

June 27, 2007

Cindy Cardwell, Manager  
Radiation Policy, Standards and Q/A Group  
Department of State Health Services  
1100 West 49<sup>th</sup> Street, MC 2828  
Austin, TX 78756-3189

Dear Ms. Cardwell:

We have reviewed the proposed changes to the Texas regulations 289.202, 289.255, and 289.256 received by our office on May 16, 2007. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 32, 34, 35 and the requirements of the six amendments identified in the enclosed State Regulation Status (SRS) Data Sheet.

As a result of our review, we have four old comments which stand from previous letters and nine new 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 Texas 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 Texas 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 Texas 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://www.hsrdr.gov/nrc/rulemaking.htm>.

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 (email: [kxs@nrc.gov](mailto:kxs@nrc.gov)) or Monica Orendi at (301) 415-3938 (email: [mlo1@nrc.gov](mailto:mlo1@nrc.gov)).

Sincerely,

***RA By D.White For***

Scott W. Moore, 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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**IRA By D.White For**

Scott W. Moore, 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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**COMMENTS OUTSTANDING FROM PREVIOUS LETTERS SENT TO TEXAS**

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	§289.257 (s)(5)(F)(v)	20 Appendix G.I.B5	1995-3	B	<p><b>Transfer for disposal and manifests</b></p> <p>Appendix G only includes the radionuclide activity of H-3, C-14, Tc-99, and I-129 contained in the shipment. However, in Texas' §289.257(s)(5)(F)(v), they include not only the above elements, but also chlorine-36, nickel-63, strontium-90, cesium-137 and any other isotopes with a half-life greater than 35 years.</p> <p>Texas should eliminate chlorine-36, nickel-63, strontium-90, cesium-137, and other isotopes with a half-life greater than 35 years for the activity contained in the shipment to meet the Compatibility Category B designation assigned to 10 CFR 20 Appendix G.I.B5.</p> <p>COMMENT STANDS: Texas did not address this comment, from letter dated October 21, 2005, during this rulemaking and will need to address it in future rulemakings.</p>
2	289.201 (b)(94)	20.1003	2002-1	A	<p><b>Definitions: Shallow Dose Equivalent (Hs)</b></p> <p>Texas states "... external exposure of the skin or an extremity...". According to 10 CFR 20.1003 "... external exposure of the skin of the whole body or the skin of an extremity..." should be listed in the definition of Shallow dose equivalent.</p> <p>Texas needs to change its definition for Shallow-dose equivalent in 289.201 (b)(94) to meet the Compatibility Category A designation assigned to this definition in 10 CFR 20.1003.</p> <p>COMMENT STANDS: Texas did not address this comment, from a letter dated November 21, 2006, during this rulemaking and will need to address it in future rulemakings.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
3	289.202(n)	20.1301(a)&(c)	2002-2	A	<p><b>Dose limits for individual members of the public</b></p> <p>Texas regulations omit 10 CFR 20.1301(c) "...a licensee may permit visitors to an individual who cannot be released, under §35.75, to receive a radiation dose greater than 0.1 rem (1 Mev) if ...".</p> <p>Texas needs to add the above section to meet the Compatibility Category A designation assigned to 10 CFR 20.1301.</p> <p>COMMENT STANDS: Texas did not address this comment, from a letter dated November 21, 2006, during this rulemaking and will need to address it in future rulemakings.</p>
4	289.252 (o)	32.74(a)	2002-2	B	<p><b>Manufacture and distribution of sources or devices containing byproduct material for medical use</b></p> <p>Texas omits 10 CFR 32.74(a)(2)(vii) from its regulations. Also Texas adds a section (289.252 (o)(1)(H)) which does not appear in 10 CFR 32.74(a)</p> <p>Texas needs to add section (a)(2)(vii) and remove 289.252 (o)(1)(H) to meet the Compatibility Category B designation assigned to 10 CFR 32.74(a).</p> <p>COMMENT STANDS: Texas did not address this comment, from a letter dated November 21, 2006, during this rulemaking and will need to address it in future rulemakings.</p>

