#), "Review of State Regulatory Requirements," please highlight the final changes, and provide a copy to Division of Materials Safety and State Agreements, FSME.

The SRS Data Sheet summarizes our knowledge of the status of other Tennessee regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the FSME website: <http://nrc-stp.ornl.gov/rulemaking.html>.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Kathleen Schneider, State Regulation Review Coordinator, at (301) 415-2320 (Kathleen.Schneider@nrc.gov) or Janine F. Katanic at (817) 860-8151 (Janine.Katanic@nrc.gov).

Sincerely,

/RA/

Terrence Reis, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:
As stated

Lawrence E. Nanney, Director
 Division of Radiological Health
 401 Church Street
 Nashville, TN 37243

Dear Mr. Nanney:

We have reviewed the proposed changes to the Tennessee regulations, "State Regulations for Protection Against Radiation," received by our office on October 13, 2008. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 32, 35, 40, and 70 and the requirements of the five amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Beth Murphy on December 5, 2008.

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Sincerely,

/RA/
 Terrence Reis, Deputy Director
 Division of Materials Safety and State Agreements
 Office of Federal and State Materials and Environmental
 Management Programs

Enclosures: As stated

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COMPATIBILITY COMMENTS ON *TENNESSEE* PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	1200-2-5-.60	20.1301 (a)	2002-2	A	<p>Dose limits for individual members of the public</p> <p>Tennessee’s regulation 1200-2-5-.60(1)(a) omits the word “medical” and instead states “...from any administration the individual has received...”</p> <p>Tennessee needs to add the word “medical” to 1200-2-5-.60(1)(a) in order to meet the Compatibility Category A designation assigned to 10 CFR 20.1301(a).</p>
2	1200-2-7-.10	35.11(a)	2002-2	C	<p>License Required</p> <p>Tennessee regulation 1200-2-7-.10(1) omits the wording “, US Nuclear Regulatory Commission, or Agreement State” after the words “... license issued by the Division”.</p> <p>Tennessee needs to make the above change to 1200-2-7-.10(1) in order to meet the Compatibility Category C designation assigned to 10 CFR 35.11(a).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
3	1200-2-7-.30	35.63	2002-2	H&S	<p>Determination of dosages of unsealed byproduct material for medical use</p> <p>In Tennessee's proposed regulation 1200-2-7-.30(3)(c), they state "... or equivalent Agreement State requirements." The regulation omits allowing for equivalent NRC requirements.</p> <p>Tennessee should change 1200-2-7-.30(3)(c) to read "... or preparer licensed under 1200-2-10-.13(10) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements." In order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.63.</p>
4	1200-2-7-.05 (3)	35.2	2006-1	B	<p>Definitions: Authorized medical physicist</p> <p>Tennessee's definition of Authorized medical physicist omits language equivalent to 10 CFR 35.2 definition Authorized medical physicist sections (2)(ii) and (2)(iv) regarding Commission master material licensees.</p> <p>Tennessee needs to add language equivalent to sections (2)(ii) and (2)(iv) to 1200-2-7-.05(3) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition Authorized medical physicist.</p>
5	1200-2-7-.05 (4)	35.2	2006-1	B	<p>Definitions: Authorized nuclear pharmacist</p> <p>Tennessee's definition of Authorized nuclear pharmacist omits language equivalent to 10 CFR 35.2 definition Authorized nuclear pharmacist sections (2)(ii) and (2)(iv) regarding</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>Commission master material licensees.</p> <p>Tennessee needs to add language equivalent to sections (2)(ii) and (2)(iv) to 1200-2-7-.05(4) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition Authorized nuclear pharmacist.</p>
6	1200-2-7-.05 (5)	35.2	2006-1	B	<p>Definitions: Authorized user</p> <p>Tennessee's definition of Authorized user omits language equivalent to 10 CFR 35.2 definition Authorized user sections (2)(ii) and (2)(iv) regarding Commission master material licensees.</p> <p>Tennessee needs to add language equivalent to sections (2)(ii) and (2)(iv) to 1200-2-7-.05(5) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition Authorized user.</p>
