

October 29, 2009

Cindy Cardwell, Manager
Radiation Policy, Standards and Q/A Group
Department of State Health Services
P.O. Box 149347
Austin, TX 78714-9347

Dear Ms. Cardwell:

We have reviewed the final revision to the Texas Department of State Health Services regulations 25 T.A.C. 289, received by our office on September 2, 2009. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 32, and 35 and the requirements of the two amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Monica Perez on October 27, 2009.

As a result of our review, we have 11 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. We have determined that if these regulations are revised, 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 you revise your regulations to address our comments, 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 location of any changes made by Texas, in response to our comments, 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 Texas Department of State Health Services 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).

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

Cindy Cardwell, Manager
 Radiation Policy, Standards and Q/A Group
 Department of State Health Services
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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 TEXAS FINAL REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	289.252(r)	32.72	2002-2	B	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35</p> <p>Texas is more restrictive by adding requirements to labeling required for a syringe or vial. Texas needs to remove 289.252(r)(1)(C)(ii)(II) & (III) from its regulation.</p> <p>Texas omits an equivalent section to 10 CFR 32.72(b)(3) from its regulations. Texas needs to add equivalent text to 289.252(r).</p> <p>Texas needs to make the above changes to 289.252(r) in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72.</p>
2	289.252(o)	32.74	2002-2	B	<p>Manufacture and distribution of sources or devices containing byproduct material for medical use</p> <p>Texas omits 289.256(q) from the introductory paragraph in 289.252(o). The sentence should read "...or for use of sealed sources listed in 289.256(q), (rr), (bbb), and (ddd) of this title ..."</p> <p>Texas also allows in 289.252(o)(2) for "...labeling for sealed sources that do not require long-term storage may be on a leaflet or brochure that accompanies the sealed source;". NRC does not have an equivalent provision in its regulations making Texas' regulation less restrictive. Texas needs to remove this wording from 289.252(o)(2).</p> <p>Texas needs to make the above</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					changes to 289.252(o) in order to meet the Compatibility Category B designation assigned to 10 CFR 32.74.
3	289.256 (c)(3)	35.2	2002-2	B	<p>Definition: Authorized Medical Physicist</p> <p>Texas adds an additional section (289.256(c)(3)(C)) to their definition of Authorized Medical Physicist. This section makes this definition more restrictive than NRC's definition.</p> <p>Texas needs to remove section (C) from 289.256(c)(3) Authorized Medical Physicist to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized Medical Physicist.</p>
4	289.256 (c)(4)	35.2	2002-2	B	<p>Definition: Authorized nuclear pharmacist</p> <p>Texas adds an additional section (289.256(c)(4)(E)) to their definition of Authorized Nuclear Pharmacist. This section makes this definition more restrictive than NRC's definition.</p> <p>Texas omitted an "or" at the end of 289.256(c)(4)(B)(iv).</p> <p>Texas needs to make the above changes to their definition of Authorized Nuclear Pharmacist to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized Nuclear Pharmacist.</p>
5	289.256 (c)(5)	35.2	2002-2	B	<p>Definition: Authorized user</p> <p>Texas adds additional text to this definition making it more restrictive than NRC's definition. Texas requires the physician, dentist, and podiatrist be licensed by the Texas Medical</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>Board, the Texas State Board of Dental Examiners, and the Texas State Board of Podiatric Medicine respectfully. Texas needs to remove this language from the definition.</p> <p>Texas needs to make the above change to 289.256(c)(5) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition Authorized User.</p>
6	289.256 (c)(22)	35.2	2002-2	C	<p>Definition: Prescribed dosage</p> <p>Texas uses the term “radiopharmaceutical” instead of unsealed byproduct material in their definition of Prescribed dosage. This makes their definition less restrictive than NRC’s definition.</p> <p>Texas needs to remove the word radiopharmaceutical and replace it with unsealed byproduct material (or unsealed radioactive material) in order to meet the Compatibility Category C designation assigned to 10 CFR 35.2 Definition Prescribed Dosage.</p>
7	289.201 (B)(94)	35.2	2002-2	[B]	<p>Definition: Sealed Source</p> <p>Texas adds language to their definition of Sealed Source and device which makes the definition less restrictive than NRC’s definition. Texas needs to remove “under the most severe conditions that are likely to encountered in normal use and handling” from the definition.</p> <p>Texas needs to make the above change in order to meet the Compatibility Category [B] designation assigned to 10 CFR 35.2 Definition Sealed Source.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	289.256(r)	35.11	2002-2	[C]	<p>License Required</p> <p>Texas submitted a cross walk stating that this section's equivalent was 289.256(r), however there is no equivalent text in this section to 10 CFR 35.11.</p> <p>Texas needs to add a section equivalent to 10 CFR 35.11 in order to meet the Compatibility Category [C] designation assigned to 10 CFR 35.11.</p>
9	289.256(h)	35.50	2002-2 2005-2	B	<p>Training for the Radiation Safety Officer</p> <p>Texas lists the wrong citation in the introductory paragraph of 289.256(h)(1). Texas states "... and who meets the requirements of sections (4) and (5) of this subsection." The correct statement is "...and who meets the requirements of sections (5) and (6) of this section."</p> <p>Texas needs to make the above change to 289.256(h) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.50.</p>
10	289.256(jj)	35.290	2002-2 2005-2	B	<p>Training for imaging and localization studies</p> <p>Texas regulation 289.256(jj)(2) contains additional requirements for the use of PET radionuclides. This paragraph is more restrictive than Section 35.290 and should be removed.</p> <p>Texas needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.290..</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
11	289.202 (bbb)	35.3067	2002-2	C	<p>Report of a leaking source</p> <p>Texas omits that the written report must include “the model number and serial number if assigned of the leaking source, and the radionuclide and its estimated activity” making their regulation less restrictive.</p> <p>Texas needs to add the above to 289.202(bbb) in order to meet the Compatibility Category C designation assigned to 10 CFR 35.3067.</p>