**COMPATIBILITY COMMENTS ON TEXAS PROPOSED REGULATIONS**

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	289.256 (c)(3)	35.2	2002-2 2006-1	B	<p><b>Definitions: Authorized medical physicist</b></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>
2	289.256 (c)(4)	35.2	2002-2 2006-1	B	<p><b>Definitions: Authorized nuclear pharmacist</b></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 needs to remove section (E) from 289.256(c)(4) Authorized Nuclear Pharmacist to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized Nuclear Pharmacist.</p>
3	289.256(h)	35.50	2002-2 2005-2 2006-1	B	<p><b>Training for Radiation Safety Officer</b></p> <p>Texas cites the wrong paragraph in 289.256(h)(5). Texas states: "... has successfully completed the requirements in paragraph (5)...". Texas should state: "... has successfully completed the requirements in paragraph (6)...".</p> <p>Texas needs to change 289.256(h) to reflect the above comment in order to meet the Compatibility Category B designation assigned to 10 CFR 35.50.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
4	289.256(k)	35.55	2002-2 2005-2	B	<p><b>Training for an authorized nuclear pharmacist</b></p> <p>Texas states in 289.256(k)(1) "... an agreement state and who meets the requirements of subparagraph (C) of this paragraph.". The statement should be corrected to say "... an agreement state and who meets the requirements of subparagraph (2)(C) of this paragraph." since subparagraph (2)(C) is the correct reference to NRC 10 CFR 35.55(b)(2).</p> <p>Texas needs to make the above correction in order to meet the Compatibility Category B designation assigned to 10 CFR 35.55.</p>
5	289.256(qq)	35.396	2005-2 2006-1	B	<p><b>Training for the parenteral administration of unsealed byproduct material requiring a written directive.</b></p> <p>Texas adds an "or" written at the end of subsection 289.256(qq)(3). This should be removed and replaced with a ".".</p> <p>Texas needs to remove the "or" written at the end of subsection 289.256(qq)(3) and replace it with a "." in order to meet the Compatibility Category B designation assigned to 10 CFR 35.396.</p>
6	N/A	20. Appendix B	2006-1	A	<p><b>Standards For Protection Against Radiation "List of Elements"</b></p> <p>Texas only addressed part 35 changes in this rulemaking.</p> <p>Texas will need to address this section in a future rulemaking in order to meet the Compatibility Category A designation assigned to 10 CFR 20 Appendix B.</p>
7	N/A	32.72	2006-1	B	<p><b>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.</b></p> <p>Texas only addressed part 35 changes in this rulemaking.</p> <p>Texas will need to address this section in a future rulemaking in order to meet the Compatibility Category A designation assigned to 10 CFR 20 Appendix B.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	N/A	32.74	2006-1	B	<p><b>Manufacture and distribution of sources or devices containing byproduct material for medical use.</b></p> <p>Texas only addressed part 35 changes in this rulemaking.</p> <p>Texas will need to address this section in a future rulemaking in order to meet the Compatibility Category A designation assigned to 10 CFR 20 Appendix B.</p>
9	289.202 (c)(39) (hhh)(2)	20. Appendix E	2006-3	B	<p><b>Nationally tracked sources threshold</b></p> <p>Texas lists the Promethium-147 Category 2 limit as 11,100.0 Ci instead of 11000 Ci, and the Ytterbium-169 Category 1 limit as 8,1000 Ci instead of 8100 Ci.</p> <p>Texas needs to change these Category 1 and Category 2 limits to the proper amounts to meet the Compatibility Category B designation assigned to 10 CFR 20 Appendix E.</p>



**STATE REGULATION STATUS**

**State: Texas**  
**(6 Amendments reviewed identified by a ★**  
**at the beginning of the equivalent NRC requirement.)**

**Tracking Ticket Number: 7-41**  
**Date: June 27, 2007**

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F) <sup>1</sup> Rule / License Condition (LC) ML # <sup>5</sup>	NRC Review / Y, N <sup>2</sup> / Date / ML # <sup>5</sup>	Final State Regulation <sup>1</sup> (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F ML051520266	N 10/31/05 ML053050013	Superceded by 1997-5
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required <sup>3</sup>
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; (1/1/94)	1991-3	F	N 11/6/97	9/1/93
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F ML052060129	N 9/29/05 ML052720491	10/00
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			Superceded by 2002-2
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30, 35	57 FR 45566; (none)	1992-2			Not required <sup>3</sup>
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	F ML052060129	Y 9/29/05 ML052720491	09/04
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	F ML051520266	N 8/12/05 ML052280032	10/01/2000
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Part 61 not applicable to TX-DOH
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1	F ML062860025	N 11/21/06 ML063200232	
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not applicable SECY-95-112 <sup>4</sup>

