TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • http://www.dshs.state.tx.us

May 27, 2005

05 MAY 31 PM 1:53

STP

Dennis Sollenberger
Office of State and Tribal Programs
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Sollenberger:

This is in response to a request from NRC made during the March 15, 2005 additional periodic meeting between NRC and DSHS. DSHS' radiation control program staff have reviewed historic rulemaking case files, microfiche, and computer hard drives to find documentation that proposed and final rules had been submitted to NRC for review. This is the summary of those findings.

Background

The NRC maintains a State Regulation Status (SRS) chart for each Agreement State in order to track NRC review of proposed and final compatibility rules and adoption by the State of compatibility rules. The SRS chart lists all identified items of compatibility in chronological order and each is identified by a unique number known as a "RATS ID". DSHS maintains a concurrent version in order to ensure that compatibility rules are adopted.

During the June 2004 periodic meeting, NRC staff pointed out that the NRC SRS chart did not match the one Texas maintains and therefore gives the appearance that several compatibility items have not been adopted by DSHS. DSHS radiation control program staff provided NRC a copy of the SRS chart maintained by DSHS. However, NRC indicated during the March 2005 meeting that DSHS should review its records for documentation that the rules were submitted to NRC for review in order to update the NRC SRS chart.

DSHS radiation control program staff reviewed historic rulemaking case files, microfiche, and computer hard drives for rulemaking documentation. Staff decided to look at missing and/or incorrect data on the NRC SRS chart for all RATS ID numbers (Attachment 1, SRS chart dated June 14, 2004), rather than just the RATS ID numbers identified in the NRC's summary of the March 2005 additional periodic meeting. The RATS ID numbers begin in 1991 and continue through June 14, 2004.

STP-006 Template
RIDS: SP08
SISP Review Complete

Summary of Findings

There are 44 separate RATS ID numbers on the June 14, 2004 NRC SRS chart.

One RATS ID number falls fully under the jurisdiction of TCEQ and is therefore not within DSHS authority to adopt (1993-3).

One RATS ID number involved the quality management program for medical licensees. DSHS chose not to adopt this requirement and fully explained the reasons in several IMPEP reports and this rule has since been superceded by another NRC rule revision (1992-1).

Seven RATS ID numbers are not required to be adopted by the State for compatibility (1991-2, 1992-2, 1996-2, 1997-4, 1998-2, 1998-3, 1999-2).

Two RATS ID numbers are covered by Texas statute and pre-existing rule. These will be discussed further in terms of not being identified as non-compatible during previoius IMPEP reviews of our program (1997-2, 1998-1).

Two RATS ID numbers are not yet due to be adopted by Agreement States (2002-2, 2003-1).

Five RATS ID numbers have indications that the final DSHS rules have been reviewed and found to be compatible with no errors in the NRC SRS chart (1991-3, 1997-1, 1997-6, 1998-5, 1998-6).

The remaining RATS ID numbers have missing data concerning final rules and/or have errors in the data recorded by NRC. The enclosed chart shows details concerning the status of those 26 RATS ID numbers, the actions being taken by DSHS, and the associated references (additional enclosures). The status of the 26 RATS ID numbers is summarized as follows.

Eleven have associated documentation from DSHS showing the compatibility items were adopted by DSHS and the final rules were submitted to NRC for review.

Six were adopted and sent to NRC for final review. DSHS combined several RATS ID numbers when doing rulemaking, but it appears NRC only entered data in its SRS chart concerning its review for two RATS ID numbers, when in fact DSHS had adopted all compatibility rules.

Two indicate the compatibility items were reviewed and found to be compatible, but the NRC SRS chart is incorrect or incomplete in terms of dates.

Two are currently going through the DSHS rulemaking process and are estimated to be proposed in August 2005.

Five will be sent to NRC for review of the final rules. Three of those items were adopted in September 2004 and the final rules have not been sent. The remaining two were adopted within timeframes, but the department could not find documentation that the final rules were sent to NRC for review. However, all five of these RATS ID numbers have been adopted by DSHS.

Other Issues Identified

DSHS identified two RATS ID numbers that are met by statute and by existing rule. The department believes that RATS ID 1997-1 was met by existing rule in 1997 and continues to be met by that reciprocity rule contained in §289.252(ee). No proposed rule was submitted for review because the department believes no new rule is necessary. This item was discussed at the previous two IMPEP reviews of the Texas DSHS program and no compatibility issues were raised at those times.

The department believes that RATS ID 1998-1 is covered by statute and that a separate rulemaking was not necessary. Health and Safety Code Chapter 401.381 and 401.382 give the agency authority to assess both civil and criminal penalties against persons who violate the statute or rules. The term "persons" is broadly defined both in statute and rule and includes licensed or unlicensed persons. This item was discussed at a previous IMPEP review of the Texas DSHS program and no compatibility issues were raised at that time.

In addition to the above issues regarding the accuracy of the NRC SRS chart, DSHS has identified two more examples of process issues. We would be happy to discuss all of these issues to determine a solution that involves both DSHS and NRC and makes the most efficient use of the resources in each agency. The additional two issues involve the rule review process.

In the first example, NRC identified a non-compatibility issue with the final rule that incorporated RATS ID 1999-1 concerning major construction at uranium recovery and byproduct material disposal facilities before a license is issued. The rule became effective December 2002. DSHS agreed to consider the comment when the rule was next opened for revision. When next opened, the rule was corrected to make it compatible (rule text which had previously been found compatible was restored in the April 2004 proposal) and the proposed rule was sent to NRC for review in April 2004. In May 2004, DSHS received a confusing letter (Attachment 5) indicating the proposed text was contradictory and suggesting that DSHS adopt the rule text of NRC. Upon closer look, it became apparent to DSHS staff that whomever reviewed the proposed rule at NRC did not look at the rule legend which indicated what was to be added and what was to be deleted, but instead read added and deleted language as one. We declined to use the language suggested in the comment because it contains a definition. DSHS believes it is inappropriate to include definitions within the text of requirements.

The suggested definitions have always been in the rule, just in the subsection titled "Definitions". This fact was apparently missed during the NRC review of the proposed rule. Therefore, we had to determine NRC's comment on the April 2004 proposed rule was invalid. This issue is addressed in the final rule being submitted for review (Appendix B).

A second example concerns a DSHS letter to NRC in May 2004 specifically asking for comment on a draft rulemaking concept concerning clearance of equipment for unrestricted use. This letter and draft rule were sent through channels outside those required by Procedure SA-201 for review of state regulations for compatibility because it was not a request for a compatibility review and was only a draft rule, not a proposed one. The draft rule did also contain language regarding a RATS ID number, but we did not request review of that language. However, DSHS received a letter that said the requirements were reviewed and no comments issued. Our concern is that when we actually send the proposed RATS ID number for review (August 2005), the NRC SRS sheet will again be incorrect, because a draft rule was mistakenly reviewed.

Finally, DSHS staff has always ensured that compatibility items are adopted as appropriate. In an effort to ensure our NRC SRS chart is accurate, the staff has spent many hours researching rulemaking case files. We hope this provides the information NRC needs to update the SRS chart. We will be more diligent in the future in monitoring the data entered by NRC in the Texas-DSHS SRS chart.

If you have questions, please call me at (512)834-6688, extension 2239.

Sincerely,

Cynthia C. Cardwell

Cynthia C. Cardwell, Manager
Radiation Policy, Standards and Quality Assurance Group
Policy, Standards and Quality Assurance Unit
Department of State Health Services

cc: Richard Ratliff, P.E.

RATS ID Number	DSHS Action	Reference
1991-1 1995-4 1997-5 1998-4	DSHS has had extensive industrial radiography rules in place since 1986. In 1997, NRC adopted a comprehensive revision to 10 CFR 34 that incorporated most of the Texas requirements. However, there were a few rule differences that NRC made items of compatibility. DSHS changed the rule to incorporate those items in April 1999. The April 1999 change to 289.255 incorporated the compatibility items identified in these four RATS ID numbers. NRC's SRS chart indicates the 4/99 final rule version was reviewed with no comments. However, NRC's SRS chart indicates an incorrect effective date of 3/30/00.	
1991-4	DSHS is sending documentation dated 3/26/98 showing final rules were sent for review by NRC on disk	Attachment 2
1993-1	DSHS is sending documentation dated 3/26/98 showing final rules were sent for review by NRC on disk.	Attachment 2
1993-2	DSHS is sending the final rule for review (§289.258) but no compatibility chart. The two comments from NRC were editorial and did not involve items of compatibility.	Attachment 3 Appendix A
1993-3	Regulatory jurisdiction for the requirements in 10 CFR Part 61 is under TCEQ, not DSHS. This should continue to be noted in NRC's SRS chart for Texas-DSHS.	
1994-1	DSHS is sending documentation dated 3/26/98 showing final rules were sent for review by NRC on disk.	Attachment 2
1994-2	DSHS is sending documentation dated 3/26/98 showing final rules were sent for review by NRC on disk.	Attachment 2
1994-3	DSHS is sending documentation dated 3/26/98 showing final rules were sent for review by NRC on disk.	Attachment 2
1995-1	The NRC SRS chart is not complete. The effective date of the rule was 10/1/00	
1995-2	DSHS is sending documentation dated 3/26/98 showing final rules were sent for review by NRC on disk.	Attachment 2
1995-3	DSHS is sending documentation dated 3/26/98 showing final rules were sent for review by NRC on disk. This rule was changed along with all the others that were sent on the disk as per the 3/26/98 email. The NRC SRS chart is incorrect. The date of the NRC review of the proposed rule should be 11/21/97.	Attachment 2
1995-5	The NRC SRS chart is not complete. The effective date of the rule was 10/1/00.	
1995-6	DSHS is sending documentation dated 3/26/98 showing final rules were sent for review by NRC on disk.	Attachment 2
1995-7 1997-3	The NRC SRS chart is incomplete. DSHS adopted the items of compatibility identified in RATS ID #1995-7 and 1997-3 in one rulemaking. The NRC SRS chart indicates NRC reviewed the final rules and had no comments.	
1996-1	DSHS is sending documentation dated 3/26/98 showing final rules were sent for review by NRC on disk.	Attachment 2

May 2005

RATS ID Number	DSHS Action	Reference
1996-3	DSHS is sending documentation dated 3/26/98 showing final rules were sent for review by NRC on disk. This rule was changed along with all the others that were sent on the disk as per the 3/26/98 email. The NRC SRS chart is incorrect. The date of the NRC review of the proposed rule should be 11/21/97.	Attachment 2
1997-7	DSHS is sending documentation dated 11/2/00 showing final rules were sent for review by NRC via email.	Attachment 4
1999-1	NRC comments on the final rule were received after the effective date. DSHS considered the comments when the rule was next opened for change. The comments are addressed in the chart for the final rule effective 9/1/04	Appendix B
1999-3	Addressed in current rulemaking.	
2000-1 2000-2	DSHS is sending the final rule for review. The rule became effective 9/1/04	Appendix C
2001-1	DSHS is sending the final rule for review. The rule became effective 9/1/04	Appendix B
2002-1	Addressed in current rulemaking.	
2002-2	Not due yet.	
2003-1	Not due yet.	

Attachment 1

STATE REGULATION STATUS

State: Texas
[One amendment reviewed is identified by a ★ at the beginning of each equivalent NRC regulation]

Tracking Ticket Number: 4-118
Date: June 14, 2004

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F)[1] Rule / 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	P	Y 1/12/99	
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	P	N 11/21/97	
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			
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	P	N 11/21/97	
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	P	Y 3/13/96	
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	P	N 11/21/97	
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2	P	N 11/21/97	Not applicable SECY-95-112[4]
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	P	N 11/21/97	

Attachment 1

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F)[1] Rule / ML #[5]	NRC Review / Y, N[2] / Date / ML #[5]	Final State Regulation[1] (Effective Date)
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			
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	P	N 11/8/96	Part 61 not applicable to TX-DOH
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	P	Y 1/22/99	
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	P	N 11/21/97	
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7			
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724 (4/1/99)	1996-1	P	Y 11/21/97	
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	P (Part 30)	N 11/8/96	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
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required[3]

Attachment 1

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F)[1] Rule / ML #[5]	NRC Review / Y, N[2] / Date / ML #[5]	Final State Regulation[1] (Effective Date)
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			
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	P	Y 1/12/99	
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			
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	P ML041330243	N 6/14/04 ML041670214	
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	P ML023040140	Y 1/9/03 ML030210400	
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	P ML023040140	N 1/9/03 ML030210400	

Attachment 1

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F)[1] Rule / ML #[5]	NRC Review / Y, N[2] / Date / ML #[5]	Final State Regulation[1] (Effective Date)
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	P ML040640989	Y 4/02/04 ML040930285	
Revision of the Skin Dose Limit -Part 20	67 FR 16298; (4/5/05)	2002-1			
Medical Use of Byproduct Material- Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2			
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1			

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

Attachment 2a

From: Self <TDHBRC1/CCARDWEL>
To: phl@nrc.gov
Subject: Final and proposed rules
Date sent: Thu, 26 Mar 1998 14:07:23 -0600 (CST)

Paul,

We're at it again! We just proposed a revision to our comparable version of 10 CFR 20 (our 289.202). This is not an item of compatibility, but we thought y'all would want to look at it. It incorporates into rule the basics contained in an NRC staff technical position on the disposition of cesium-137 contaminated emission control dust and other incident-related material.

Some background on this rulemaking....one of our licensees submitted a petition for rulemaking to incorporate some of this technical position. Because the wording of the suggested rule that was submitted with the petition wasn't entirely acceptable and because of our strict timeframes for responding to a petition, the licensee agreed to withdraw the petition and we committed to doing the rulemaking.

Because this isn't a compatibility issue, we haven't done the table comparing our rule to 10 CFR, but I've attached the text of the proposed rule. The comment deadline is April 27, 1998.

We've also completed the last round of rulemaking we sent you for comment. We're sending all the final rules to you on disks because the files are huge. The disks contain the table showing changes made to the proposed rules based on NRC comments and the entire text of the rules. We've also included the final versions of the rules that you had no comments on because we're changing the format of our rules and thought you would want an updated copy. We'll continue to send you each final rule as its updated. This way, you will eventually have all of the pertinent sections of the Texas Regulations for Control of Radiation in the new format.

If you have questions about the proposed rule or the final ones that you should soon be receiving, please give me a call.

Thanks,
Cindy

Attachments:
V:\LRS\STD\CCARDWEL\202prm98.wpd

Attachment 26

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 21, 1997

RECEIVED
TDH
DEC - 8 1997
BUREAU OF
RADIATION CONTROL

Ms. Cynthia Cardwell, Branch Administrator
Regulations and Standards
Texas Bureau of Radiation Control
1100 West 49th Street
Austin, TX 78756-3189

Dear Ms. Cardwell:

As requested, we have reviewed the proposed Texas regulations in §§289.201, 289.202, 289.252, 289.257, and 289.260. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 20, 30, 40, and 71. We also discussed our review of the regulations with Ms. Monica Gonzales on November 5, 1997.

As a result of our review we have two 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 a State regulation meets the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final State regulation. However, we have determined that if your proposed regulations were adopted incorporating the comments, as appropriate, and without other significant change, they would meet the compatibility and health and safety categories established in OSP Internal Procedure B.7.

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 our All Agreement States Letter SP-96-027, "Request to Highlight Changes to Agreement State Regulations Submitted to NRC for Compatibility Review" (March 1, 1996), please highlight the final changes and send one copy in a computer readable format, if possible.

If you have any questions regarding the comments or any of the NRC regulations used in the review, please contact me or Mr. Richard Blanton of my staff at (301) 415-2322, or by Internet at RLB@NRC.GOV.

Sincerely,

Paul H. Lohaus

Paul H. Lohaus, Deputy Director
Office of State Programs

Enclosure:
As stated

Attachment 2c

COMMENTS ON PROPOSED TEXAS REGULATIONS AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES

Category	State Regulation	NRC Regulation	NRC-Approved SSR (if any)	Subject and Comment
B	289.257(f)(2)	71.10(b)	-	General license: NRC-approved package. Text equivalent to 10 CFR 71.10(b)(3) is missing. This provision needs to be adopted in order to assure consistent regulation of sources shipped in interstate commerce.
B	289.257(g)(2)	71.13(b)(1)	-	Previously approved package. In 289.257(g)(2)(B)(i), the date "April 1, 1996," needs to be changed to "April 1, 1999." This provision needs to be adopted in order to assure consistent regulation of materials shipped in interstate commerce.

Nickie B. 7/2004

Attachment 3a

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 13, 1996

96 MAR 19 AM 10:52
TX. DEPT. OF HEALTH
BUREAU OF
RADIATION CONTROL

Ms. Cynthia C. Cardwell, Deputy Director
Standards and Special Projects
Division of Licensing, Registration
and Standards
Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-7111

Dear Mrs. Cardwell:

We have reviewed the proposed rules for Part 39 of the Texas Regulations for Control of Radiation, dated January 30, 1996. The rules were reviewed in comparison to the equivalent NRC regulations in 10 CFR Part 36. We acknowledged receipt of the proposed rules on March 4, 1996, by electronic mail to Mrs. Sonia Simmons.