7	1200-2-7-.05 (30)	35.2	2006-1	B	<p>Definitions: Radiation Safety Officer</p> <p>Tennessee's definition of Radiation safety officer omits language equivalent to 10 CFR 35.2 definition Radiation safety officer section (2)(ii) regarding Commission master material licensees.</p> <p>Tennessee needs to add language equivalent to section (2)(ii) to 1200-2-7-.05(30) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition Radiation safety officer.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	1200-2-7-.39	35.190	2006-1	B	<p>Training for uptake, dilution and excretion studies</p> <p>Tennessee's regulation 1200-2-7-.39(1)(a) states "...who meets the requirements of subsection (1)(c) of this section.". However this section should state "... who meets the requirements of subsection (1)(c)2 of this section.".</p> <p>Tennessee needs to change 1200-2-7-.39(1)(a) to correct for the above in order to meet the Compatibility Category B designation assigned to 10 CFR 35.190.</p>
9	1200-2-7-.47	35.390	2006-1	B	<p>Training for use of unsealed byproduct material for which a written directive is required</p> <p>Tennessee's regulation 1200-2-7-.47(1)(a) states "... who meets the requirements of (1)(b) of this section.". However this section should state "... who meets the requirements of (1)(b)1(ii)(VI) and (1)(b)2 of this section.".</p> <p>Tennessee needs to change 1200-2-7-.47(1)(a) to reflect the above in order to meet the Compatibility Category B designation assigned to 10 CFR 35.390.</p>
10	1200-2-7-.49	35.394	2006-1	B	<p>Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)</p> <p>Tennessee's regulation 1200-2-7-.49(1)(a) omits the text "...and who meets the requirements in paragraph 1(c)3 of this section." After the words "...or an Agreement State".</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					Tennessee should make the above change to 1200-2-7-.49(1)(a) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.394.
11	1200-2-7-.59	35.490	2006-1	B	<p>Training for use of manual brachytherapy sources</p> <p>Tennessee's regulation 1200-2-7-.59(1)(a) omits the text "...and who meets the requirements in paragraph 1(b)3 of this section." After the words "...or an Agreement State".</p> <p>Tennessee should make the above change to 1200-2-7-.59(1)(a) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.490.</p>
12	1200-2-7-.60	35.491	2006-1	B	<p>Training for ophthalmic use of strontium-90</p> <p>Tennessee regulation 1200-2-7-.60 omits the words "clinic or private practice" after the words "medical institution" in 1200-2-7-.60(1)(b)2.</p> <p>Tennessee needs to make the above change to 1200-2-7-.60(1)(b)2 in order to meet the Compatibility Category B designation assigned to 10 CFR35.491.</p>
13	1200-2-10-.13 (10)	32.72	2007-1	B	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35</p> <p>Tennessee's proposed regulation 1200-2-10-.13(10)(b)(5)(iii) states "The license issued by a licensee of a broad scope; and ... ". However, 1200-2-10-.13(10)(b)(5)(iii) should read: "The permit issued by a licensee of a broad scope; and ..."</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					Tennessee needs to change the word license to the word permit in 1200-2-10-.13(10(b)(5)(iii) in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72.

STATE REGULATION STATUS

State: Tennessee

Tracking Ticket Number: 8-93

[5 amendment(s) reviewed is identified by a ★
at the beginning of the equivalent NRC requirement.]

Date: December 8, 2008

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (Superceded by 1997-5)	01/10/1994	Not Required	Not Required	Tennessee has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 (Superceded by 1997-5)	none	Not Required	Not Required	Tennessee has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-3	Standards for Protection Against Radiation Part 20 56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183;	01/01/1994	Final ML062130090	No Comments 09/01/2006 ML062490270	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final	No Comments 12/02/1996	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995			Tennessee has not yet adopted Final Regulations equivalent to RATS ID: 2002-2.
1992-2	Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30, 35 57 FR 45566	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628	10/25/1996	Final	No Comments 05/21/1997	1997-current LBR adequate per MRB
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Not Applicable ¹	Not Applicable	Tennessee does not have any licensees subject to these regulations. (See SECY-95-112)