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Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F ML052060129	N 9/29/05 ML052720491	09/04
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; (1/1/98)	1995-1	F	N 3/17/99	
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F ML051520266	N 10/31/05 ML053050013	04/2002
★Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	R <sup>9</sup> ML071370165	Y 06/27/07 ML071790090	04/2002
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F ML051520266	N 10/31/05 ML053050013	04/11/1999
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	N 3/17/99	
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F ML052060129	N 9/29/05 ML052720491	09/04
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F ML051520266	N 10/31/05 ML053050013	10/1/2000
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724 (4/1/99)	1996-1	F ML052060129	Y 9/29/05 ML052720491	3/1/98
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required <sup>3</sup>
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F (Part 30) ML062860025	N 11/21/06 ML063200232	Part 61 not applicable to TX-DOH
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1	F	N 7/7/00	10/1/00
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2	F ML063030232	N 11/27/06 ML063200389	
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F	N 7/7/00	10/1/00
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required <sup>3</sup>

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Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5	F	N 7/7/00	3/30/00
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F	N 7/7/00	10/1/00
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7	F ML052060129	N 9/29/05 ML052720491	9/1/04
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	F ML063030232	N 11/27/06 ML063200389	
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required <sup>3</sup>
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required <sup>3</sup>
★Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	R <sup>9</sup> ML071370165	N 6/27/07 ML071790090	04/11/1999
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5	F	N 7/7/00	10/1/00
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F	N 7/7/00	10/1/00
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1	F ML051520266	Y 8/12/05 ML052280032	09/01/04
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			Not required <sup>3</sup>
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3	F ML062750348	N 11/21/06 ML063200232	03/29/06

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Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML051520266	N 11/30/06 ML063340007	04/29/03
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML051520266	N 8/12/05 ML052280032	04/29/03
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F <sup>7</sup> ML051520266	Y 8/31/2006 ML062410004	09/01/04
Revision of the Skin Dose Limit -Part 20	67 FR 16298; (4/5/05)	2002-1	F ML062750348	Y 11/21/06 ML063200232	03/29/06
★Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2	R <sup>9</sup> ML071370165	Y 6/27/07 ML071790090	
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327; (12/3/06)	2003-1			
Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments - Part 71	69 FR 3697; (10/01/07)	2004-1			
Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1			
★Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2	P ML071370165	Y 6/27/07 ML071790090	
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) <sup>6</sup>	70 FR 72128; (12/1/05)	2005-3	LC ML052240226	N 12/12/05 ML053420404	12/2/05
★Minor Amendments - Parts 20, 30, 32, 35, 40, and 70	71 FR 15005 (3/27/09)	2006-1	P ML071370165	Y 6/27/07 ML071790090	
National Source Tracking System - Serialization Requirements - Part 32 with reference to Part 20 Appendix E	71 FR 65685 (2/6/07)	2006-2	LC ML070100405	N 01/22/07 ML070240176	

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★National Source Tracking System - Part 20 <sup>8</sup>	71 FR 65865 (11/15/07) & (11/30/07)	2006-3	P ML071370165	Y 6/27/07 ML071790090	

1. Or other generic Legally Binding Requirements.
2. (Y/N) Y means "Yes," there are comments in the review letter that the State needs to address. N means "No," there are no comments in the review letter.
3. Not required means these regulations are not required for purposes of compatibility.
4. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1. Time Frame for Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
5. ADAMS ML Number
6. By letter dated September 2, 2005, from Paul H. Lohaus, Director, Office of State and Tribal Programs, Agreement States were given 90 days to issue legally binding requirements satisfying the requirements of NRC Order EA-05-090.
7. A re-review was completed on this item due to the change in compatibility category of 31.5 and 31.6. More information can be found in the All Agreement States letter STP 05-072.
8. RATS ID 2006-3 will not be considered under the Non-Common Performance Indicator "Compatibility Requirements" for IMPEP reviews until such time as the National Source Tracking System is ready for use. Revisions in the implementation date for Agreement States will be provided to the States under separate correspondence and the SRS sheet will be revised as appropriate.
9. R stands for proposed changes made to final regulations.