STATE REGULATION STATUS

State: Texas Department of Health
 [2 amendment(s) reviewed is identified by a ★
 at the beginning of the equivalent NRC requirement.]

Tracking Ticket Number: 9-41
 Date: October 29, 2009

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	Final ML051520266	No Comments 10/31/2005 ML053050013	Texas 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	Texas 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	No Comments 11/06/1997	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final ML052060129	No Comments 09/29/2005 ML052720491	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995	Not Required	Not Required	Texas has 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 ML052060129	Comments 09/29/2005 ML052720491	
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Final ML051520266	No Comments 08/12/2005 ML052280032	

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1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable	Not Applicable	Texas DOH does not have responsibility for these regulations. See SRS sheet for Texas CEQ.
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Final ML062860025	No Comments 11/21/2006 ML063200232	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	Texas CEQ Responsibility
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997	Final ML052060129	No Comments 09/29/2005 ML052720491	
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	No Comments 03/17/1999	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final ML051520266	No Comments 10/31/2005 ML053050013	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	R ⁱ ML071370165	Comments 06/27/2007 ML071790090	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superseded by 1997-5)	06/30/1998	Final ML051520266	No Comments 10/31/2005 ML053050013	Texas 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	No Comments 03/17/1999	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final ML052060129	No Comments 09/29/2005 ML052720491	

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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 ML051520266	No Comments 10/31/2005 ML053050013	Texas has not yet adopted Final Regulations equivalent to RATS ID: 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 ML052060129	Comments 09/29/2005 ML052720491	Texas 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	Final ML062860025	No Comments 11/21/2006 ML063200232	Part 30 only. Part 61 applies to TXCEQ.
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final	No Comments 07/07/2000	
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 ML063030232	No Comments 11/27/2006 ML063200389	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final	No Comments 07/07/2000	
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)

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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	No Comments 07/07/2000	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final	No Comments 07/07/2000	
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 ML052060129	No Comments 09/29/2005 ML052720491	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773	02/12/2001	Final ML063030232	No Comments 11/27/2006 ML063200389	
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) Texas has adopted Final Regulations equivalent to RATS ID: 2002-2.
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	R ¹ ML071370165	No Comments 06/27/2007 ML071790090	
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	No Comments 07/07/2000	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final	No Comments 07/07/2000	

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1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Final ML051520266	Comments 08/12/2005 ML052280032	
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 64 FR 42269	10/04/2002	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	Final ML062750348	No Comments 11/21/2006 ML063200232	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML051520266	No Comments 11/30/2006 ML063340007	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML051520266 Proposed ML073170379	No Comments 08/12/2005 ML052280032 No Comments 01/02/2008 ML080020160	Part 36 only in 2007 review
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31, 32 65 FR 79162	02/16/2004	R ¹ ML073170379	Comments 01/02/2008 ML080020160	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Proposed ML083250011	Comments 01/13/2009 ML083440015	
★2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML092390185 ML092400365	Comments 10/29/2009 ML092870302	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Proposed ML073170379	Comments 01/02/2008 ML080020160	

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2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Proposed ML072560678	Comments 11/05/2007 ML073060016	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Proposed ML083250011	No Comments 01/13/2009 ML083440015	
★2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Final ML092390185 ML092400365	Comments 10/29/2009 ML092870302	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML052240226	No Comments 12/12/2005 ML053420404	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	R ¹ ML092650466	Comments 10/05/2009 ML092660410	
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	R ¹ ML083250011	No Comments 01/13/2009 ML083440015	
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	R ¹ ML083250011	No Comments 01/13/2009 ML083440015	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010			
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			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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 ML080350004	No Comments 02/13/2008 ML080440203	
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011	Proposed MI083250011	No Comments 01/13/2009 ML083440015	
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012			

ⁱ R stands for proposed changes to final regulations.