As the result of the review we have a two comments, as enclosed. Neither of the comments involve matters of compatibility.

If you have any questions regarding the comments or any of the rules reviewed, please contact me or Mr. Richard Blanton, of my staff, at (301) 415-2322.

Sincerely,

Paul H. Lohaus

Paul H. Lohaus, Deputy Director
Office of State Programs

Enclosure:
As stated

Attachment 3b

SteriGenics

COMMENTS ON PROPOSED TEXAS PART 39 REGULATIONS

Equivalent to 10 CFR Part 36

[illegible] 20, 1996

[illegible] C. Caldwell, Deputy Director
[illegible] and Special Projects
[illegible] Licensing, Registration, and Standards
[illegible] 78756

REFERENCE: Proposed Part 39

Dear Mr. Caldwell:

You provided a copy of the propo[illegible] Safety Officer for our Fort Worth [illegible] view. I have completed the review of the proposed regulation and have comments on two separate paragraphs. In addition, I found one clerical error where a citation was made to the Nuclear Regulatory regulations instead o[illegible] summarize these three comments.

At this time, both Ms. Knight and [illegible] regulation on April 2, 1996. I wo[illegible] for that meeting is changed.

If you have any questions on any [illegible] reached at my Charlotte, NC, offi[illegible]

TRCR 39. 37 — Equivalent to 10 CFR 36.37 (Division 2)

In subsection (b), the phrase "... shall remain locked in the event of a power failure" suggests that a licensee would not be allowed to manually unlock the door during a power failure. We suggest that this be changed to clarify the requirement that the loss of electric power itself would not cause the door to become unlocked.

TRCR 39.61 — Equivalent to 10 CFR 36.61 (Division 2)

In subsection (b), the TRCR rule adds the provision that the irradiator not be used until the repairs have been made. This is compatible; however, we suggest that you consider modifying the provision to make it clear whether the operator could continue to operate in the case of minor defects and malfunctions that are not significant to the safe operation of the irradiator.

Sincerely,

Mark A. Smith, CHP
Corporate Manager of Technical Services

cc: Cynthia Knight

Vicki B: 9/20/04 443

Attachment 4a

From: Self <TDHBRC1/CCARDWEL>
To: phl@nrc.gov
Subject: Final Texas rules
Date sent: Thu, 2 Nov 2000 16:05:55 -0500 (CDT)

Paul,

Here are the files for five rules that have been adopted and became effective October 1, 2000. The files show the changes made from the proposed version to the final version (legends explaining changes are at the beginning of each file). We didn't get any NRC comments suggesting changes on the proposed versions, so the changes are based on public or our staff comments. Please let me know if you have any problems with the files. There should be seven separate files and some are pretty large, so if I need to send them separately, just holler.

Thanks,
Cindy

Attachments:
V:\LRS\STD\mgonzale\texregwp\201adp00.wpd
V:\LRS\STD\mgonzale\texregwp\202adp00.wpd
V:\LRS\STD\mgonzale\texregwp\251adp90.wpd
V:\LRS\STD\mgonzale\texregwp\253adp90.wpd
V:\LRS\STD\mgonzale\texregwp\252adp90.wpd
V:\LRS\STD\mgonzale\texregwp\257adp00.wpd
V:\LRS\STD\mgonzale\texregwp\258adp90.wpd

Attachment 4b

289.202
2000 Rev
Comments

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 7, 2000

REM
CCC

RECEIVED
TDH
JUL 13 2000
BUREAU OF
RADIATION CONTROL

Mr. Richard A. Ratliff, PE, LMP, Chief
Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3189

Dear Mr. Ratliff:

We have reviewed the final Texas Regulations for Control of Radiation (25 Texas Administrative Code 289) Sections 210 and 202 adopted in February 2000 which became effective on March 30, 2000 and Section 257, also adopted in February 2000 that will become effective on October 1, 2000. The regulations were sent on April 5, 2000. The final regulations are in response to the six amendments identified in the enclosed Regulations Assessment Tracking System (RATS) Data Sheet. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 20 and 71. We also discussed our review of the regulations with Ms. Cindy Cardwell on June 1, 2000.

As a result of the NRC review, we have determined that the Texas Bureau of Radiation Control (BRC) regulations, as adopted, meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

We have also summarized on the RATS Data Sheet our knowledge of the status of other BRC regulations. Please let us know if you note any inaccuracies or have any comments on the information contained in the RATS Data Sheet.

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 me or James Myers of my staff at (301) 415-2328 or JHM@NRC.GOV.

Sincerely,

Frederick C. Combs, Deputy Director
Office of State and Tribal Programs

Enclosure:
As stated

UNITED STATES
NUCLEAR REGULATORY
WASHINGTON, D.C. 205

Attachment 5a

February 12, 2003

RECEIVED
TDH
FEB 14 2003
BUREAU OF
RADIATION CONTROL

Mr. Richard A. Ratliff, PE, LMP, Chief
Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3189

Dear Mr. Ratliff:

As requested, we have reviewed the final Texas regulations for Control of Radiation (25 Texas Administrative Code 289) Section 289.252, "Licensing of Radioactive Material," Section 289.254, "Licensing of Waste Processing and Storage Facilities," and Section 289.260, "Licensing of Uranium Recovery and Byproduct Material Disposal Facilities" received in letters, dated January 2, 2003. The proposed regulations are not in response to specific amendments identified in the State Regulation Status (SRS) Data Sheet. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 30 and 40. We discussed our review of the regulations with you on February 11, 2003.

As a result of our review, we have one comment that has 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 a State regulation meets the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final State regulation. However, we have determined that if your proposed regulations were adopted incorporating the comment and without other significant change, they would meet the compatibility and health and safety categories established in Office of State and Tribal Programs (STP) 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 STP Procedure SA-201, *Review of State Regulations* (November 10, 1998), please highlight the final changes and send one copy to STP.

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 me, or Vivian Campbell of the Region IV stafff at 817-860-8143 or vhc@NRC.GOV.

Sincerely,

Patricia Larkins, Acting for
Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

Enclosure(*s*):
As stated

Attachment 5b

COMMENTS ON PROPOSED TEXAS REGULATIONS
AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
289.260(f)(2)	40.32(e)	NONE	H&S	**General requirements for issuance of specific licenses** The State's proposed rule would allow major construction for uranium recovery and byproduct material disposal facilities before a license is issued. NRC's regulations in 40.32(e) and 150.31(b)(3)(iv) prohibits any major construction activity prior to the issuance of a license. In addition, Section 274o.(3)(D) of the Atomic Energy Act of 1954 requires the State to have procedures for licensing and regulation of byproduct material, as defined in Section 11e. (2), that prohibit any major construction activity prior to license issuance. The State's current section of the rule meets the health and safety category of the equivalent NRC regulation and should remain unchanged. The State should retain this paragraph but consider amending this paragraph to define what is meant by "commencement of construction" similar to the definition of the phrase in 10 CFR 40.32 (e).

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

Attachment 5C

May 19, 2004

RECEIVED
MAY 24 2004
RADIATION CONTROL

Mr. Richard A. Ratliff, PE, LMP, Chief
Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin TX 78756-3189

Dear Mr. Ratliff:

We have reviewed the final changes to the Texas Regulations for Control of Radiation, 25 Texas Administrative Code, §289.260(f)(2), "*Licensing of Uranium Recovery and Byproduct Material Disposal Facilities*", received by our office on April 21, 2004 and with additional electronic material arriving on April 29, 2004. We also reviewed our February 12, 2002 letter to you that contained our comments on the proposed version of this rule. These regulations were reviewed by comparison to the equivalent NRC rules in 10 CFR Part 40. We discussed our review of the regulations with Ms. Cindy Cardwell, of your staff, on May 10, 2004.

As a result of our review, we have one comment as enclosed. Please provide an amended final version of your rules showing the location of any changes made, by the State, in response to our comment. If there are any comments which the State believes are in error, the State should identify the section of their regulations that meet the designated compatibility category. 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 adopted, incorporating our comments and without 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.

The SRS Data Sheet summarizes our knowledge of the status of other Texas regulations. 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 STP website: Http://www.hrsd.ornl.gov/nrc/rulemaking.htm.

If you have any questions regarding the comments, the compatibility and health categories, or any of the NRC regulations used in the review, please contact me or John Zabko of my staff at 301-415-2308 or JGZ@NRC.GOV.

Sincerely,

Kathleen J. Schneider for
Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

Enclosure(s):
As stated

Attachment 5d

COMMENTS ON PROPOSED TEX
AGAINST COMPATIBILITY AND HEALTH

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
289.260 (f)(2)	40.32(e)	None	H&S	**General requirements for issuance of specific licenses** When the State incorporated the comment from the February 12, 2002 NRC letter, the State produced a contradicting paragraph concerning the requirements for the commencement of construction of a uranium mill. In the same paragraph the State has used both "shall not commence construction" and " major construction is prohibited" without defining what "major construction" is or if it differs from "construction" The State is urged to use 40.32 (e) as a template to construct the wording of this section and to meet the H&S compatibility designation. 40.32 is shown below with the optional areas shown in **bold.**

<u>40.32 (e)</u>

In the case of an application for a license for a uranium enrichment facility, or for a license to possess and use source and byproduct material for uranium milling, production of uranium hexafluoride, or for the conduct of any other activity which the **Commission** determines will significantly affect the quality of the environment, **the Director of Nuclear Material Safety and Safeguards or his designee**, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made **pursuant to subpart A of part 51 of this chapter**, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to this conclusion is grounds for denial of a license to possess and use source and byproduct material in the plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, roads necessary for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

Attachment 5e

STATE REGULATION STATUS

State: Texas
[No amendment reviewed]

Tracking Ticket Number: 4-108
Date: May 19, 2004

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F)[1] Rule / 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	P	Y 1/12/99	
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	P	N 11/21/97	
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			
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	P	N 11/21/97	
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	P	Y 3/13/96	
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	P	N 11/21/97	
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2	P	N 11/21/97	Not applicable SECY-95-112[4]
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	P	N 11/21/97	
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			

Legend: (Proposed amendments)
Single-Underline = Proposed new language
[Bold Print and Brackets] = Current language proposed for deletion
Regular Print = Current language
(No change.) = No changes are being considered for designated subdivisions

§289.260. Licensing of Uranium Recovery and Byproduct Material Disposal Facilities.

(a) (No change.)

(b) Scope. In addition to the requirements of this section, all licensees, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials **[Material]**), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.251 of this title (relating to Exemptions, General Licenses, and General License Acknowledgements), §289.252 of this title, and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(c) Definitions. The following words and terms when used in this section shall have the following meaning unless the context clearly indicates otherwise.

(1) Aquifer - A geologic formation, group of formations, or part of a formation capable of yielding a significant amount of groundwater to wells or springs. Any saturated zone created by uranium or thorium recovery operations would not be considered an aquifer unless the zone is or potentially is:

(A)-(B) (No change.)

(C) reasonably accessible because of migration beyond the vertical projection of the boundary of the land transferred for long-term government ownership and care in accordance with subsection (p) **[(r)]** of this section.

(2)-(10) (No change.) Commencement of Construction

(11) Disposal area - The area containing byproduct materials to which the requirements of subsection (o)(16)-(27) **[(q)(16)-(27)]** of this section apply.

(12) Existing portion - As used in subsection (o)(9)(A) **[(q)(9)(A)]** of this section, "existing portion" is that land surface area of an existing surface impoundment on which significant quantities of byproduct materials had been placed prior to September 30, 1983.

(2) As expeditiously as practicable considering technological feasibility - As quickly as possible considering the physical characteristics of the byproduct material and the site, the limits of "available technology" (as defined in this subsection), the need for consistency with mandatory requirements of other regulatory programs, and "factors beyond the control of the licensee" (as defined in this subsection). The phrase permits consideration of the cost of compliance only to the extent specifically provided for by use of the term "available technology."

(3) Available technology - Technologies and methods for emplacing a final radon barrier on byproduct material piles or impoundments. This term shall not be construed to include extraordinary measures or techniques that would impose costs that are grossly excessive as measured by practice within the industry (or one that is reasonably analogous), (for example, by way of illustration only, unreasonable overtime, staffing, or transportation requirements, etc., considering normal practice in the industry; laser fusion of soils; etc.), provided there is reasonable progress toward emplacement of the final radon barrier. To determine grossly excessive costs, the relevant baseline against which costs shall be compared is the cost estimate for tailings impoundment closure contained in the licensee's approved reclamation plan, but costs beyond these estimates shall not automatically be considered grossly excessive.

(4) Byproduct material - Tailings or wastes produced by or resulting from the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by such solution extraction operations do not constitute "byproduct material" within this definition.

(5) Capable fault - As used in this section, "capable fault" has the same meaning as defined in Section III(g) of Appendix A of Title 10 Code of Federal Regulations (CFR) Part 100.

(6) Closure - The post-operational activities to decontaminate and decommission the buildings and site used to produce byproduct materials and reclaim the tailings and/or disposal area, including groundwater restoration, if needed.

(7) Closure plan - The plan approved by the agency to accomplish closure. The closure plan consists of a decommissioning plan and may also include a reclamation plan.

(8) Commencement of construction - Any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site, but does not include necessary borings to determine site characteristics or other preconstruction monitoring to establish background information related to the suitability of a site, or to the protection of the environment.

Attachment 5h

(1) An application for a license shall include the following:

(A) (No change.)

(B) a closure plan for decontamination, decommissioning, restoration, and reclamation of buildings and the site to levels that would allow unrestricted use and for reclamation of the byproduct material disposal areas in accordance with the technical requirements of subsection (o) [(q)] of this section;

(C) proposal of an acceptable form and amount of financial security consistent with the requirements of subsection (m) [(o)] of this section;

(D) procedures describing the means employed to meet the requirements of subsections (g)(1) and (2) and (o)(15) [(h)(7) and (8) and (q)(15)] of this section during the operational phase of any project;

(E)-(F) (No change.)

(2) Unless otherwise exempted, the applicant shall not commence construction at the site until the agency has issued the license. Commencement of construction prior to issuance of the license shall be grounds for denial of a license. **[commencement of major construction is prohibited until 30 days after the agency has given notice that a license is proposed to be granted. If a hearing is requested, the commencement of major construction is prohibited until notice of the contested case hearing is noticed in accordance with the Act. Commencement of major construction subsequent to issuance of the notices is at the economic risk of the applicant.]**

(3) (No change.)

[(g) Issuance of specific licenses.]

[(1) When the agency determines that an application meets the requirements of the Act and the requirements of the agency, the agency will issue a license authorizing the proposed activity in such form and containing the conditions and limitations as it deems appropriate or necessary.]

[(2) The agency may incorporate in any license at the time of issuance or thereafter by amendment, additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this section as it deems appropriate or necessary in order to:]

[(A) minimize danger to occupational and public health and safety or the environment;]

proposed

Appendix A

TDH
TEXAS DEPARTMENT OF HEALTH

25 TEXAS ADMINISTRATIVE CODE

§289.258

Licensing and Radiation Safety Requirements for Irradiators

Texas Regulations for Control of Radiation

(effective August 1, 1996)

		Page
§289.258(a)	Purpose (revision effective October 1, 2000)	258-1
§289.258(b)	Scope (revision effective October 1, 2000)	258-1
§289.258(c)	Definitions (revision effective October 1, 2000)	258-1
§289.258(d)	Application for a Specific License (revision effective October 1, 2000)	258-3
§289.258(e)	Specific Licenses for Irradiators (revision effective October 1, 2000)	258-3
§289.258(f)	Start of Construction (revision effective October 1, 2000)	258-4
§289.258(g)	Applications for Exemptions (revision effective October 1, 2000)	258-5
§289.258(h)	Performance Criteria for Sealed Sources (revision effective October 1, 2000)	258-5
§289.258(i)	Access Control Requirements (revision effective October 1, 2000)	258-6
§289.258(j)	Shielding (revision effective October 1, 2000)	258-8
§289.258(k)	Fire Protection (revision effective October 1, 2000)	258-8
§289.258(l)	Radiation Monitors (revision effective October 1, 2000)	258-8
§289.258(m)	Control of Source Movement (revision effective October 1, 2000)	258-9

(October 2000)

Licensing and Radiation Safety Requirements for Irradiators (Continued)

		Page
§289.258(n)	Irradiator Pools (revision effective October 1, 2000)	258-9
§289.258(o)	Source Rack Protection (revision effective October 1, 2000)	258-10
§289.258(p)	Power Failures (revision effective October 1, 2000)	258-10
§289.258(q)	Design Requirements for Irradiators (revision effective October 1, 2000)	258-10
§289.258(r)	Construction Monitoring and Acceptance Testing Requirements (revision effective October 1, 2000)	258-12
§289.258(s)	Training (revision effective October 1, 2000)	258-13
§289.258(t)	Operating, Safety, and Emergency Procedures (revision effective October 1, 2000)	258-15
§289.258(u)	Personnel Monitoring (revision effective October 1, 2000)	258-17
§289.258(v)	Radiation Surveys (revision effective October 1, 2000)	258-17
§289.258(w)	Detection of Leaking Sources (revision effective October 1, 2000)	258-18
§289.258(x)	Inspection and Maintenance (revision effective October 1, 2000)	258-19
§289.258(y)	Pool Water Purity (revision effective October 1, 2000)	258-21
§289.258(z)	Attendance During Operation (revision effective October 1, 2000)	258-21
§289.258(aa)	Entering and Leaving the Radiation Room (revision effective October 1, 2000)	258-22
§289.258(bb)	Irradiation of Explosive or Flammable Materials (revision effective October 1, 2000)	258-22
§289.258(cc)	Records/Documents (revision effective October 1, 2000)	258-22
§289.258(dd)	Reports (revision effective October 1, 2000)	258-24

TEXAS REGISTER FORMAT EXPLANATION

The following example is the outline format used for all agency rules. This explanation will help you locate the different references stated throughout the rule:

§289.xxx = sections are the titles

(a) = subsections are the lowercase letters in parenthesis

(1) = paragraphs are the numbers in parenthesis

(A) = subparagraphs are the UPPERCASE letters in parenthesis

(*i*) = clauses are the *italicized* lowercase roman numerals in parenthesis

(*I*) = subclauses are the *italicized* UPPERCASE roman numerals in parenthesis

(-a-) = items are the lowercase letters with hyphens in parenthesis

(-1-) = subitems are the numbers with hyphens in parenthesis

289.252 Licensing of Radioactive Material.

(a) Appendices.