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Final	No Comments 12/02/1996	
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1994-2	Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220	07/01/1997	Not Applicable	Not Applicable	Tennessee does not have the authority to regulate this material under its Agreement.
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997	Final ML071560152	No Comments 07/11/2007 ML071920135	
1995-1	Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use Parts 30, 32, 35 59 FR 61767; 59 FR 65243; 60 FR 322	01/01/1998	Final ML020320229	No Comments 02/01/2002 ML020360223	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment	03/13/1998	Final ML020320229	No Comments 02/01/2002 ML020360223	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final ML020320229	No Comments 02/01/2002 ML020360223	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superceded by 1997-5)	06/30/1998	Final ML020320229	No Comments 02/01/2002 ML020360223	Tennessee has adopted Final Regulations equivalent to RATS ID: 1997-5.
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final ML020320229	No Comments 02/01/2002 ML020360223	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 (Superceded by 2002-2 and 2005-2)	10/20/1998	Final ML040980538	No Comments 05/06/2004 ML041270512	Tennessee has not yet adopted Final Regulations equivalent to RATS IDs: 2002-2 and 2005-2.
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 (Superceded by 2004-1)	04/01/1999	Final ML020320229	No Comments 02/01/2002 ML020360223	Tennessee has not yet adopted Final Regulations equivalent to RATS ID: 2004-1.
1996-2	One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40, 70 61 FR 1109	02/15/1999	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1996-3	Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61, 70 61 FR 24669	06/17/1999			
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final ML020320229	No Comments 02/01/2002 ML020360223	
1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662	02/27/2000	Final ML020320229	No Comments 02/01/2002 ML020360223	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final ML020320229	No Comments 02/01/2002 ML020360223	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superceded by 2004-1)	02/10/2000	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078)
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, 150 62 FR 28947	06/27/2000	Final ML020320229	No Comments 02/01/2002 ML020360223	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final ML040980538	Comments 05/06/2004 ML041270512	
1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	Final ML020320229	No Comments 02/01/2002 ML020360223	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150	02/12/2001	Final ML020320229	No Comments 02/01/2002 ML020360223	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535	07/01/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1998-3	License Term for Medical Use Licenses Part 35 63 FR 31604 (Superseded by 2002-2)	07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074)
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final ML040980538	No Comments 05/06/2004 ML041270512	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 35, 36 63 FR 39477; 63 FR 45393	10/26/2001	Final ML062130094	No Comments 09/01/2006 ML062490270	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML062130094	No Comments 09/01/2006 ML062490270	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	Tennessee does not have the authority to regulate this material under its Agreement.
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested	10/04/2002	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
	Information Part 31 64 FR 42269				
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	Final ML062130094	No Comments 09/01/2006 ML062490270	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML062130094	No Comments 09/01/2006 ML062490270	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML062130094	No Comments 09/01/2006 ML062490270	
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material	02/16/2004	Final ML071560152	Comments 07/11/2007 ML071920135	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML071560152	No Comments 07/11/2007 ML071920135	
★2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Proposed ML082880557	Comments 12/08/2008 ML083181114	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006			
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007			
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	License Condition ML081260292	No Comments 05/13/2008 ML081340237	
★2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35	04/29/2008	Proposed ML082880557	No Comments 12/08/2008 ML083181114	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML052590043	No Comments 09/19/2005 ML052630474	
★2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Proposed ML082880557	Comments 12/08/2008 ML083181114	
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Not Applicable ¹	Not Applicable	Tennessee does not have any licensees subject to these regulations.
★2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Proposed ML082880557	No Comments 12/08/2008 ML083181114	
★2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Proposed ML082880557	Comments 12/08/2008 ML083181114	
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, 150 72 FR 58473	12/17/2010			
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010			
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901	06/05/2008	License Condition ML080840479	No Comments 04/14/2008 ML081050443	
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011			

¹ IMPEP Team: verify that Tennessee does not have any licensees subject to these regulations during each review.