

November 21, 2006

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

Dear Ms. Cardwell:

We have reviewed the final revision to the Texas regulations, 25 TAC 289.202 and 289.256, received by our office on October 6, 2006 and October 10, 2006. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 32, 35, 40, 61, 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 you on November 13, 2006.

As a result of our review, we have 24 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 State and Tribal Programs (STP) 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 STP 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, Office of Federal and State Materials and Environmental Management Programs (FSME) (see letter [FSME 06-94](#) dated October 6, 2006 for further information).

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.hsr.doh.state.tx.us/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 (e-mail: kxs@nrc.gov), or Monica Orendi at 301-415-3938 (e-mail: mlo1@nrc.gov).

Sincerely,

IRA By S.W. Moore

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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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 STP 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, Office of Federal and State Materials and Environmental Management Programs (FSME) (see letter FSME 06-94 dated October 6, 2006 for further information).

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Sincerely,

IRA By S.W. Moore

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

Distribution:

DIR RF (6-268 & 6-271)

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Linda Mclean, RSAO

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COMPATIBILITY COMMENTS ON TEXAS FINAL REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	289.201 (b)(94)	20.1003	2002-1	A	<p>Definitions: Shallow Dose Equivalent (Hs)</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>
2	289.202(n)	20.1301(a)&(c)	2002-2	A	<p>Dose limits for individual members of the public</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>
3	289.252 (o)	32.74(a)	2002-2	B	<p>Manufacture and distribution of sources or devices containing byproduct material for medical use</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>
4	289.256 (c)(9)	35.2	2002-2	B	<p>Definitions: Authorized medical physicist</p> <p>Texas's definition for Licensed medical physicist does not closely identify with the definition listed in 10 CFR 35.2 for Authorized medical physicist.</p> <p>Texas needs to change their definition of Licensed medical physicist to meet the Compatibility Category B designation assigned to Authorized medical physicist in 10 CFR 35.2.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
5		35.2	2002-2	B	<p>Definitions: Authorized nuclear pharmacist</p> <p>Texas omits the definition for Authorized nuclear pharmacist from its regulations.</p> <p>Texas needs to add this definition in order to meet the Compatibility Category B designation assigned to Authorized nuclear pharmacist in 10 CFR 35.2</p>
6	289.256(c)(3)	35.2	2002-2	B	<p>Definitions: Authorized user</p> <p>Texas's definition of Authorized user does not closely identify with the definition listed in 10 CFR 35.2</p> <p>Texas needs to change its definition of Authorized user to meet the Compatibility Category B designation assigned to this definition in 10 CFR 35.2.</p>
7	289.201 (b)(79)	35.2	2002-2	B	<p>Definitions: Radiation Safety Officer</p> <p>Texas's definition of Radiation Safety Officer does not closely identify with the definition listed in 10 CFR 35.2.</p> <p>Texas needs to change this definition to meet the Compatibility Category B designation assigned to Radiation Safety Officer in 10 CFR 35.2.</p>
8	289.256(s)	35.49	2002-2	[C]	<p>Suppliers for sealed sources or devices for medical use</p> <p>Texas omits 10 CFR 35.49 (b) and (c) from its regulations.</p> <p>Texas needs to change its regulation to include the essential elements of 10 CFR 35.49 (b) and (c) to meet the Compatibility Category C designation assigned to 10 CFR 35.49.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
9	289.256(h)	35.50	2002-2	B	<p>Training for Radiation Safety Officer</p> <p>Texas regulation 289.256(h) is not essentially identical to 10 CFR 35.50(a), (a)(1), (b)(1)(ii)(F), (c)(2), and(e).</p> <p>Also Texas regulation 289.256 (h) states "...qualifications for RSOs for licenses for medical use of radioactive material with broad scope authorization shall include...". 10 CFR 35.50 makes no such distinction for RSO's with broad scope authorization. This section needs to be removed from the Texas regulations.</p> <p>Texas needs to change the above items in order to meet the Compatibility Category B designation assigned to 10 CFR 35.50.</p>
10		35.51	2002-2	B	<p>Training for an authorized medical physicist</p> <p>Texas omits 10 CFR 35.51 from its regulations.</p> <p>Texas needs to incorporate this section in order to meet the Compatibility category B designation assigned to 10 CFR 35.51.</p>
11		35.55	2002-2	B	<p>Training for an authorized nuclear pharmacist</p> <p>Texas omits 10 CFR 35.55 from its regulations.</p> <p>Texas needs to incorporate this section in order to meet the Compatibility category B designation assigned to 10 CFR 35.55.</p>
12	289.256 (h) 289.256 (ff)(1)(H)	35.57	2002-2	B	<p>Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user and nuclear pharmacist</p> <p>Texas needs to change the date listed in section 289.256 (h) from October 1, 2000 to October 24,2002.</p> <p>Texas needs to make the change to the date in order to meet the Compatibility Category B designation assigned to 10 CFR 35.57.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