(1) Criteria relating to use of financial tests and parent company...

(A) Financial test.

(*i*) To pass the financial test, the parent company...

(*I*) The parent company shall have:

(-a-) two of the following...:

(-1-) a ratio of total liabilities to...;

FOR EXAMPLE:

When the rule states "paragraph (1) of this subsection", the rule is referring to paragraph "(1)" within subsection "(a)."
When the rule states "subsection (d) of this section", the rule is referring to subsection "(d)" within the section, for example, §289.252.

WHERE CAN THE FORMS REFERENCED WITHIN THE RULE BE FOUND?

Forms that are referenced in this rule can be downloaded from the Bureau of Radiation Control web site at:

www.tdh.state.tx.us/ech/rad/pages/brc.htm

Or call (512) 834-6688 to request a copy of the forms

(October 2000)

§289.258 Licensing and Radiation Safety Requirements for Irradiators.

(a) Purpose. This section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive material in irradiators that irradiate objects or materials using gamma radiation. This section also contains radiation safety requirements for operating irradiators.

(b) Scope.

(1) In addition to the requirements of this section, all licensees, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Material), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.252 of this title (relating to Licensing of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material). Nothing in this section relieves the licensee from complying with other applicable federal, state and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(2) The requirements in this section apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 500 rads (5 grays) per hour at 1 meter (m) from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this section.

(3) The requirements in this section do not apply to self-contained, dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

(c) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Annually - At intervals not to exceed 390 days.

(2) Doubly encapsulated sealed source - A sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

(3) Category I self-contained, dry-source irradiator - An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials and is shielded at all times, and in which human access to the sealed source and the volume undergoing irradiation is not physically possible in its designed configuration.

(4) Irradiator - A facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 500 rads (5 grays) per hour exist at 1 m from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

(5) Irradiator operator - An individual who has successfully completed the training and testing described in subsection (s) of this section and is authorized by the terms of the license to operate the irradiator without the presence of a supervisor who has completed the requirements of subsection (s)(1)-(3) of this section.

(6) Onsite - A physical presence within the building housing the irradiator or on property controlled by the licensee that is contiguous with the building housing the irradiator.

(7) Panoramic dry-source-storage irradiator - An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

(8) Panoramic irradiator - An irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

(9) Panoramic wet-source-storage irradiator - An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

(10) Pool irradiator - Any irradiator in which the sources are stored or used in a pool of water, including panoramic wet-source-storage irradiators and underwater irradiators.

(11) Product conveyor system - A system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

(12) Radiation room - A shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

(13) Seismic area - Any area where the probability of horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the United States Geological Survey.

(14) Underwater irradiator - An irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

(d) Application for a specific license. Applications for specific licenses shall be filed in accordance with §289.252(d) of this title.

(e) Specific licenses for irradiators.

(1) The agency will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(2) The applicant shall satisfy the general requirements specified in §289.252 of this title and the requirements contained in this section.

(3) The application shall describe the training provided to irradiator operators including:

(A) classroom training;

(B) on-the-job or simulator training;

(C) safety reviews;

(D) means employed by the applicant to test each operator's understanding of the agency's rules and licensing requirements and the irradiator operating, safety, and emergency procedures; and

(E) minimum training and experience of personnel who may provide training.

(4) The application shall include a copy of the written operating, safety, and emergency procedures as outlined in subsection (t) of this section that describes the radiation safety aspects of the procedures.

(5) The application shall describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer (RSO) and those management personnel who have radiation safety responsibilities or authorities. In particular, the application shall specify who, within the management structure, has the authority to stop unsafe operations. The application shall also describe the training and experience required for the position of RSO.

(6) The application shall include a description of the access control systems required by subsection (i) of this section, the radiation monitors required by subsection (l) of this section, the method of detecting leaking sources required by subsection (w) of this section, including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(7) If the applicant intends to perform and analyze leak tests of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the agency. The description shall include at least the following:

(A) instruments to be used;

(B) methods of performing the analysis; and

(C) pertinent experience of the individual who analyzes the samples.

(8) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading shall be done by a person specifically authorized by the agency, the United States Nuclear Regulatory Commission (NRC), an agreement state, or a licensing state to load or unload irradiator sources.

(9) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by subsection (x) of this section.

(f) Start of construction. The applicant may not begin construction of a new irradiator prior to the submission to the agency of both an application for a license for the irradiator and the fee required by §289.204 of this title. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work; purchase of a site; site surveys or soil testing; site preparation; site excavation; construction of warehouse or auxiliary structures; and other similar tasks. Any construction activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Texas Radiation Control Act (Act), rules, and orders issued under the Act.

(g) Applications for exemptions. Any applications for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this section. The agency will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

(h) Performance criteria for sealed sources.

(1) Cesium-137 shall not be used in any irradiator other than a Category I self-contained, dry-source irradiator as defined in subsection (c) of this section.

(2) Sealed sources. Sealed sources installed after August 1, 1996, shall meet the following requirements:

(A) have been evaluated in accordance with §289.252(v) of this title;

(B) be doubly encapsulated;

(C) use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

(D) be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

(E) have been leak tested and found leak-free in prototype testing of the sealed source after each of the tests described in paragraphs (3)-(8) of this subsection.

(3) Temperature. The test source shall be held at -40 degrees Celsius for 20 minutes, 600 degrees Celsius for one hour, and then be subjected to thermal shock test with a temperature drop from 600 degrees Celsius to 20 degrees Celsius within 15 seconds.

(4) Pressure. The test source shall be twice subjected for at least five minutes to an external pressure (absolute) of 2 million newtons per square meter.

(5) Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, shall be dropped from a height of 1 m onto the test source.

(6) Vibration. The test source shall be subjected three times for ten minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source shall be vibrated for 30 minutes at each resonant frequency found.

(7) Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, shall be dropped from a height of 1 m onto the test source.

(8) Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source shall be subjected to a force of 2,000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

(i) Access control requirements in addition to the requirements of §289.202(u) of this title.

(1) Each entrance to a radiation room at a panoramic irradiator shall have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It shall not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed shall cause the sources to return promptly to the shielded position. The personnel entrance door or barrier shall have a lock that is operated by the same key used to move the sources. The doors and barriers shall not prevent any individual in the radiation room from leaving.

(2) In addition, each entrance to a radiation room at a panoramic irradiator shall have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed shall cause the sources to return to their fully shielded position and shall also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm shall also make at least one other individual who is onsite aware of the entry. That individual shall be trained on how to respond to the alarm and be prepared to promptly render or summon assistance.

(3) A radiation monitor shall be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor shall be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels shall activate the alarm described in paragraph (2) of this subsection. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

(4) Before the sources move from their shielded position in a panoramic irradiator, the source control shall automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms shall give individuals enough time to leave the room and to operate the control described in paragraph (5) of this subsection before the sources leave the shielded position.

(5) Each radiation room at a panoramic irradiator shall have a clearly visible and readily accessible control that allows an individual in the room to return the sources to their fully shielded position.

(6) Each radiation room of a panoramic irradiator shall contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(7) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator shall have a sign bearing the radiation symbol and the words, "CAUTION (or DANGER), RADIOACTIVE MATERIAL." Panoramic irradiators shall also have a sign stating "CAUTION (or DANGER), HIGH RADIATION AREA," as defined in §289.201(b) of this title, or "GRAVE DANGER, VERY HIGH RADIATION AREA," as defined in §289.201(b) of this title, whichever is applicable, but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(8) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it shall not be possible to operate the irradiator unless the shielding is in its proper location. The requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(9) Underwater irradiators shall have a personnel access barrier around the pool that shall be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There shall be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm shall alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

(j) Shielding.

(1) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 2 millirems (mrem) (0.02 millisievert (mSv)) per hour at any location 30 centimeters (cm) or more from the wall of the room when the sources are exposed. The dose rate shall be averaged over an area not to exceed 100 square centimeters (cm^2) having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 2 mrem (0.02 mSv) per hour shall be locked, roped off, or posted.

(2) The radiation dose at 30 cm over the edge of the pool of a pool irradiator may not exceed 2 mrem (0.02 mSv) per hour when the sources are in the fully shielded position.

(3) The radiation dose rate at 1 m from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 2 mrem (0.02 mSv) per hour and at 5 cm from the shield may not exceed 20 mrem (0.2 mSv) per hour.

(k) Fire protection.

(1) The radiation room at a panoramic irradiator shall have heat and smoke detectors. The detectors shall activate an audible alarm. The alarm shall be capable of alerting a person who is prepared to summon assistance promptly. The sources shall automatically become fully shielded if a fire is detected.

(2) The radiation room at a panoramic irradiator shall be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. If water is used, the system for the radiation room shall have a shut-off valve to control flooding into unrestricted areas.

(l) Radiation monitors.

(1) Irradiators with automatic product conveyor systems shall have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm shall sound and product conveyors shall stop automatically. The alarm shall be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

(2) Underwater irradiators that are not in a shielded radiation room shall have a radiation monitor over the pool to detect abnormal radiation levels. The monitor shall have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm shall be capable of alerting an individual who is prepared to respond promptly.

(m) Control of source movement.

(1) The mechanism that moves the sources of a panoramic irradiator shall require a key to actuate. Actuation of the mechanism shall cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key shall be attached to a portable radiation survey meter by a chain or cable. The lock for source control shall be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room shall require the same key.

(2) The console of a panoramic irradiator shall have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are in the fully exposed position.

(3) The control console of a panoramic irradiator shall have a control that when activated, shall return the source to its fully shielded position within its normal transit time.

(4) Each control for a panoramic irradiator shall be clearly marked as to its function.

(n) Irradiator pools.

(1) For licenses initially issued after August 1, 1996, irradiator pools shall either:

(A) have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

(B) be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

(2) For licenses initially issued after August 1, 1996, irradiator pools shall have no outlets more than 0.5 m below the normal low water level that could allow water to drain out of the pool. Pipes that have openings more than 0.5 m below the normal low water level and that could act as siphons shall have siphon breakers to prevent the siphoning of pool water.

(3) A means shall be provided to replenish water losses from the pool.

(4) A visible indicator shall be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(5) Irradiator pools shall be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

(6) A physical barrier, such as a railing or cover, shall be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(7) If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 2 mrem (0.02 mSv) per hour.

(o) Source rack protection. If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack shall be protected by a carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

(p) Power failures.

(1) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources shall automatically return to the shielded position.

(2) The lock on the door of the radiation room of a panoramic irradiator shall not be deactivated by a power failure.

(3) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

(q) Design requirements for irradiators. The following are design requirements for irradiators that have construction beginning after August 1, 1996.

(1) Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entrance ways to meet the radiation shielding requirements of subsection (j) of this section. If the irradiator will use more than 5 million curies (2×10^{17} becquerels) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(2) Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

(3) Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of subsection (n)(2) of this section, and that metal components are metallurgically compatible with other components in the pool.

(4) Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of subsection (n)(5) of this section. The system shall be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(5) Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by subsection (l)(1) of this section. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under subsection (w)(2) of this section, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(6) Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(7) Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of subsection (i) of this section.

(8) Fire protection. For panoramic irradiators, the licensee shall verify that the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

(9) Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if power is lost for more than 10 seconds.

(10) Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

(11) Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

(r) Construction monitoring and acceptance testing requirements. The following are construction monitoring and acceptance testing requirements to be met prior to loading sources in irradiators that have begun construction after August 1, 1996.

(1) Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(2) Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that the foundation construction meets design specifications.

(3) Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of subsection (n)(2) of this section.

(4) Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(5) Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by subsection (l)(1) of this section. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet subsection (w)(2) of this section. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by subsection (l)(2) of this section.

(6) Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading. Testing shall include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in subsection (o) of this section are met for protection of the source rack and the mechanism that moves the rack. Testing shall include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves that rack from moving product carriers.

(7) Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(8) Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

(9) Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without power.

(10) Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

(11) Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

(s) Training.

(1) Before an individual is permitted to operate an irradiator without a supervisor present, who has completed the requirements of this paragraph and paragraphs (2) and (3) of this subsection, the individual shall be instructed in:

(A) the fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, dose limits, why large radiation doses shall be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and individual monitoring devices, other radiation safety features of an irradiator, and the basic function of the irradiator);

(B) the requirements of this section and §289.203 of this title that are relevant to the irradiator;

(C) the operation of the irradiator;

(D) those operating, safety, and emergency procedures listed in subsection (t) of this section that the individual is responsible for performing; and

(E) case histories of accidents or problems involving irradiators.

(2) Before an individual is permitted to operate an irradiator without a supervisor present, who has completed the requirements of this paragraph and paragraphs (1) and (3) of this subsection, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating, safety, and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(3) Before an individual is permitted to operate an irradiator without a supervisor present, who has completed the requirements of this paragraph and paragraphs (1) and (2) of this subsection, the individual shall have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating, safety, and emergency procedures that he or she is to perform.

(4) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review shall include, to the extent appropriate, each of the following:

(A) changes in operating, safety, and emergency procedures since the last review, if any;

(B) changes in rules and license conditions since the last review, if any;

(C) reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(D) relevant results of inspections of operator safety performance;

(E) relevant results of the facility's inspection and maintenance checks; and

(F) a drill to practice an emergency or abnormal event procedure.

(5) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that agency rules, license conditions, and operating, safety, and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(6) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the RSO, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in subsection (t) of this section that they are expected to perform or comply with, and their proper response to alarms required in this section. Tests may be oral.

(7) Individuals who shall be prepared to respond to alarms required by subsections (i)(2) and (9), (k), (l), and (w)(2) of this section shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

(t) Operating, safety, and emergency procedures.

(1) The licensee shall have and follow written operating, safety, and emergency procedures for:

(A) operation of the irradiator, including entering and leaving the radiation room;

(B) use of individual monitoring devices;

(C) surveying the shielding of panoramic irradiators;

(D) monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(E) leak testing of sources;

(F) inspection and maintenance checks required by subsection (x) of this section;

(G) loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(H) inspection of movable shielding required by subsection (i)(8) of this section, if applicable.

(2) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

(A) sources stuck in the unshielded position;

(B) personnel overexposures;

(C) a radiation alarm from the product exit portal monitor or pool monitor;

(D) detection of leaking source, pool contamination, or alarm caused by contamination of pool water;

(E) a low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

(F) a prolonged loss of electrical power;

(G) a fire alarm or explosion in the radiation room;

(H) an alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

(I) natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

(J) the jamming of automatic conveyor systems.

(3) The licensee may revise operating, safety, and emergency procedures without agency approval only if all of the following conditions are met:

(A) the revisions do not reduce the safety of the facility;

(B) the revisions are consistent with the outline or summary of procedures including procedures for changes to operating, safety, and emergency procedures submitted with the license application;

(C) the revisions have been reviewed and approved by the radiation safety officer; and

(D) the users or operators are instructed and tested on the revised procedures before they are put into use.

(4) Changes to operating, safety, and emergency procedures shall be submitted to the agency after the provisions of paragraph (3) of this subsection are completed.

(u) Personnel monitoring.

(1) Irradiator operators shall wear either a film badge, a thermoluminescent dosimeter (TLD), or optically stimulated luminescence device (OSL) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge, TLD, or OSL processor shall be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges (see §289.202(p)(3) of this title). Each film badge. TLD, or OSL shall be assigned to and worn by only one individual. Film badges shall be replaced at an interval not to exceed monthly and TLDs or OSLs shall be replaced at an interval not to exceed three months. After replacement, each film badge, TLD, or OSL shall be returned to the supplier for processing within 14 calendar days of the exchange date specified by the personnel monitoring supplier or as soon as practicable. In circumstances that make it impossible to return each film badge, TLD, or OSL within 14 calendar days, such circumstances shall be documented and available for review by the agency.

