

October 5, 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 proposed changes to the final Texas regulations 25 Texas Administrative Code 289.202, 289.252, and 289.256, received by our office on September 22, 2009 (see acceptance email ML092650466). These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 32, 35, 40, and 70 and the requirements of the one amendment identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with you on October 2, 2009.

As a result of our review, we have two comments which stand from an NRC response letter dated June 27, 2007 and we have four 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://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 KNScheinder for/

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

Enclosures:
As stated

[CONCURRENCE PAGE]

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 KNSchneider for/

Terrence Reis, 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 (9-47)
DCD (SP08)
LMcLean, RSAO
WRautzen, ASPB
JKatanic, ASPB
TX File

SUNSI Review Complete

- Publicly Available Non-Publicly Available
- Non-Sensitive Sensitive

DOCUMENT NAME: G:\DMSSA\SAISB\REGULATION TOOLBOX\STATES\TEXAS\9-47\9-47.DOC

Incoming Document: ML092650466

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 | ASPB | | ASPB | | OGC | | ASPB:BC | | MSSA:DD | |
| NAME | MOrendi | | KSchneider | | BJones | | DWhite/kns | | TReis/kns | |
| DATE | 09/23/09 | | 09/23/09 | | 09/29/09 | | 10/05/09 | | 10/05/09 | |

ML092660423

OFFICIAL RECORD COPY

Package ML092660410

COMPATIBILITY COMMENTS ON TEXAS PROPOSED REGULATIONS

| STATE SECTION | | NRC SECTION | RATS ID | CATEGORY | SUBJECT and COMMENTS |
|---------------|-------------------|-------------|---------|----------|--|
| 1 | 289.256 (c)(3) | 35.2 | 2006-1 | B | <p>Definitions: 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> <p>Comment Stands from NRC letter dated June 27, 2007.</p> |
| 2 | 289.256 (c)(4) | 35.2 | 2006-1 | B | <p>Definitions: 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 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> <p>Comment Stands from NRC letter dated June 27, 2007.</p> <p>Texas omitted an "or" at the end of 289.256(c)(4)(B)(iv).</p> <p>Texas needs to add an "or" at the end of 289.256(c)(4)(B)(iv) to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized Nuclear Pharmacist.</p> |
| 3 | 289.252(r) | 32.72 | 2006-1 | B | <p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing</p> |

| STATE SECTION | | NRC SECTION | RATS ID | CATEGORY | SUBJECT and COMMENTS |
|---------------|---------------|-------------|---------|----------|--|
| | | | | | <p>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> |
| 4 | 289.252(o) | 32.74 | 2006-1 | 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 changes to 289.252(o) in order to meet the Compatibility Category B designation assigned to 10 CFR 32.74.</p> |
| 5 | 289.256(c)(5) | 35.2 | 2006-1 | 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(h) | 35.50 | 2006-1 | B | <p>Training for 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> |

STATE REGULATION STATUS

State: Texas Department of Health

Tracking Ticket Number: 9-47

[1 amendment(s) reviewed is identified by a ★

Date: October 5, 2009

at the beginning of the equivalent NRC requirement.]

| 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 | |
| | | | | | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|---|-----------------------------|-------------------------------|--|--|
| 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 | |
| 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 (Superceded 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. |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|--|-----------------------------|----------------------|--|--|
| 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 | |
| 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 | |
| | | | | | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|---|-----------------------------|-------------------------------|--|---|
| 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) |
| 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, | 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 (Superceded 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 | |
| | | | | | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|--|-----------------------------|---|--|--|
| 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 | |
| 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 | 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 | R ¹ ML073170379 | Comments 01/02/2008 ML080020160 | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|---|-----------------------------|----------------------------------|--|-------|
| 2003-1 | Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327 | 12/03/2006 | Proposed ML073170379 | Comments 01/02/2008 ML080020160 | |
| 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 | 04/29/2008 | Proposed ML071370165 | Comments 06/27/2007 ML071790090 | |
| 2005-3 | Increased Controls for Risk-Significant Radioactive Sources | 12/01/2005 | License Condition ML052240226 | No Comments 12/12/2005 ML053420404 | |
| ★2006-1 | Minor Amendments Parts 20, 30, 32, 35, 40 and 70 | 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 | | | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|--|-----------------------------|----------------------------------|--|-------|
| 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 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.