13	289.256 (ff)(1)(l)	35.59	2002-2	B	<p>Recentness of training</p> <p>Texas is more restrictive in their regulation stating that "...must have been obtained within 5 years...". Where as 10 CFR 35.59 states "... must have been obtained within 7 years...".</p> <p>Texas needs to make the above change to meet the Compatibility Category B designation assigned to 10 CFR 35.59.</p>
14		35.61(a)(1), (a)(2), (b), (c)	2002-2	H&S	<p>Calibration of survey instruments</p> <p>Texas omits 10 CFR 35.61 from its regulations.</p> <p>Texas needs to add the essential elements of this section in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.61.</p>
15	289.256 (dd)(13)	35.80(a)(2), (a)(3), (b)	2002-2	H&S	<p>Provision of mobile medical service</p> <p>Texas omits 10 CFR 35.80(b) from its regulations.</p> <p>Texas needs to add the essential objectives of this section in order to meet the Compatibility Category H&S assigned to 10 CFR 35.80(b)</p>
16	289.256 (y)	35.190	2002-2	B	<p>Training for uptake, dilution, and excretion studies</p> <p>Texas omits 10 CFR 35.190(c)(2) from its regulations.</p> <p>Texas needs to add this section in order to meet the Compatibility Category B designation assigned to 10 CFR 35.190.</p>
17	289.256(z)(4)	35.290	2002-2	B	<p>Training for imaging and localization studies</p> <p>Texas omits 10 CFR 35.290(b)(2) from its regulations.</p> <p>Texas needs to add this section in order to meet the Compatibility Category B designation assigned to 10 CFR 35.290.</p>
18	289.256 (aa)(4)	35.390	2002-2	B	<p>Training for use of unsealed byproduct material for which a written directive is required</p> <p>Texas's regulation does not closely identify with 10 CFR 35.390 in its entirety.</p> <p>Texas needs to change its regulations to closely identify with this section in order to meet the Compatibility Category B designation assigned to 10 CFR 35.390.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
19	289.256 (ff)(1)(C)	35.392	2002-2	B	<p>Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)</p> <p>Texas omits 10 CFR 35.392 (c)(2) from its regulations.</p> <p>Texas needs to add this section in order to meet the Compatibility Category B designation assigned to 10 CFR 35.392.</p>
20	289.256 (ff)(1)(C)	35.394	2002-2	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>Texas omits 10 CFR 35.394 (c)(2) from its regulations.</p> <p>Texas needs to add this section in order to meet the Compatibility Category B designation assigned to 10 CFR 35.394.</p>
21		35.433(a)	2002-2	H&S	<p>Decay of Strontium-90 sources for ophthalmic treatments</p> <p>Texas omits 10 CFR 35.433(a) from its regulations.</p> <p>Texas needs to add the essential elements of this section in order to meet the Compatibility Category H&S designation assigned to this section.</p>
22	289.256 (ff)(1)(D)	35.490	2002-2	B	<p>Training for use of manual brachytherapy sources</p> <p>Texas omits 10 CFR 35.490 (b)(3) from its regulations.</p> <p>Texas needs to add this section in order to meet the Compatibility category B designation assigned to 10 CFR 35.490.</p>
23	289.256 (ff)(1)(E)	35.491	2002-2	B	<p>Training for ophthalmic use of Strontium-90</p> <p>Texas omits 10 CFR 35.491 (b)(3) from its regulations.</p> <p>Texas needs to add this section to meet the Compatibility Category B designation assigned to 10 CFR 35.491.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
24	289.256 (dd)(17)	35.690	2002-2	B	Training for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units Texas's regulation omits 10 CFR 35.690(b)(2). Texas needs to add this section in order to meet the Compatibility Category B designation assigned to 10 CFR 35.690.

STATE REGULATION STATUS

State: Texas

(5 Amendments reviewed identified by a ★ at the beginning of the equivalent NRC requirement.)

Tracking Ticket Number: 6-268/6-271

Date: November 21, 2006

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F) ¹ Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (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 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; (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 ³
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 ML06300232	
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 ⁴
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F ML052060129	N 9/29/05	09/04

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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	F ML051520266	Y 10/31/05 ML053050013	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 ³
★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 ML06300232	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			
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

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Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required ³
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			
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees-Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required ³
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	F ML051520266	Y 10/31/05 ML053050013	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 ³
★Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3	F ML062750348	Y 11/21/06 ML06300232	

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F) ¹ Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML051520266	Y 8/12/05 ML052280032	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 ⁷ 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 ML06300232	
★Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2	F ML062750348	Y 11/21/06 ML06300232	10/01/00
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			
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) ⁶	70 FR 72128; (12/1/05)	2005-3	LC ML052240226	N 12/12/05 ML053420404	12/2/05

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Minor Amendments - Parts 20, 30, 32, 35, 40, and 70	71 FR 15005 (3/27/09)	2006-1			

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.