(2) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of the paragraph, a check of their response to radiation shall be done at least annually. Acceptable dosimeters shall read within plus or minus 30% of the true radiation dose.

(v) Radiation surveys.

(1) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator shall be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators shall be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding shall be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(2) If the radiation levels specified in subsection (j) of this section are exceeded, the facility shall be modified to comply with the requirements in subsection (j) of this section.

(3) Portable radiation survey meters shall be calibrated at least annually to an accuracy of plus or minus 20% for the gamma energy of the sources in use. The calibration shall be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters shall be of a type that does not saturate and read zero at high radiation dose rates.

(4) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming shall be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations shall not exceed those specified in Table 2, Column 2 or Table 3 of §289.202(ggg)(2) of this title.

(5) Before releasing resins for unrestricted use, they shall be monitored in an area with a background level less than 0.05 mrem (0.5 μSv) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used shall be capable of detecting radiation levels of 0.05 mrem (0.5 μSv) per hour.

(w) Detection of leaking sources.

(1) Each dry-source-storage sealed source shall be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the agency, the commission, an agreement state, or a licensing state. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test shall be capable of detecting the presence of 0.005 microcurie (200 becquerels) of radioactive material and shall be performed by a person approved by the agency, the NRC, an agreement state, or a licensing state to perform the test.

(2) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the six months before the transfer. Water from the pool shall be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis shall be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels shall activate an alarm. The alarm set-point shall be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clear up contamination in the pool if specifically provided for in written emergency procedures.

(3) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an agency, NRC, agreement state, or licensing state licensee who is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination shall be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an agency, NRC, agreement state, or licensing state licensee who is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2 of §289.202(ggg)(2) of this title. (See §289.202(xx) and (yy) of this title for reporting requirements.)

(x) Inspection and maintenance.

(1) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(A) operability of each aspect of the access control system required by subsection (i) of this section;

(B) functioning of the source position indicator required by subsection (m)(2) of this section;

(C) operability of the radiation monitor for radioactive contamination in pool water required by subsection (w)(2) of this section using a radiation check source, if applicable;

(D) operability of the over-pool radiation monitor at underwater irradiators as required by subsection (l)(2) of this section;

(E) operability of the product exit monitor required by subsection (l)(1) of this section;

(F) operability of the emergency source return control required by subsection (m)(3) of this section;

(G) leak-tightness of systems through which pool water circulates (visual inspection);

(H) operability of the heat and smoke detectors and extinguisher system required by subsection (k) of this section (but without turning extinguishers on);

(I) operability of the means of pool water replenishment required by subsection (n)(3) of this section;

(J) operability of the indicators of high and low pool water levels required by subsection (n)(4) of this section;

(K) operability of the intrusion alarm required by subsection (i)(8) of this section, if applicable;

(L) functioning and wear of the system, mechanisms, and cables used to raise and lower sources;

(M) condition of the barrier to prevent products from hitting the sources or source mechanism as required by subsection (o) of this section;

(N) amount of water added to the pool to determine if the pool is leaking;

(O) electrical wiring on required safety systems for radiation damage;

(P) pool water conductivity measurements and analysis as required by subsection (y)(2) of this section; and

(Q) operability of automatic communications systems used to alert individuals to alarms, emergencies, or abnormal event conditions if required by subsection (z)(2)(A) of this section.

(2) Malfunctions and defects found during inspection and maintenance checks shall be repaired without undue delay. If repairs are required, the irradiator shall not be operated unless alternative methods are utilized to provide an equivalent level of safety until repairs are completed.

(y) Pool water purity.

(1) Pool water purification system shall be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(2) The licensee shall measure the pool water conductivity no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters shall be calibrated at least annually.

(z) Attendance during operation.

(1) Both an irradiator operator and at least one other individual, who is trained on how to respond to alarms in accordance with subsection (s)(7) of this section and is prepared to promptly render or summon assistance, shall be present onsite whenever it is necessary to enter the radiation room.

(2) At least one individual who has received the training on how to respond to alarms described in subsection (s)(7) of this section shall be available and prepared to promptly respond to alarms, emergencies, or abnormal event conditions at any time a panoramic irradiator is operating. If the individual is not onsite, the following requirements shall be met:

(A) Automatic means of communications shall be provided from the irradiator control system to alert the individual to alarms, emergencies, or abnormal event conditions. As a minimum, the automatic communication system shall alert the individual to those emergency or abnormal events listed in subsection (t)(2) of this section.

(B) The irradiator control system shall be secured from unauthorized access at any time an irradiator operator is not onsite. This security shall include physically securing the key described in subsection (m)(1) of this section to ensure the key is not removed from the control console.

(3) At an underwater irradiator, an irradiator operator shall be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they shall have received the training described in subsection (s)(6) and (7) of this section. Static irradiations may be performed without a person present at the facility.

(aa) Entering and leaving the radiation room.

(1) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(2) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall do the following:

(A) visually inspect the entire radiation room to verify that no one else is in it; and

(B) activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(3) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by subsection (l)(2) of this section is operating with backup power.

(bb) Irradiation of explosive or flammable materials.

(1) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the agency. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(2) Irradiation of more than small quantities of flammable material (flash point below 140 degrees Fahrenheit) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the agency. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

(cc) Records/documents. The licensee shall maintain the following records/documents at the irradiator for the time intervals indicated for inspection by the agency:

(1) a copy of the license, license conditions, documents incorporated into a license by reference, and amendments to the license until superseded by new documents or until the agency terminates the license;

(2) records of each individual's training, tests, and safety reviews provided to meet the requirements of subsection (s)(1)-(4), (6), and (7) of this section until three years after the individual terminates work;

(3) records of the annual evaluations of the safety performance of irradiator operators required by subsection (s)(5) of this section for three years after the evaluation;

(4) a copy of the current operating, safety, and emergency procedures required by subsection (t) of this section until superseded or the agency terminates the license. Records of the RSO review and approval of changes in procedures as required by subsection (t)(3)(C) of this section, retained for three years from the date of the change;

(5) film badge, TLD, or OSL results required by subsection (u) of this section until the agency terminates the license;

(6) records of radiation surveys required by subsection (v) of this section for three years from the date of the survey;

(7) records of radiation survey meter calibrations required by subsection (v) of this section and pool water conductivity meter calibrations required by subsection (y)(2) of this section until three years from the date of calibration;

(8) records of the results of leak tests required by subsection (w)(1) of this section and the results of contamination checks required by subsection (w)(2) of this section for three years from the date of each test;

(9) records of inspection and maintenance checks required by subsection (x) of this section for three years;

(10) records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed;

(11) records of the receipt, transfer and disposal, of all licensed sealed sources as required by §289.201(d) and §289.252(x) and (cc) of this title;

(12) records on the design checks required by subsection (q) of this section and the construction control checks as required by subsection (r) of this section until the license is terminated. The records shall be signed and dated. The title or qualification of the person signing shall be included; and

(13) records related to decommissioning of the irradiator as required by §289.252(gg)(7) of this title.

(dd) Reports.

(1) In addition to the reporting requirements in other sections of this title, the licensee shall report the following events if not reported under other sections of this title:

(A) source stuck in an unshielded position;

(B) any fire or explosion in a radiation room;

(C) damage to the source racks;

(D) failure of the cable or drive mechanism used to move the source racks;

(E) inoperability of the access control system;

(F) detection of radiation source by the product exit monitor;

(G) detection of radioactive contamination attributable to licensed radioactive material;

(H) structural damage to the pool liner or walls;

(I) abnormal water loss or leakage from the source storage pool; and

(J) pool water conductivity exceeding 100 microsiemens per centimeter during normal operations.

(2) The report shall include a telephone report within 24 hours as described in §289.202(xx)(8)(A) of this title, and a written report within 30 days as described in §289.202(xx)(8)(B) of this title.

Appendix B

TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • http://www.dshs.state.tx.us

May 27, 2005

Mr. Dennis Rathbun
Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Rathbun:

Enclosed is a copy of the final revisions to the Texas Regulations for Control of Radiation, 25 Texas Administrative Code, §289.251 relating to Exemptions, General Licenses, and General License Acknowledgements, §289.252 relating to Licensing of Radioactive Material, §289.254 relating to Licensing of Radioactive Waste Processing and Storage Facilities, and §289.260 relating to Licensing of Uranium Recovery and Byproduct Material Disposal Facilities.

Please see the following table that identifies the specific items noted as a result of NRC's review of the proposed regulations per the NRC letters dated April 2, 2004, and May 19, 2004, and the agency's responses.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

If you have any questions, please feel free to contact me at 512-834-6688, ext. 2239, or Cindy.Cardwell@dshs.state.tx.us.

Sincerely,

Cynthia C. Cardwell

Cynthia C. Cardwell, Manager
Radiation Policy, Standards, and Quality Assurance Group
Policy, Standards, and Quality Assurance Unit
Department of State Health Services

Final Revisions of Texas Regulations that Incorporate Equivalent NRC Amendments into State Regulations

NRC Regulation	FR Notice (State Due Date)	RATS ID	Texas Regulation*	Final Texas Regulation (Effective Date)**
31.5(c)(13)(iv)	65 FR 79162 (02/16/04)	2001-1	289.251(g)(2) Meets compatibility	09/01/04
40.32(e)	64 FR 17506 (06/11/02)	1999-1	289.260(f)(2) Meets compatibility	09/01/04

* For generic legally binding requirements, mark Legally Binding Requirements with the effective date.
** The last column is used only when the regulations are final.

25 TEXAS ADMINISTRATIVE CODE

§289.251

Exemptions, General Licenses, and General Licenses Acknowledgments

Texas Regulations for Control of Radiation

(revisions effective September 1, 2004
are shown as shaded text)

		Page
§289.251(a)	Purpose	251-1
§289.251(b)	Scope	251-1
§289.251(c)	Definitions	251-1
§289.251(d)	Exemptions for Source Material	251-1
§289.251(e)	Exemptions for Radioactive Material other than Source Material	251-4
§289.251(e)(1)	Exempt Concentrations	251-4
§289.251(e)(2)	Exempt Quantities	251-5
§289.251(e)(3)	Exempt Items	251-5
§289.251(e)(3)(A)	Certain Items Containing Radioactive Material	251-6
§289.251(e)(3)(B)	Self-luminous Products Containing Tritium, Krypton-85, Promethium-147, or Radium-226	251-8
§289.251(e)(3)(C)	Gas and Aerosol Detectors Containing Radioactive Material	251-8
§289.251(e)(3)(D)	Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells	251-9
§289.251(e)(4)	Exemption for Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use in Humans	251-9
§289.251(f)	General Licenses	251-10
§289.251(f)(1)	Compliance History	251-10
§289.251(f)(2)	Modification, Suspension, and Revocation of a General License	251-10
§289.251(f)(3)	General Licenses for Source Material	251-11
§289.251(f)(4)	General Licenses for Radioactive Material Other Than Source Material	251-13
§289.251(f)(4)(A)	General Licenses for Static Elimination Devices and Ion Generating Tubes	251-13
§289.251(f)(4)(B)	General License for Luminous Safety Devices for Aircraft	251-13
§289.251(f)(4)(C)	General License for Ownership of Radioactive Material	251-14

Exemptions, General Licenses, and General Licenses Acknowledgments (Continued)

		Page
§289.251(f)(4)(D)	General License for Calibration, Stabilization, and Reference Sources	251-14
§289.251(f)(4)(E)	General License for Ice Detection Devices	251-16
§289.251(f)(4)(F)	General License for Intrastate Transportation of Radioactive Material	251-17
§289.251(f)(4)(G)	General License for the Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing, Not to Include Research and Development	251-17
§289.251(f)(4)(H)	General License for Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere	251-20
§289.251(g)	General License Acknowledgements for Radioactive Material other than Source Material	251-24
§289.251(h)	Issuance of General License Acknowledgments	251-25
§289.251(i)	Specific Terms and Conditions	251-26
§289.251(j)	Expiration of General License Acknowledgement and Administrative Renewal	251-27
289.251(k)	Termination of General License Acknowledgements	251-27
§289.251(l)	Amendment of General License Acknowledgements	251-28
§289.251(m)	**APPENDICES**	251-28
§289.251(m)(1)	Exempt Concentrations	251-29
§289.251(m)(2)	Exempt Quantities	251-35

§289.251 Exemptions, General Licenses, and General License Acknowledgements.

(a) Purpose. This section provides for exemptions to licensing requirements, general licensing of radioactive material, and acknowledgement of general licenses.

(b) Scope. Except as otherwise authorized, no person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a general license or general license acknowledgement issued in accordance with this section, or in a specific license issued in accordance with §289.252 of this title (relating to Licensing of Radioactive Material), §289.254 of this title (relating to Licensing of Radioactive Waste Processing and Storage Facilities), §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material), §289.258 of this title (relating to Licensing and Radiation Safety Requirements for Irradiators), §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material (NORM)), or §289.260 of this title (relating to Licensing of Uranium Recovery and Byproduct Material Disposal Facilities).

(c) Definitions. The following words and terms when used in this section shall have the following meanings unless the context clearly indicates otherwise.

(1) General license - An authorization in accordance with this section that grants authority to a person for certain activities involving radioactive material and is effective without the filing of applications with the agency or the issuance of licensing documents to the particular persons. The general licensee is subject to all other applicable portions of this chapter and any limitations of the general license.

(2) General license acknowledgement - A written recognition of a general license issued in accordance with this section. The issuance of a general license acknowledgement requires the submission of an application to the agency. A written acknowledgement of a general license granted in accordance with this section is issued by the agency. The holder of a general license acknowledgement is subject to all other applicable portions of this chapter as well as any conditions specified in the acknowledgement document.

(d) Exemptions for source material.

(1) Any person is exempt from this section and §289.252 of this title if that person receives, possesses, uses, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1.0% (0.05%) of the mixture, compound, solution, or alloy.

(2) Any person is exempt from this section and §289.252 of this title if that person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore. This exemption does not apply to the mining of ore containing source material.

(3) Any person is exempt from this section and §289.252 of this title if that person receives, possesses, uses, or transfers:

(A) any quantities of thorium contained in:

(*i*) incandescent gas mantles;

(*ii*) vacuum tubes;

(*iii*) welding rods;

(*iv*) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams (mg) of thorium;

(*v*) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;

(*vi*) rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight thorium, uranium, or any combination of these; or

(*vii*) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 mg of thorium;

(B) source material contained in the following products:

(*i*) glazed ceramics, for example tableware, provided that the glaze contains not more than 20% by weight source material;

(*ii*) glassware containing not more than 10% by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

(*iii*) glass enamel or glass enamel frit containing not more than 10% by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; or

(*iv*) piezoelectric ceramic containing not more than 2.0% by weight source material;

(C) photographic film, negatives, and prints containing uranium or thorium;

(D) any finished product or part fabricated of, or containing, metal-thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that the exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

(E) depleted uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

(*i*) the counterweights are manufactured in accordance with a specific license issued by the United States Nuclear Regulatory Commission (NRC) authorizing distribution by the licensee in accordance with Title 10, Code of Federal Regulations (CFR), Part 40;

(*ii*) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM" (The requirements specified in this clause need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM," as previously required by this chapter);

(*iii*) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED" (The requirements specified in this clause need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM," as previously required by this chapter); and

(*iv*) the exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating, covering, or labeling;

(F) depleted uranium used as shielding constituting part of any shipping container, provided that:

(*i*) the shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM;" and

(*ii*) the uranium metal is encased in a one-eighth inch minimum wall thickness of mild steel or equally fire resistant material;

(G) thorium contained in finished optical lenses, provided that each lens does not contain more than 30% by weight of thorium, and that the exemption contained in this subparagraph shall not be deemed to authorize either:

(*i*) the shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or

(*ii*) the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or in other optical instruments;

(H) uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie (μCi) of uranium; or

(I) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(*i*) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

(*ii*) the thorium content in the nickel-thoria alloy does not exceed 4.0% by weight.

(4) The exemptions in subsection (d)(3) of this section do not authorize the manufacture of any of the products described.

(e) Exemptions for radioactive material other than source material.

(1) Exempt concentrations.

(A) Except as provided in subparagraph (B) of this paragraph, any person is exempt from this section and §289.252 of this title if that person receives, possesses, uses, transfers, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in subsection (q)(1) of this section.

(B) No person may introduce radioactive material into a product or material, including waste, knowing or having reason to believe that it will be transferred to persons exempt in accordance with subparagraph (A) of this paragraph or equivalent regulations of the NRC, any agreement state, or any licensing state, except in accordance with a specific license issued in accordance with §289.252(i) of this title or the general license provided in §289.252(ee) of this title.

(2) Exempt quantities.

(A) Except as provided in subparagraph (C) of this paragraph, any person is exempt from these rules if that person receives, possesses, uses, transfers, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in subsection (q)(2) of this section.

(B) Any person who possesses radioactive material received or acquired, prior to September 25, 1971, in accordance with the general license provided in subsection (f)(4)(A) of this section is exempt from the requirements for a license set forth in §289.252 of this title if that person possesses, uses, or transfers such radioactive material.

(C) This paragraph does not authorize the production, packaging, or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(D) No person may, for purposes of commercial distribution, transfer radioactive material in quantities greater than the individual quantities set forth in subsection (q)(2) of this section, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt in accordance with this paragraph or equivalent regulations of the NRC, any agreement state, or any licensing state, except in accordance with a specific license issued by the NRC in accordance with Title 10, CFR, §32.18 or by the agency in accordance with §289.252(j) of this title, which states that the radioactive material may be transferred by the licensee to persons exempt in accordance with this paragraph or the equivalent regulations of the NRC, any agreement state, or any licensing state.

(E) The schedule of quantities set forth in subsection (q)(2) of this section applies only to radioactive materials distributed as exempt quantities in accordance with a specific license issued by the agency, another licensing state, or the commission. Subsection (q)(2) of this section does not apply to radioactive materials that have decayed from quantities not originally exempt and does not make such material, or the sources or devices in which the material is contained, exempt from the licensing requirements in this section or §289.252 of this title.

(3) Exempt items.

(A) Certain items containing radioactive material.

(*i*) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from this chapter if that person receives, possesses, uses, transfers, or acquires the following products:

(*I*) timepieces, hands, or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(-a-) 25 millicuries (mCi)of tritium per timepiece;

(-b-) 5 mCi of tritium per hand;

(-c-) 15 mCi of tritium per dial (bezels when used shall be considered as part of the dial);

(-d-) 100 μCi of promethium-147 per watch or 200 μCi of promethium-147 per any other timepiece;

(-e-) 20 μCi of promethium-147 per watch hand or 40 μCi of promethium-147 per other timepiece hand;

(-f-) 60 μCi of promethium-147 per watch dial or 120 μCi of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

(-g-) the levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter (mg/cm^2) of absorber:

(-1-) for wrist watches, 0.1 millirad per hour (mrad/hr) at 10 centimeters (cm) from any surface;

(-2-) for pocket watches, 0.1 mrad/hr at 1 cm from any surface; and

(-3-) for any other timepiece, 0.2 mrad/hr at 10 cm from any surface; or

(-h-) 1 μCi of radium-226 per timepiece in timepieces, hands, or dials manufactured or initially distributed prior to January 1, 1986;

(*II*) lock illuminators containing not more than 15 mCi of tritium or not more than 2 mCi of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147 will not exceed 1 mrad/hr at 1 cm from any surface when measured through 50 mg/cm^2 of absorber;

(*III*) balances of precision containing not more than 1 mCi of tritium per balance or not more than 0.5 mCi of tritium per balance part;

(*IV*) automobile shift quadrants containing not more than 25 mCi of tritium;

(*V*) marine compasses containing not more than 750 mCi of tritium gas and other marine navigational instruments containing not more than 250 mCi of tritium gas;

(*VI*) thermostat dials and pointers containing not more than 25 mCi of tritium per thermostat;

(*VII*) electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material and that the levels of radiation from each electron tube containing byproduct material do not exceed 1 mrad/hr at 1 cm from any surface when measured through 7 mg/cm^2 of absorber (For purposes of this clause, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube designed to control electrical currents):

(-a-) 150 mCi of tritium per microwave receiver protector tube or 10 mCi of tritium per any other electron tube;

(-b-) 1 μCi of cobalt-60;

(-c-) 5 μCi of nickel-63;

(-d-) 30 μCi of krypton-85;

(-e-) 5 μCi of cesium-137; or

(-f-) 30 μCi of promethium-147;

(*VIII*) ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material not exceeding the applicable quantity set forth in subsection (q)(2) of this section or 0.05 μCi of americium-241; or

(*IX*) spark gap irradiators containing not more than 1 μCi of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons per hour.

(*ii*) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission, Washington, DC 20555.

(B) Self-luminous products containing tritium, krypton-85, promethium-147, or radium-226.

(*i*) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from this chapter if that person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the NRC in accordance with Title 10, CFR, §32.22, which authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this subparagraph does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

(*ii*) Any person is exempt from this chapter if that person receives, possesses, uses, transfers, or owns articles acquired prior to January 1, 1986, each of which contains less than 0.1 μCi of radium-226.

(C) Gas and aerosol detectors containing radioactive material.

(*i*) Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from this chapter if that person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that:

(*I*) detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the NRC in accordance with Title 10, CFR, §32.26, or an agreement state or a licensing state in accordance with §289.252(k) of this title; and

(*II*) the specific license issued in accordance with §289.252 of this title authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(*ii*) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission, Washington, DC 20555.

(*iii*) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state or a licensing state shall be considered exempt in accordance with clause (*i*) of this subparagraph, provided that the devices are labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of §289.252 of this title.

(D) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from this chapter if that person receives, possesses, uses, transfers, or acquires synthetic plastic resins containing scandium-46, which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the NRC, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer of such resins in accordance with licensing requirements equivalent to those in Title 10, CFR, §§32.16 and 32.17. This exemption does not authorize the manufacture of any resins containing scandium-46.

(4) Exemption for capsules containing carbon-14 urea for "in vivo" diagnostic use in humans.

(A) Except as provided in subparagraphs (B) and (C) of this paragraph, a person is exempt from the requirements of this section and §289.256 of this title provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 1 μCi (37 kilobecquerels) or less of carbon-14 urea each (allowing for nominal variation that may occur during the manufacturing process), for "in vivo" diagnostic use in humans.

(B) A person desiring to use the capsules for research involving human subjects shall apply for and receive a specific license in accordance with §289.256 of this title.

(C) A person desiring to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license in accordance with Title 10, CFR, §32.21

(D) Nothing in this subsection relieves a person from complying with applicable requirements of the United States Food and Drug Administration (FDA) and other federal and state requirements governing the receipt, administration, and use of drugs.

(f) General licenses. In addition to the requirements of this section, all general licenses, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202(ww) and (xx) of this title (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(1) In making a determination whether to revoke, suspend, or restrict a general license, the agency may consider the technical competence and compliance history of a general licensee. After an opportunity for a hearing, the agency may grant, deny, revoke, suspend, or restrict a general license if the general licensee's compliance history reveals that at least three agency actions have been issued against the general licensee, within the previous six years, that assess administrative or civil penalties against the general licensee, or that revoke or suspend the general license.

(2) Modification, suspension, and revocation of a general license.

(A) The terms and conditions of all general licenses shall be subject to revision or modification.

(B) A general license may be suspended or revoked by reason of amendments to the Texas Radiation Control Act (Act), Health and Safety Code, Chapter 401, by reason of rules in this chapter, or orders issued by the agency.

(C) Any general license may be revoked, suspended, or modified, in whole or in part, for any of the following:

(i) any material false statement in the application for a general license acknowledgement or any statement of fact required in accordance with provisions of the Act;

(ii) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a general license on an original application;

(iii) violation of, or failure to observe, any of the terms and conditions of the Act, this chapter, or of the general license, or order of the agency; or

(*iv*) existing conditions that constitute a substantial threat to the public health or safety or the environment.

(D) Except in cases in which the occupational and public health, interest, or safety requires otherwise, no general license shall be suspended or revoked unless, prior to the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the holder of the general license in writing and the holder of the general license shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

(E) Each general license revoked by the agency expires at the end of the day on the date of the agency's final determination to revoke the general license, or on the revocation date stated in the determination, or as otherwise provided by agency order.

(3) General licenses for source material.

(A) A general license is issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds of source material at any one time for research, development, educational, commercial, or operational purposes.

(*i*) A person authorized to use or transfer source material, in accordance with this general license, may not possess more than a total of 150 pounds of source material in any one calendar year.

(*ii*) Persons who receive, possess, use, or transfer source material in accordance with the general license in subparagraph (A) of this paragraph are prohibited from administering source material, or the radiation therefrom, either externally or internally, to humans except as may be authorized by the agency in a specific license.

(B) A general license is issued to own source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

(C) A general license is issued to mine, transport, and transfer ores containing source material without regard to quantity. In addition to the provisions of subsection (f) of this section, persons who mine, transport, and transfer ores containing source material in accordance with this section shall comply with the provisions of §289.202(n) and (ff) of this title.

(D) A general license is issued to receive, acquire, possess, use, or transfer depleted uranium contained in products or devices for the purpose of providing shielding, including beam shaping and collimation, in accordance with the provisions of clauses (*i*)-(*iv*) of this subparagraph.

(*i*) The general license in this paragraph applies only to products or devices that have been manufactured either in accordance with a specific license issued by the agency to the manufacturer of the products or devices in accordance with §289.252(s) of this title or in accordance with a specific license issued to the manufacturer by another agreement state or the NRC that authorizes manufacture of the products or devices for distribution to persons generally licensed by another agreement state or the NRC.

(*ii*) Persons who receive, acquire, possess, or use depleted uranium in accordance with the general license in this paragraph shall notify the agency within 30 days after the first receipt of acquisition of such depleted uranium. The general licensee shall furnish the following information and such other information as may be required by the agency:

(*I*) name and address of the general licensee;

(*II*) a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium in accordance with this paragraph and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(*III*) name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in clause (*ii*) of this subparagraph.

(*iii*) The general licensee possessing or using depleted uranium in accordance with the general license in this paragraph shall report in writing to the agency any changes in information furnished by the general licensee. The report shall be submitted within 30 days after the effective date of such change.

(*iv*) A person who receives, acquires, possesses, or uses depleted uranium in accordance with the general license in this paragraph:

(*I*) shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(*II*) shall not abandon such depleted uranium;

(*III*) shall transfer or dispose of such depleted uranium only in accordance with the provisions of §289.252(cc) of this title. In the case where the transferee receives the depleted uranium in accordance with the general license in this paragraph or equivalent rule of the NRC or an agreement state, the transferor shall furnish the transferee a copy of this paragraph;

(*IV*) within 30 days of transfer, shall report in writing to the agency the name and address of the person receiving the depleted uranium in accordance with such transfer; and

(*V*) shall not export such depleted uranium except in accordance with a license issued by the NRC in accordance with Title 10, CFR, Part 110.

(*v*) Any person receiving, acquiring, possessing, using, or transferring depleted uranium in accordance with the general license in this paragraph is exempt from the requirements of §289.202 of this title and §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections) with respect to the depleted uranium covered by that general license.

(4) General licenses for radioactive material other than source material.

(A) General licenses for static elimination devices and ion generating tubes. A general license is issued to transfer, receive, acquire, possess, and use radioactive material incorporated in the devices or equipment specified in the following clauses (*i*) and (*ii*) of this paragraph that have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the NRC. In addition to the provisions of subsection (f) of this section, this general license is subject to the provisions of subsection (e)(1)(B) of this section and §289.252(cc) of this title:

(*i*) static elimination devices designed for use as static eliminators that contain, as a sealed source or sources, radioactive material totaling not more than 500 μCi of polonium-210 per device; or

(*ii*) ion generating tubes designed for ionization of air that contain, as a sealed source or sources, radioactive material totaling not more than 500 μCi of polonium-210 per device or a total of not more than 50 mCi of tritium per device.

(B) General license for luminous safety devices for aircraft.

(*i*) A general license is issued to receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(*I*) each device contains not more than 10 curies (Ci) of tritium or 300 mCi of promethium-147; and

(*II*) each device has been manufactured, assembled, or initially transferred in accordance with a specific license issued by the NRC, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or any agreement state that authorizes the manufacture or assembly of the device to persons generally licensed by the agency or an agreement state.

(*ii*) The general license in clause (*i*) of this subparagraph does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(*iii*) The general license in clause (*i*) of this subparagraph does not authorize the receipt, acquisition, possession, or use of tritium or promethium-147 contained in instrument dials.

(C) General license for ownership of radioactive material. A general license is issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this section, this general license does not authorize the manufacture, production, transfer, receipt, possession, or use of radioactive material.

(D) General license for calibration, stabilization, and reference sources.

(*i*) A general license is issued to own receive, acquire, possess, use, and transfer, in accordance with the provisions of clauses (*ii*) and (*iii*) of this subparagraph, americium-241, plutonium, and/or radium-226, in the form of calibration, stabilization, or reference sources to any person who holds a specific license issued by the:

(*I*) agency that authorizes that person to receive, possess, use, and transfer radioactive material; and

(*II*) NRC that authorizes that person to receive, possess, use, and transfer radioactive material.

(*ii*) The general license in clause (*i*) of this subparagraph applies only to calibration, stabilization, or reference sources that have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the NRC in accordance with Title 10, CFR, §32.57 or Title 10, CFR, §70.39 or that have been manufactured or initially transferred in accordance with the authorizations contained in a specific license issued to the manufacturer by the agency, any agreement state, or any licensing state, in accordance with licensing requirements equivalent to those contained in Title 10, CFR, §32.57 or 10, CFR, §70.39.

(*iii*) Persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources in accordance with these general licenses:

(*I*) shall not possess at any one time, at any one location of storage or use, more than 5 μCi each of americium-241, plutonium-238, plutonium-239, and radium-226 in such sources;

(*II*) shall not receive, possess, use, or transfer such source unless the source or the storage container bears a label that includes the following statements, or a substantially similar statement that contains the information in the following statements:

(*a*) option 1, as appropriate:

The receipt, possession, use, and transfer of this source, Model _____, Serial No._____, are subject to a general license and the regulations of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM-238) (PLUTONIUM-239)*. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____; or
Name of Manufacturer or Initial Transferor

(*b*) option 2, as appropriate:

The receipt, possession, use, and transfer of this source, Model _____, Serial No._____, are subject to a general license and the regulations of any licensing state. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____;
Name of Manufacturer or Initial Transferor

* Showing only the name of the appropriate material

(*III*) shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a specific license from the agency, the NRC, an agreement state, or a licensing state to receive the source;

(*IV*) shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium-238, plutonium-239, or radium-226 that might otherwise escape during storage; and

(*V*) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(*iv*) The general license in subparagraph (A) of this paragraph does not authorize the manufacture of calibration or reference sources containing americium-241, plutonium-238, plutonium-239, or radium-226.

(E) General license for ice detection devices.

(*i*) A general license is issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 μCi of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the NRC or each device has been manufactured in accordance with the authorizations contained in a specific license issued by the agency or any agreement state to the manufacturer of such device in accordance with licensing requirements equivalent to those in Title 10, CFR, §32.61.

(*ii*) Persons who receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices in accordance with the general license in clause (*i*) of this paragraph shall do the following:

(*I*) upon occurrence of visually observable damage, such as bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license from the NRC or an agreement state to manufacture or service such devices; or dispose of the device by transfer to a person authorized by a specific license from the agency, the NRC, or an agreement state; and

(*II*) assure that all labels affixed to the device at the time of receipt, and which bear a statement prohibiting removal of the labels, are maintained on the device.

(*iii*) The general license in subparagraph (A) of this paragraph does not authorize the manufacture, assembly, disassembly, or repair of strontium-90 in ice detection devices.

(F) General license for intrastate transportation of radioactive material.

(i) A general license is issued to any common or contract carrier to transport and store radioactive material in the regular course of their carriage for another or storage incident to transport, provided the transportation and storage is in accordance with the applicable requirements of §289.257 of this title insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in those requirements shall be filed with the agency and the United States Department of Transportation (DOT). Persons who transport and store radioactive material in accordance with the general license in this paragraph are exempt from the requirements of §§289.202 and 289.203 of this title.

(ii) A general license is issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the DOT insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in those requirements shall be filed with the agency and the DOT.

(G) General license for the use of radioactive material for certain *in vitro* clinical or laboratory testing, not to include research and development. (The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.)

(i) A general license is issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of clauses (*ii*)-(*iii*) of this subparagraph, the following radioactive materials in prepackaged units:

(I) iodine-125, in units not exceeding 10 μCi each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(II) iodine-131, in units not exceeding 10 μCi each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(III) carbon-14, in units not exceeding 10 μCi each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(*IV*) hydrogen-3 (tritium), in units not exceeding 50 μCi each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(*V*) iron-59, in units not exceeding 20 μCi each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(*VI*) selenium-75, in units not to exceed 10 μCi each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(*VII*) mock iodine-125 reference or calibration sources, in units not exceeding 0.05 μCi of iodine-129 and 0.005 μCi of americium-241 each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals; or

(*VIII*) cobalt-57, in units not exceeding 10 μCi each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals.

(*ii*) A person who receives, acquires, possesses, or uses radioactive material in accordance with the general license in clause (*i*) of this subparagraph shall comply with the following.

(*I*) The general licensee shall not possess at any one time, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 μCi.

(*II*) The general licensee shall store the radioactive material in the original shipping container or in a container providing equivalent radiation protection and meeting the requirements of §289.202(cc) of this title until used.

(*III*) The general licensee shall use the radioactive material only for the uses authorized by clause (*i*) of this paragraph.

(*IV*) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it in accordance with a specific license issued by the agency, the NRC, any agreement state, or any licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(*iv*) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in clause (*i*)(*VII*) of this subparagraph as required by §289.202(ff) of this title.

(*iii*) The general licensee shall not receive, acquire, possess, or use radioactive material in accordance with the general license in clause (*i*) of this subparagraph:

(*I*) except as prepackaged units that are labeled in accordance with the provisions of an applicable specific license issued in accordance with §289.252(p) of this title or in accordance with the provisions of a specific license issued by the NRC, any agreement state, or any licensing state that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to general licensees in accordance with this subparagraph or its equivalent; and

(*II*) unless one of the statements in the following figures, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

(*-a-*) option 1, as appropriate:

This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.

_____; or
Name of Manufacturer

(*-b-*) option 2, as appropriate

This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the rules and a general license of a licensing state.

_____
Name of Manufacturer

(*iv*) No person shall receive, acquire, possess, use, or transfer radioactive material in accordance with the general license in clause (*i*) of this subparagraph until that person has filed an application for registration on a form prescribed by the agency and has received from the agency a notification of receipt with an assigned registration number. The applicant shall submit the following information and any other information as may be required by the agency:

(*I*) name and address of the physician, veterinarian, clinical laboratory, or hospital;

(*II*) the location of use; and

(*III*) a statement that the physician, veterinarian, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive material as authorized in accordance with clause (*i*) of this subparagraph, and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(H) General license for certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

(*i*) A general license is issued to commercial and industrial firms and to research, educational, and medical institutions, individuals in the conduct of their business, and state or local government agencies to receive, acquire, possess, use, or transfer in accordance with the provisions of clauses (*ii*)-(*iv*) of this subparagraph, radioactive material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere.

(*ii*) The general license in clause (*i*) of this subparagraph applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the agency in accordance with §289.252(l) of this title or in a specific license issued by the NRC, an agreement state, or a licensing state that authorizes distribution of devices to persons generally licensed by the NRC, an agreement state, or a licensing state.

(*iii*) The devices must have been received from a specific licensee described in clause (*ii*) of this subparagraph or through a transfer made in accordance with clause (*iv*)(*XII*) of this subparagraph.

(*IV*) Any person who receives, acquires, possesses, uses, or transfers radioactive material in a device in accordance with the general license in this subparagraph shall do the following:

(*I*) assure that all labels, affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained on the device and are clearly visible and legible. The general licensee shall comply with all instructions and precautions provided by such labels;

(*II*) assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as specified in the label; however:

(-a-) devices containing only krypton need not be tested for leakage of radioactive material; and

(-b-) devices containing only tritium or not more than 100 μCi of other beta and/or gamma emitting material or 10 μCi of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose, provided that each source is tested for leakage within six months prior to being used or transferred;

(*III*) assure that the tests required by subclause (*II*) of this clause and other testing, installation (removal of the manufacturer's lock and initial alignment of the radiation beam), servicing, and removal from location of installation involving the radioactive materials, its shielding or containment, are performed:

(-a-) in accordance with the instructions provided by the labels;

(-b-) in accordance with written instructions provided by the manufacturer as specified in §289.252(l)(3) of this title; or

(-c-) by a person holding a specific license from the agency, the NRC, an agreement state, or a licensing state to perform such activities;

(*IV*) maintain records for inspection by the agency showing compliance with the requirements of subclauses (*II*) and (*III*) of this clause. The records shall show the test results. The records also shall identify the device tested by manufacturer, model and serial number of the device, serial number of the sealed source, and show the dates of performance of and the names of persons performing testing, installation, servicing, and removal from location of installation, of the radioactive material, its shielding or containment. Retention shall be as follows:

(-a-) records for tests for leakage or radioactive material required by subclause (*II*) of this clause must be kept for three years after the next required leak text is performed or until the sealed source is transferred or disposed of;

(-b-) records of the test of the on-off mechanism and indicator required by subclause (*II*) of this clause must be kept for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of; and

(-c-) records of the testing, installation (removal of the manufacturer's lock and initial alignment of the radiation beam), servicing, and removal from location of installation involving the radioactive materials, its shielding or containment required by subclause (*III*) of this clause shall be kept for three years from the date of the recorded event or until the device is transferred or disposed of.

(*V*) maintain assignment records (utilization records) for portable or mobile devices for inspection by the agency at the location listed in the general license acknowledgement in accordance with subsection (g) of this section. These records shall include:

(-a-) a unique identification (for example, serial number) of each portable or mobile device;

(-b-) the location(s) where each portable or mobile device is assigned; and

(-c-) the date(s) each portable or mobile device is assigned to the location(s) in accordance with item (-b-) of this subclause;

(*VI*) have a copy of the appropriate operating and instruction manual at each temporary site for agency inspection;

(*VII*) immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism, or indicator, or upon the detection of 1.85 becquerels (0.005 μCi) or more of removable radioactive material. The device shall not be operated until it has been repaired by the manufacturer or other person holding a specific license from the agency, the NRC, an agreement state, or a licensing state to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device. A report containing a brief description of the event and the remedial action taken and in the case of detection of 1.85 becquerels (0.005 μCi) or more removable radioactive material or failure of, or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use shall be furnished to the agency within 30 days. Under these circumstances, the requirements in §289.202(ddd) of this title may be applicable, as determined by the agency on a case-by-case basis;

(*VIII*) not abandon the device containing radioactive material;

(*IX*) transfer or dispose of the device containing radioactive material only by transfer to another general licensee as authorized in subclause (*XII*) of this clause or to a person authorized to receive the device by a specific license issued by the agency in accordance with §289.252(l) of this title, or an equivalent specific license issued by the NRC, an agreement state, or a licensing state, or as otherwise approved under subclause (*XI*) of this clause;

(*X*) furnish a report to the agency within 30 days after the transfer of a device to a specific licensee. The report must contain the following:

(-a-) identification of the device by manufacturer's (or initial transferor's) name, model and serial number;

(-b-) name, address, and license number of the person receiving the device; and

(-c-) date of the transfer.

(*XI*) obtain written agency approval before transferring the device to any other specific licensee not specifically identified in subclause (*IX*) of this clause;

(*XII*) transfer the device to another general licensee only if:

(-a-) the device remains in use at a particular location. In such case, the transferor shall give the transferee a copy of this section and any safety documents identified in the label on the device. Within 30 days of the transfer, the transferor shall report the following to the agency:

(-1-) manufacturer's (or initial transferor's) name;

(-2-) model and serial number of the device transferred;

(-3-) transferee's name and mailing address for the location of use; and

(-4-) name, title, and phone number of the responsible individual identified by the transferee in accordance with subclause (*XIII*) of this clause to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(-b-) the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(*XIII*) appoint an individual responsible for having knowledge of the appropriate agency requirements and the authority for taking required actions to comply with appropriate agency requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate agency requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(*XIV*) report changes to the mailing address for the location of use (including change in name of general licensee) to the agency within 30 days of the effective date of the change. If it is a portable device, a report of address change is only required for a change in the device's primary place of storage; and

(*XV*) not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by clause (*iv*) of this subparagraph need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they shall be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby. The licensee shall make and maintain, for intervals of five years, records of the quarterly physical inventories for inspection by the agency.

(I) The general license in subparagraph (H) of this paragraph does not authorize the manufacture or import of devices containing radioactive material

(J) The written instructions specified in subparagraph (H)(*iv*)(*III*)(-a-) of this paragraph shall be followed while performing the testing and shall be maintained for inspection by the agency.

(g) General license acknowledgements for radioactive material other than source material. In addition to the requirements of this section, all general license acknowledgement holders, unless otherwise specified, are subject to the requirements of §§289.201, 289.202(ww) and (xx), 289.204, 289.205, and 289.257 of this title.

(1) Persons possessing a general license for devices in accordance with subsection (f)(4)(H) of this section and being in the possession of radioactive material in devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 37 MBq (1 mCi) of americium-241, or any transuranic (for example, element with atomic number greater than uranium (92)), based on the activity indicated on the label on the device, shall file an application for acknowledgement within 30 days of receipt, acquisition, or possession of such a device. The application shall be on a form prescribed by the agency to include the following information and any other information specifically requested by the agency:

(A) name and mailing address of the general licensee;

(B) information about each device to include the manufacturer (or initial transferor), model number, and serial number of the device, and the radioisotope and activity (as indicated on the label);

(C) name, title, and telephone number of the responsible person designated as a representative of the general licensee in accordance with subparagraph (H)(*iv*)(*XIII*) of this paragraph;

(D) address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage;

(E) certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information;

(F) certification by the responsible representative of the general licensee that they are aware of the requirements of this section; and

(G) a completed BRC Form 252-1, Business Information Form and the applicable fee as required by §289.204 of this title.

(2) Persons generally licensed by the agency with respect to devices meeting the criteria in paragraph (1) of this subsection, are not subject to the requirements of paragraph (1) of this subsection if the devices are used in areas subject to agency jurisdiction for a period less than 180 days in any calendar year.

(h) Issuance of general license acknowledgements.

(1) When the agency determines that an application meets the requirements of the Act and the rules of the agency, the agency may issue a general license acknowledgement recognizing the general license authorizing the activity in such form and containing the conditions and limitations as it deems appropriate or necessary.

(2) The agency may incorporate in any general license acknowledgement at the time of issuance, or thereafter by amendment, additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this section as the agency deems appropriate or necessary in order to:

(A) minimize danger to occupational and public health and safety or the environment;

(B) require reports and the keeping of records, and to provide for inspections of activities in accordance with the license as may be appropriate or necessary; and

(C) prevent loss or theft of material subject to this section.

(3) The agency may request, and the licensee shall provide, additional information after the general license acknowledgement has been issued to enable the agency to determine whether the general license acknowledgement should be modified in accordance with subsection (l) of this section.

(i) Specific terms and conditions.

(1) Each general license acknowledgement issued in accordance with this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable rules and orders of the agency.

(2) Each person holding a general license acknowledgement issued by the agency in accordance with this section shall confine use and possession of the devices and radioactive material identified in the general license acknowledgement to the locations specified in the general license acknowledgement.

(3) Each holder of a general license acknowledgement shall notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by the general license acknowledgement holder or its parent company.

(4) The notification in paragraph (3) of this subsection shall include:

(A) the bankruptcy court in which the petition for bankruptcy was filed; and

(B) the date of the filing of the petition.

(5) A copy of the "Petition for Bankruptcy" shall be submitted to the agency with the written notification.

(j) Expiration of general license acknowledgement and administrative renewal.

(1) Effective September 1, 2004, the term of the general license acknowledgement is two years. Each general license acknowledgement expires at the end of the day, in the month and year stated in the general license acknowledgement. Upon payment of the fee required by §289.204 of this title and if the agency does not deny the renewal in accordance with subsection (f)(1) of this section, the general license acknowledgement will be administratively renewed.

(2) Expiration of the general license acknowledgement does not relieve the holder of the general license acknowledgement of the requirements of this chapter.

(3) If the holder of the general license acknowledgement does not pay the fee required by §289.204 of this title and the general license acknowledgement is not renewed, the holder of the general license acknowledgement shall:

(A) terminate use of all generally licensed devices; and

(B) submit to the agency a record of the disposition of the devices and if transferred, to whom it was transferred, within 30 days following the expiration date.

(k) Termination of general license acknowledgements.

(1) Each holder of a general license acknowledgement shall notify the agency immediately, in writing, and request termination of the general license acknowledgement when the holder of the general license acknowledgement decides to terminate all activities involving materials specified in the general license acknowledgement.

(2) Each holder of a general license acknowledgement shall, no less than 30 days before vacating or relinquishing possession of control of premises that have been used as a place of storage or use of radioactive material as a result of general licensed activities, notify the agency in writing of intent to vacate and do the following:

(A) terminate use of radioactive material;

(B) dispose of radioactive material in accordance with this section and/or §289.202(ff) of this title; and

(C) pay any outstanding fees in accordance with §289.204 of this title.

(l) Amendment of general license acknowledgements.

(1) The holder of the general license acknowledgement required by subsection (g)(1) of this section shall report in writing to the agency any changes in information furnished by the holder of the general license acknowledgement. The report shall be submitted within 30 days after the effective date of such change.

(2) Applications for amendments of a general license acknowledgement shall be filed in accordance with subsection (g)(1)(A)-(F) of this section, as applicable, and shall specify the respects in which the holder of a general license acknowledgement desires a general license acknowledgement to be amended.

(m) Appendices.

(1) Exempt concentrations.

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

Element (atomic number)	Isotope	Column I Gas Concentration Ci/ml*	Column II Liquid and Solid Concentration μCi/ml**
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	1×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-138	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}

* Values are given in Column I only for those materials normally used in gases.

** μCi/gm for solids

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml*	Column II Liquid and Solid Concentration μCi/ml**
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152 (T/2=9.2 h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}

* Values are given in Column I only for those materials normally used in gases.

** μCi/gm for solids

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml*	Column II Liquid and Solid Concentration μCi/ml**
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbium) (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}
Palladium (46)	Pd-103		3×10^{-3}
	Pd-109		9×10^{-4}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
Polonium (84)	Po-210		7×10^{-6}
Potassium (19)	K-42		3×10^{-3}
Praseodymium	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}
Radium (88)	Ra-226		1×10^{-7}
	Ra-228		3×10^{-7}

* Values are given in Column I only for those materials normally used in gases.

** μCi/gm for solids

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml*	Column II Liquid and Solid Concentration μCi/ml**
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-131		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-82		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}

* Values are given in Column I only for those materials normally used in gases.

** μCi/gm for solids

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml*	Column II Liquid and Solid Concentration μCi/ml**
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Y-175		1×10^{-3}
Ittrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}

* Values are given in Column I only for those materials normally used in gases.

** μCi/gm for solids

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml*	Column II Liquid and Solid Concentration μCi/ml**
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		1×10^{-10}	1×10^{-6}

NOTE 1: Many radioisotopes disintegrate into isotopes that are also radioactive. In expressing the concentrations in this paragraph, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of subsection (d) of this section where a combination of isotopes is involved, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in this paragraph for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (for example, unity).

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt Concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt Concentration of Isotope B}} \leq 1$$

* Values are given in Column I only for those materials normally used in gases.

** μCi/gm for solids

(2) Exempt quantities.

Radioactive Material	Microcuries
Antimony-122 (Sb-122)	100
Antimony-124 (Sb-124)	10
Antimony-125 (Sb-125)	10
Arsenic-73 (As-73)	100
Arsenic-74 (As-74)	10
Arsenic-76 (As-76)	10
Arsenic-77 (As-77)	100
Barium-131 (Ba-131)	10
Barium-133 (Ba-133)	10
Barium-140 (Ba-140)	10
Beryllium-7 (Be-7)	100
Bismuth-210 (Bi-210)	1
Bromine-82 (Br-82)	10
Cadmium-109 (Cd-109)	10
Cadmium-115m (Cd-115m)	10
Cadmium-115 (Cd-115)	100
Calcium-45 (Ca-45)	10
Calcium-47 (Ca-47)	10
Carbon-14 (C-14)	100
Cerium-141 (Ce-141)	100
Cerium-143 (Ce-143)	100
Cerium-144 (Ce-144)	1
Cesium-129 (Cs-129)	100
Cesium-131 (Cs-131)	1,000
Cesium-134m (Cs-134m)	100
Cesium-134 (Cs-134)	1
Cesium-135 (Cs-135)	10
Cesium-136 (Cs-136)	10
Cesium-137 (Cs-137)	10
Chlorine-36 (Cl-36)	10
Chlorine-38 (Cl-38)	10
Chromium-51 (Cr-51)	1,000
Cobalt-57 (Co-57)	100
Cobalt-58m (Co-58m)	10
Cobalt-58 (Co-58)	10
Cobalt-60 (Co-60)	1
Copper-64 (Cu-64)	100
Dysprosium-165 (Dy-165)	10
Dysprosium-166 (Dy-166)	100

Radioactive Material	Microcuries
Erbium-169 (Er-169)	100
Erbium-171 (Er-171)	100
Europium-152 (Eu-152) 9.2h	100
Europium-152 (Eu-152) 13 yr	1
Europium-154 (Eu-154)	1
Europium-155 (Eu-155)	10
Fluorine-18 (F-18)	1,000
Gadolinium-153 (Gd-153)	10
Gadolinium-159 (Gd-159)	100
Gallium-67 (Ga-67)	100
Gallium-72 (Ga-72)	10
Germanium-68 (Ge-68)	10
Germanium-71 (Ge-71)	100
Gold-195 (Au-195)	10
Gold-198 (Au-198)	100
Gold-199 (Au-199)	100
Hafnium-181 (Hf-181)	10
Holmium-166 (Ho-166)	100
Hydrogen-3 (H-3)	1,000
Indium-111 (In-111)	100
Indium-113m (In-113m)	100
Indium-114m (In-114m)	10
Indium-115m (In-115m)	100
Indium-115 (In-115)	10
Iodine-123 (I-123)	100
Iodine-125 (I-125)	1
Iodine-126 (I-126)	1
Iodine-129 (I-129)	0.1
Iodine-131 (I-131)	1
Iodine-132 (I-132)	10
Iodine-133 (I-133)	1
Iodine-134 (I-134)	10
Iodine-135 (I-135)	10
Iridium-192 (Ir-192)	10
Iridium-194 (Ir-194)	100
Iron-52 (Fe-52)	10
Iron-55 (Fe-55)	100
Iron-59 (Fe-59)	10
Krypton-85 (Kr-85)	100

Radioactive Material	Microcuries
Krypton-87 (Kr-87)	10
Lanthanum-140 (La-140)	10
Lutetium-177 (Lu-177)	100
Manganese-52 (Mn-52)	10
Manganese-54 (Mn-54)	10
Manganese-56 (Mn-56)	10
Mercury-197m (Hg-197m)	100
Mercury-197 (Hg-197)	100
Mercury-203 (Hg-203)	10
Molybdenum-99 (Mo-99)	100
Neodymium-147 (Nd-147)	100
Neodymium-149 (Nd-149)	100
Nickel-59 (Ni-59)	100
Nickel-63 (Ni-63)	10
Nickel-65 (Ni-65)	100
Niobium-93m (Nb-93m)	10
Niobium-95 (Nb-95)	10
Niobium-97 (Nb-97)	10
Osmium-185 (Os-185)	10
Osmium-191m (Os-191m)	100
Osmium-191 (Os-191)	100
Osmium-193 (Os-193)	100
Palladium-103 (Pd-103)	100
Palladium-109 (Pd-109)	100
Phosphorus-32 (P-32)	10
Platinum-191 (Pt-191)	100
Platinum-193m (Pt-193m)	100
Platinum-193 (Pt-193)	100
Platinum-197m (Pt-197m)	100
Platinum-197 (Pt-197)	100
Polonium-210 (Po-210)	0.1
Potassium-42 (K-42)	10
Potassium-43 (K-43)	10
Praseodymium-142 (Pr-142)	100
Praseodymium-143 (Pr-143)	100
Promethium-147 (Pm-147)	10
Promethium-149 (Pm-149)	10
Radon-222 (Rn-222)	100
Rhenium-186 (Re-186)	100
Rhenium-188 (Re-188)	100

Radioactive Material	Microcuries
Rhodium-103m (Rh-103m)	100
Rhodium-105 (Rh-105)	100
Rubidium-81 (Rb-81)	10
Rubidium-86 (Rb-86)	10
Rubidium-87 (Rb-87)	10
Ruthenium-97 (Ru-97)	100
Ruthenium-103 (Ru-103)	10
Ruthenium-105 (Ru-105)	10
Ruthenium-106 (Ru-106)	1
Samarium-151 (Sm-151)	10
Samarium-153 (Sm-153)	100
Scandium-46 (Sc-46)	10
Scandium-47 (Sc-47)	100
Scandium-48 (Sc-48)	10
Selenium-75 (Se-75)	10
Silicon-31 (Si-31)	100
Silver-105 (Ag-105)	10
Silver-110m (Ag-110m)	1
Silver-111 (Ag-111)	100
Sodium-22 (Na-22)	10
Sodium-24 (Na-24)	10
Strontium-85 (Sr-85)	10
Strontium-87m (Sr-87m)	10
Strontium-89 (Sr-89)	1
Strontium-90 (Sr-90)	0.1
Strontium-91 (Sr-91)	10
Strontium-92 (Sr-92)	10
Sulphur-35 (S-35)	100
Tantalum-182 (Ta-182)	10
Technetium-96 (Tc-96)	10
Technetium-97m (Tc-97m)	100
Technetium-97 (Tc-97)	100
Technetium-99m (Tc-99m)	100
Technetium-99 (Tc-99)	10
Tellurium-125m (Te-125m)	10
Tellurium-127m (Te-127m)	10
Tellurium-127 (Te-127)	100
Tellurium-129m (Te-129m)	10
Tellurium-129 (Te-129)	100
Tellurium-131m (Te-131m)	10

Radioactive Material	Microcuries
Tellurium-132 (Te-132)	10
Terbium-160 (Tb-160)	10
Thallium-200 (Tl-200)	100
Thallium-201 (Tl-201)	100
Thallium-202 (Tl-202)	100
Thallium-204 (Tl-204)	10
Thulium-170 (Tm-170)	10
Thulium-171 (Tm-171)	10
Tin-113 (Sn-113)	10
Tin-125 (Sn-125)	10
Tungsten-181 (W-181)	10
Tungsten-185 (W-185)	10
Tungsten-187 (W-187)	100
Vanadium-48 (V-48)	10
Xenon-131m (Xe-131m)	1,000
Xenon-133 (Xe-133)	100
Xenon-135 (Xe-135)	100
Ytterbium-175 (Yb-175)	100
Yttrium-87 (Y-87)	10
Yttrium-88 (Y-88)	10
Yttrium-90 (Y-90)	10
Yttrium-91 (Y-91)	10
Yttrium-92 (Y-92)	100
Yttrium-93 (Y-93)	100
Zinc-65 (Zn-65)	10
Zinc-69m (Zn-69m)	100
Zinc-69 (Zn-69)	1,000
Zirconium-93 (Zr-93)	10
Zirconium-95 (Zr-95)	10
Zirconium-97 (Zr-97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

25 TEXAS ADMINISTRATIVE CODE

§289.252

Licensing of Radioactive Material

Texas Regulations for Control of Radiation

(revisions effective September 1, 2004
are shown as shaded text)

		Page
§289.252(a)	Purpose	252-1
§289.252(b)	Scope	252-1
§289.252(c)	Types of Licenses	252-3
§289.252(d)	Filing Application for Specific Licenses	252-3
§289.252(e)	General Requirements for the Insurance of Specific Licenses	252-5
§289.252(f)	Radiation Safety Officer	252-6
§289.252(g)	The Duties and Responsibilities of the Radiation Safety Committee (RSC) Include but are not Limited to the Following	252-9
§289.252(h)	Specific Licenses for Broad Scope Authorization for Multiple Quantities or Types of Radioactive Material for Use in Research and Development	252-10
§289.252(i)	Specific Licenses for Introduction of Radioactive Material into Products in Exempt Concentrations	252-11
§289.252(j)	Specific Licenses for Commercial Distribution of Radioactive Material in Exempt Quantities	252-12
289.252(k)	Specific Licenses for Incorporation of NARM into Gas and Aerosol Detectors	252-14
§289.252(l)	Specific Licenses for the Manufacture and Commercial Distribution of Devices to Persons Generally Licensed in Accordance with §289.251(f)(4)(H) of this title	25214
§289.252(m)	Specific Licenses for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft for Commercial Distribution to Persons Generally Licensed in Accordance with f)(4)(B) of this title	252-23

Licensing of Radioactive Material (Continued)

		Page
§289.252(n)	Specific Licenses for the Manufacture of Calibration Sources Containing Americium-241, Plutonium, or Radium-226 for Commercial Distribution to Persons Generally Licensed in Accordance with §289.251(f)(4)(D) of this title	252-23
§289.252(o)	Specific Licenses for the Manufacture and Commercial Distribution of Sealed Sources or Devices Containing Radioactive Material for Medical Use	252-23
§289.252(p)	Specific Licenses for the Manufacture and Commercial Distribution of Radioactive Material for Certain in *vitro* Clinical or Laboratory Testing in Accordance with the General License	252-25
§289.252(q)	Specific Licenses for the Manufacture and Commercial Distribution of Ice Detection Devices	252-27
§289.252(r)	Specific Licenses for the Manufacture, Preparation or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Materials for Medical Use	252-27
§289.252(s)	Specific Licenses for the Manufacture and Commercial Distribution of Products Containing Depleted Uranium For Mass-Volume Applications	252-30
§289.252(t)	Specific Licenses for the Processing of Loose Radioactive Material for Manufacture and Commercial Distribution.	252-32
§289.252(u)	Specific Licenses for Other Manufacture and Commercial Distribution off Radioactive Material	252-33
§289.252(v)	Sealed Sources or Device Evaluation	252-34
§289.252(w)	Issuance of Specific Licenses	252-36
§289.252(x)	Specific Terms and Conditions of Licenses	252-37
§289.252(y)	Expiration and Termination of Licenses and Administrative Renewal; Decommissioning for Sites and Separate Buildings or Outdoor Areas	252-38
§289.252(z)	Technical Review of Licenses	252-43
§289.252(aa)	Amendment of Licenses at Request of Licensee	252-44
§289.252(bb)	Agency Action on Request to Renew or Amend. In Considering a Request by a Licensee too Renew or Amend a License, the Agency will Apply the Criteria in Subsection (e) of this Section as Applicable	252-44

Licensing of Radioactive Material (Continued)

		Page
§289.252(cc)	Transfer of Material	252-44
§289.252(dd)	Modification, Suspension, and Revocation of Licenses	252-45
§289.252(ee)	Reciprocal Recognition of Licenses	252-46
§289.252(ff)	Preparation of Radioactive Material for Transport	252-48
§289.252(gg)	Financial Assurance and Record Keeping for Decommissioning	252-48
§289.252(hh)	Emergency Plan for Responding to a Release	252-53
§289.252(ii)	APPENDICES	252-56
§289.252(ii)(1)	Subjects to be Included in Training Courses	252-56
§289.252(ii)(2)	Isotope Quantities (for use in subsection (gg) of this section)	252-58
§289.252(ii)(3)	Criteria Relating to Use of Financial Test and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning	252-59
§289.252(ii)(4)	Criteria Relating to Use of Financial Test and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning	252-61
§289.252(ii)(5)	Criteria Relating to Use of Financial Test and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies that have no Outstanding Rated Bonds	252-63
§289.252(ii)(6)	Criteria Relating to Use of Financial Test and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning by Nonprofit Entities, such as Colleges, Universities, and Nonprofit Hospitals	252-65
§289.252(ii)(7)	Quantities off Radioactive Materials Requiring Consideration of the need for an Emergency Plan for Responding too a Release. The Following Table Contains Quantities of Radioactive Materials Requiring Consideration of the need for an Emergency Plan for Responding to a Release	252-67
§289.252(ii)(8)	Requirements for Demonstrating Financial Qualifications	252-69

§289.252. Licensing of Radioactive Material.

(a) Purpose. The intent of this section is as follows.

(1) This section provides for the specific licensing of radioactive material.

(2) Unless otherwise exempted, no person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized by the following:

(A) a specific license issued in accordance with this section and/or any of the following sections:

(*i*) §289.254 of this title (relating to Licensing of Radioactive Waste Processing and Storage Facilities);

(*ii*) §289.255 of this title (relating to Radiation Safety, Requirements and Licensing and Registration Procedures for Industrial Radiography);

(*iii*) §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material);

(*iv*) §289.258 of this title (relating to Licensing and Radiation Safety Requirements for Irradiators);

(*v*) §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material (NORM));

(*vi*) §289.260 of this title (relating to Licensing of Uranium Recovery and Byproduct Material Disposal Facilities); or

(B) a general license or general license acknowledgment issued in accordance with §289.251 of this title (relating to Exemptions, General Licenses, and General License Acknowledgements).

(3) A person who receives, possesses, uses, transfers, owns, or acquires radioactive materials prior to receiving a license is subject to the requirements of this chapter.

(b) Scope. In addition to the requirements of this section, the following additional requirements are applicable.

(1) All licensees, unless otherwise specified, are subject to the requirements in the following sections:

(A) §289.201 of this title (relating to General Provisions for Radioactive Material);

(B) §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Material);

(C) §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections);

(D) §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);

(E) §289.205 of this title (relating to Hearing and Enforcement Procedures); and

(F) §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(2) Licensees engaged in well logging service operations and tracer studies are subject to the requirements of §289.253 of this title (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies).

(3) Licensees engaged in radioactive waste processing and/or storage are subject to the requirements of §289.254 of this title.

(4) Licensees engaged in industrial radiographic operations are subject to the requirements of §289.255 of this title.

(5) Licensees using radioactive material for medical or veterinary use are subject to the requirements of §289.256 of this title.

(6) Licensees using sealed sources in irradiators are subject to the requirements of §289.258 of this title.

(7) Licensees possessing or using naturally occurring radioactive material are subject to the requirements of §289.259 of this title.

(8) Licensees engaged in uranium recovery and byproduct material disposal are subject to the requirements of §289.260 of this title.

(c) Types of licenses. Licenses for radioactive materials are of two types: general and specific.

(1) General licenses provided in §289.251 and §289.259 of this title are effective without the filing of applications with the agency or the issuance of licensing documents to the particular persons, although the filing of an application for acknowledgement with the agency may be required for a particular general license. The general licensee is subject to any other applicable portions of this chapter and any limitations of the general license.

(2) Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable portions of this chapter as well as any limitations specified in the licensing document.

(d) Filing application for specific licenses. The agency may, at any time after the filing of the original application, require further statements in order to enable the agency to determine whether the application should be denied or the license should be issued.

(1) Applications for specific licenses shall be filed in a manner prescribed by the agency.

(2) Each application shall be signed by the chief executive officer or other individual delegated the authority to manage, direct, or administer the licensee's activities.

(3) An application for a license may include a request for a license authorizing one or more activities. The agency may require the issuance of separate specific licenses for those activities.

(4) Each application for a specific license, other than a license exempted from §289.204 of this title, shall be accompanied by the fee prescribed in §289.204 of this title.

(5) Each application shall be accompanied by a completed BRC Form 252-1 (Business Information Form).

(6) Each applicant shall demonstrate to the agency that the applicant is financially qualified to conduct the activity requested for licensure, including any required decontamination, decommissioning, reclamation, and disposal before the agency issues a license. Each licensee shall demonstrate to the agency that it remains financially qualified to conduct the licensed activity before a license is renewed. Methods for demonstrating financial qualifications are specified in subsection (ii)(8) of this section. The requirement for demonstration of financial qualification is separate from the requirement specified in subsection (gg) of this section for certain applicants or licensees to provide financial assurance.

(7) If facility drawings submitted in conjunction with the application for a license are prepared by a professional engineer or engineering firm, those drawings shall be final and shall be signed, sealed and dated in accordance with the requirements of the Texas Board of Professional Engineers, 22 Texas Administrative Code, Chapter 131.

(8) Applications for licenses shall be processed in accordance with the following time periods.

(A) The first period is the time from receipt of an application by the Division of Licensing, Registration and Standards to the date of issuance or denial of the license or a written notice outlining why the application is incomplete or unacceptable. This time period is 60 days.

(B) The second period is the time from receipt of the last item necessary to complete the application to the date of issuance or denial of the license. This time period is 30 days.

(C) These time periods are exclusive of any time period incident to hearings and post-hearing activities required by the Government Code, Chapter 2001.

(9) Notwithstanding the provisions of §289.204(d)(1) of this title, reimbursement of application fees may be granted in the following manner.

(A) In the event the application is not processed in the time periods as stated in paragraph (8) of this subsection, the applicant has the right to request of the director of the Radiation Control Program full reimbursement of all application fees paid in that particular application process. If the director does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request will be denied.

(B) Good cause for exceeding the period established is considered to exist if:

(*i*) the number of applications for licenses to be processed exceeds by 15% or more the number processed in the same calendar quarter the preceding year;

(*ii*) another public or private entity utilized in the application process caused the delay; or

(*iii*) other conditions existed giving good cause for exceeding the established periods.

(C) If the request for full reimbursement authorized by subparagraph (A) of this paragraph is denied, the applicant may then request a hearing by appeal to the Commissioner of Health for a resolution of the dispute. The appeal will be processed in accordance with Title 1, Texas Administrative Code, Chapter 155, and the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title.

(10) Applications for licenses may be denied for the following reasons:

(A) any material false statement in the application or any statement of fact required under provisions of the Texas Radiation Control Act (Act);

(B) conditions revealed by the application or statement of fact or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a license on an application; or

(C) failure to clearly demonstrate how the requirements in this chapter have been addressed.

(e) General requirements for the issuance of specific licenses. A license application will be approved if the agency determines that:

(1) the applicant and all personnel who will be handling the radioactive material are qualified by reason of training and experience to use the material in question for the purpose requested in accordance with this chapter in such a manner as to minimize danger to occupational and public health and safety and the environment;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to occupational and public health and safety and the environment;

(3) the issuance of the license will not be inimical to the health and safety of the public;

(4) the applicant satisfies any applicable special requirement in this section and other sections as specified in subsection (a)(2)(A) of this section;

(5) the radiation safety information submitted for requested sealed source(s) or device(s) containing radioactive material is in accordance with subsection (v) of this section;

(6) qualifications of the designated radiation safety officer (RSO) as specified in subsection (f) of this section are adequate for the purpose requested in the application;

(7) the applicant submits an adequate operating, safety, and emergency procedures manual;

(8) the applicant's permanent facility is located in Texas (if the applicant's permanent facility is not located in Texas, reciprocal recognition shall be sought as required by subsection (ee) of this section); and

(9) the owner of the property is aware that radioactive material is stored on the property, if the proposed storage facility is not owned by the applicant. The applicant shall provide a written statement from the owner, or from the owner's agent, indicating such. This paragraph does not apply to property owned or held by a government entity or to property on which radioactive material is used under an authorization for temporary job site use.

(10) there is no reason to deny the license as specified in subsection (d)(10) or (x)(7) of this section.

(f) Radiation safety officer.

(1) An RSO shall be designated for every license issued by the agency. A single individual may be designated as RSO for more than one license if authorized by the agency.

(2) The RSO's documented qualifications shall include as a minimum:

(A) possession of a high school diploma or a certificate of high school equivalency based on the GED test;

(B) completion of the training and testing requirements specified in this chapter for the activities for which the license application is submitted; and

(C) training and experience necessary to supervise the radiation safety aspects of the licensed activity.

(3) The specific duties of the RSO include, but are not limited to, the following:

(A) to establish and oversee operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and to review them at least annually to ensure that the procedures are current and conform with this chapter;

(B) to oversee and approve all phases of the training program for operations and/or personnel so that appropriate and effective radiation protection practices are taught;

(C) to ensure that required radiation surveys and leak tests are performed and documented in accordance with this chapter, including any corrective measures when levels of radiation exceed established limits;

(D) to ensure that individual monitoring devices are used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made in accordance with §289.203 of this title;

(E) to investigate and cause a report to be submitted to the agency for each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter and each theft or loss of source(s) of radiation, to determine the cause(s), and to take steps to prevent a recurrence;

(F) to investigate and cause a report to be submitted to the agency for each known or suspected case of release of radioactive material to the environment in excess of limits established by this chapter;

(G) to have a thorough knowledge of management policies and administrative procedures of the licensee;

(H) to assume control and have the authority to institute corrective actions, including shutdown of operations when necessary in emergency situations or unsafe conditions;

(I) to ensure that records are maintained as required by this chapter;

(J) to ensure the proper storing, labeling, transport, use and disposal of sources of radiation, storage, and/or transport containers;

(K) to ensure that inventories are performed in accordance with the activities for which the license application is submitted;

(L) to perform an inventory of the radioactive sealed sources authorized for use on the license every six months and make and maintain records of the inventory of the radioactive sealed sources authorized for use on the license every six months to include, but not be limited to the following:

(*i*) isotope(s);

(*ii*) quantity(ies);

(*iii*) activity(ies); and

(*iv*) date inventory is performed.

(M) to ensure that personnel are complying with this chapter, the conditions of the license, and the operating, safety, and emergency procedures of the licensee; and

(N) to serve as the primary contact with the agency.

(4) Requirements for RSOs for specific licenses for broad scope authorization for research and development. In addition to the requirements in paragraphs (1) and (3) of this subsection, the RSO's qualifications for specific licenses for broad scope authorization for research and development shall include evidence of the following:

(A) a bachelor's degree in health physics, radiological health, physical science or a biological science with a physical science minor and four years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed;

(B) a master's degree in health physics or radiological health and three years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed;

(C) two years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed and one of the following:

(*i*) doctorate degree in health physics or radiological health;

(*ii*) comprehensive certification by the American Board of Health Physics;

(*iii*) certification by the American Board of Radiology in Medical Nuclear Physics;

(*iv*) certification by the American Board of Science in Nuclear Medicine in Radiation Protection;

(*v*) certification by the American Board of Medical Physics in Medical Health Physics; or

(D) equivalent qualifications as approved by the agency.

(5) The qualifications in paragraph (4)(A)-(D) do not apply to individuals who have been adequately trained and designated as RSOs on licenses issued prior to October 1, 2000.

(g) The duties and responsibilities of the Radiation Safety Committee (RSC) include but are not limited to the following:

(1) meeting as often as necessary to conduct business but no less than three times a year;

(2) reviewing summaries of the following information presented by the RSO:

(A) over-exposures;

(B) significant incidents, including spills, contamination, or medical events; and

(C) items of non-compliance following an inspection;

(3) reviewing the program for maintaining doses ALARA, and providing any necessary recommendations to ensure doses are ALARA;

(4) reviewing the overall compliance status for authorized users;

(5) sharing responsibility with the RSO to conduct periodic audits of the radiation safety program;

(6) reviewing the audit of the radiation safety program and acting upon the findings;

(7) developing criteria to evaluate training and experience of new authorized user applicants;

(8) evaluating and approving authorized user applicants who request authorization to use radioactive material at the facility;

(9) evaluating new uses of radioactive material; and

(10) reviewing and approving permitted program and procedural changes prior to implementation.

(h) Specific licenses for broad scope authorization for multiple quantities or types of radioactive material for use in research and development.

(1) In addition to the requirements in subsection (e) of this section, a specific license for multiple quantities or types of radioactive material for use in research and development, not to include the internal or external administration of radiation or radioactive material to humans, will be issued if the agency approves the following documentation submitted by the applicant:

(A) that staff has substantial experience in the use of a variety of radioisotopes for a variety of research and development uses;

(B) of a full-time RSO meeting the requirements of subsection (f)(4) of this section;

(C) establishment of an RSC, including names and qualifications, with duties and responsibilities in accordance with subsection (g) of this section. The RSC shall be composed of an RSO, a representative of executive management, and one or more persons trained or experienced in the safe use of radioactive materials.

(2) Unless specifically authorized, persons licensed according to paragraph (1) of this subsection shall not conduct tracer studies involving direct release of radioactive material to the environment.

(3) Unless specifically authorized, in accordance with a separate license, persons licensed according to paragraph (1) of this subsection shall not:

(A) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

(B) conduct activities for which a specific license issued by the agency in accordance with subsections (i)-(u) of this section and §§289.254, 289.255, 289.256, and §289.259 of this title is required;

(C) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being; or

(D) commercially distribute radioactive material.

(i) Specific licenses for introduction of radioactive material into products in exempt concentrations.

(1) In addition to the requirements in subsection (e) of this section, a specific license authorizing the introduction of radioactive material into a product or material in the possession of the licensee or another to be transferred to persons exempt from this chapter in accordance with §289.251(e)(1)(A) of this title will be issued if the agency approves the following information submitted by the applicant:

(A) a description of the product or material into which the radioactive material will be introduced;

(B) intended use of the radioactive material and the product or material into which it is introduced;

(C) method of introduction;

(D) initial concentration of the radioactive material in the product or material;

(E) control methods to assure that no more than the specified concentration is introduced into the product or material;

(F) estimated time interval between introduction and transfer of the product or material;

(G) estimated concentration of the radioactive material in the product or material at the time of transfer; and

(H) procedures for disposition of unwanted or unused radioactive material; and

(2) the applicant provides reasonable assurance that:

(A) the concentrations of radioactive material at the time of transfer will not exceed the concentrations in §289.251(m)(1) of this title;

(B) reconcentration of the radioactive material in concentrations exceeding those in §289.251(m)(1) of this title will not occur;

(C) the use of lower concentrations is not feasible; and

(D) the product or material is not to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human.

(3) Each person licensed in accordance with this subsection shall file an annual report with the agency and shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period. The report shall cover the year ending June 30, shall be filed within 30 days thereafter, and shall include the following:

(A) name and address of the person who owned or possessed the product or material when the radioactive material was introduced;

(B) the type and quantity of radionuclide introduced into each such product or material; and

(C) the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

(4) If no transfers of radioactive material have been made in accordance with this subsection during the reporting period, the report shall so indicate.

(j) Specific licenses for commercial distribution of radioactive material in exempt quantities.

(1) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission, Washington, DC 20555.

(2) In addition to the requirements in subsection (e) of this section, a specific license to distribute naturally occurring or accelerator-produced radioactive material (NARM) to persons exempt from this chapter in accordance with §289.251(e)(2) of this title will be issued if the agency approves the following information submitted by the applicant:

(A) that the radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human;

(B) that the radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution;

(C) copies of prototype labels and brochures; and

(D) procedures for disposition of unwanted or unused radioactive material.

(3) The license issued in accordance with paragraph (2) of this subsection is subject to the following conditions.

(A) No more than 10 exempt quantities shall be sold or commercially distributed in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantities provided the sum of the fractions shall not exceed unity.

(B) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any other package for commercial distribution to persons exempt from this chapter in accordance with §289.251(e)(2) of this title. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour (mrem/hr).

(C) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label that:

(*i*) identifies the radionuclide and the quantity of radioactivity; and

(*ii*) bears the words "Radioactive Material."

(D) In addition to the labeling information required by subparagraph (C) of this paragraph, the label affixed to the immediate container, or an accompanying brochure, shall:

(*i*) state that the contents are exempt from the United States Nuclear Regulatory Commission (NRC), agreement state, or licensing state requirements;

(*ii*) bear the words "Radioactive Material--Not for Human Use-- Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not Be Combined"; and

(*iii*) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(4) Each person licensed in accordance with this subsection shall maintain records identifying, by name and address, each person to whom radioactive material is commercially distributed for use in accordance with §289.251(e)(2) of this title or the equivalent regulations of an agreement state or a licensing state, and stating the kinds and quantities of radioactive material commercially distributed. An annual summary report stating the total quantity of each radionuclide commercially distributed in accordance with the specific license shall be filed with the agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no commercial distributions of radioactive material have been made in accordance with this subsection during the reporting period, the report shall so indicate.

(5) Licenses issued in accordance with this subsection do not authorize the following:

(A) combining of exempt quantities of radioactive material in a single device;

(B) any program advising persons to combine exempt quantity sources and providing devices for them to do so; and

(C) the possession and use of combined exempt sources, in a single unregistered device, by persons exempt from licensing in accordance with §289.251(e)(2) of this title.

(k) Specific licenses for incorporation of NARM into gas and aerosol detectors. In addition to the requirements in subsection (e) of this section, a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt from this chapter in accordance with §289.251(e)(3)(C) of this title will be issued if the agency approves the information submitted by the applicant. This information shall satisfy the requirements equivalent to those contained in Title 10, Code of Federal Regulations (CFR), §32.26. The maximum quantity of radium-226 in each device shall not exceed 0.1 μCi.

(l) Specific licenses for the manufacture and commercial distribution of devices to persons generally licensed in accordance with §289.251(f)(4)(H) of this title.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture or commercially distribute devices containing radioactive material to persons generally licensed in accordance with §289.251(f)(4)(H) of this title or equivalent requirements of the NRC, an agreement state, or a licensing state will be issued if the agency approves the following information submitted by the applicant:

(A) the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(*i*) the device can be safely operated by persons not having training in radiological protection;

(*ii*) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one year a dose in excess of 10% of the limits specified in §289.202(f) of this title; and

(*iii*) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

(*I*) 15 rems to the whole body; head and trunk; active blood-forming organs; gonads; or lens of eye;

(*II*) 200 rems to the hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter (cm^2); or

(*III*) 50 rems to other organs;

(B) procedures for disposition of unused or unwanted radioactive material;

(C) each device bears a durable, legible, clearly visible label or labels approved by the agency that contain the following in a clearly identified and separate statement:

(*i*) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(*ii*) the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(*iii*) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(*I*) For radioactive materials other than NARM, the following statement is appropriate:

> The receipt, possession, use, and transfer of this device, Model _____, Serial No._____ are subject to a general license or the equivalent and the regulations of the NRC or a state with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL _____ (Name of Manufacturer or Distributor);

(*II*) For NARM, the following statement is appropriate:

> The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL _____ (Name of Manufacturer or Distributor);

(*III*) The model and serial number and name of manufacturer or distributor may be omitted from this label provided they are elsewhere stated in labeling affixed to the device.

(D) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial numbers, the isotope and quantity, the words "Caution-Radioactive Material," the radiation symbol described in §289.202(z) of this title, and the name of the manufacturer or initial distributor.

(E) Each device meeting the criteria of §289.251(g)(1) of this title bears a permanent (for example, embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words "Caution-Radioactive Material," and, if practicable, the radiation symbol described in §289.202(z) of this title.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material, or for both, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the device or similar devices and by design features that have a significant bearing on the probability or consequences of radioactive material leakage from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for radioactive material leakage, the agency will consider information that includes, but is not limited to the following:

(A) primary containment (sealed source capsule);

(B) protection of primary containment;

(C) method of sealing containment;

(D) containment construction materials;

(E) form of contained radioactive material;

(F) maximum temperature withstood during prototype tests;

(G) maximum pressure withstood during prototype tests;

(H) maximum quantity of contained radioactive material;

(I) radiotoxicity of contained radioactive material; and

(J) operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee in accordance with §289.251(f)(4)(H) of this title or in accordance with equivalent regulations of the NRC, an agreement state, or a licensing state, be authorized to mount the device, collect the sample to be analyzed by a specific licensee for radioactive material leakage, perform maintenance of the device consisting of replacement of labels, rust and corrosion prevention, and for fixed gauges, repair and maintenance of sealed source holder mounting brackets, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated annual doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices in accordance with the general license, is unlikely to cause that individual to receive an annual dose in excess of 10% of the limits specified in §289.202(f) of this title.

(4) Before the device may be transferred, each person licensed in accordance with this subsection to commercially distribute devices to generally licensed persons shall furnish:

(A) a copy of the general license in §289.251(f)(4)(H) of this title to each person to whom the licensee directly commercially distributes radioactive material in a device for use in accordance with the general license in §289.251(f)(4)(H) of this title;

(B) a copy of the general license in the NRC's, agreement state's, or licensing state's regulation equivalent to §289.251(f)(4)(H) of this title, or alternatively, a copy of the general license in §289.251(f)(4)(H) of this title to each person to whom the licensee directly commercially distributes radioactive material in a device for use in accordance with the general license of the NRC, the agreement state, or the licensing state. If certain requirements of the regulations do not apply to the particular device, those requirements may be omitted. If a copy of the general license in §289.251(f)(4)(H) of this title is furnished to such a person, it shall be accompanied by an explanation that the use of the device is regulated by the NRC, agreement state, or licensing state in accordance with requirements substantially the same as those in §289.251(f)(4)(H) of this title;

(C) a copy of §289.251(g) of this title;

(D) a list of the services that can only be performed by a specific licensee;

(E) information on acceptable disposal options including estimated costs of disposal;

(F) the name or position, address, and phone number of a contact person at the agency, an agreement state, or licensing state, or the NRC from which additional information may be obtained; and

(G) an indication that it is the NRC's policy to issue high civil penalties for improper disposal if the device is commercially distributed to a general licensee of the NRC.

(5) An alternative approach to informing customers may be submitted by the licensee for approval by the agency.

(6) In the case of a transfer through an intermediate person, each licensee who commercially distributes radioactive material in a device for use in accordance with the general license in §289.251(f)(4)(H) of this title, shall furnish the information in paragraph (4) of this subsection to the intended user prior to the initial transfer to the intermediate person.

(7) Each person licensed in accordance with this subsection to commercially distribute devices to generally licensed persons shall:

(A) report to the agency all commercial distributions of devices to persons for use in accordance with the general license in §289.251(f)(4)(H) of this title and all receipts of devices from general licensees licensed in accordance with §289.251(f)(4)(H) of this title.

(*i*) The report shall:

(*I*) cover each calendar quarter;

(*II*) be filed within 30 days thereafter;

(*III*) be submitted on a form prescribed by the agency or in a clear and legible report containing all of the data required by the form;

(*IV*) clearly indicate the period covered by the report;

(*V*) clearly identify the specific licensee submitting the report and include the license number of the specific licensee;

(*VI*) identify each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

(*VII*) identify an individual by name, title, and phone number who has knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(*VIII*) identify the type, model and serial number of device, and serial number of sealed source commercially distributed;

(*IX*) identify the quantity and type of radioactive material contained in the device; and

(*X*) include the date of transfer.

(*ii*) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall also include the information in accordance with paragraph (7)(A)(*i*) of this subsection for both the intended user and each intermediate person and clearly designate the intermediate person(s).

(*iii*) If no commercial distributions have been made to persons generally licensed in accordance with §289.251(f)(4)(H) of this title during the reporting period, the report shall so indicate.

(*iv*) For devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(B) report the following to the NRC to include covering each calendar quarter to be filed within 30 days thereafter, clearly indicating the period covered by the report, the identity of the specific licensee submitting the report, and the license number of the specific licensee:

(*i*) all commercial distributions of such devices to persons for use in accordance with the NRC general license in Title 10, CFR, §31.5 and all receipts of devices from general licensees in areas under NRC jurisdiction including the following:

(*I*) identity of each general licensee by name and address;

(*II*) the type, model and serial number of device, and serial number of sealed source commercially distributed;

(*III*) the quantity and type of radioactive material contained in the device;

(*IV*) the date of transfer; or

(*II*) if the licensee makes changes to a device possessed in accordance with the general license in §289.251(f)(4)(H) of this title, such that the label must be changed to update required information, the report shall identify the licensee, the device and the changes to information on the device label;

(*III*) in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor;

(*IV*) if no commercial distributions have been made to the NRC licensees during the reporting period; the report shall so indicate;

(C) report to the appropriate agreement state or licensing state all transfers of devices manufactured and commercially distributed in accordance with this subsection for use in accordance with a general license in that state's requirements equivalent to §289.251(f)(4)(H) of this title and all receipts of devices from general licensees.

(*i*) The report shall:

(*I*) be submitted within 30 days after the end of each calendar quarter in which such a device is commercially distributed to the generally licensed person;

(*II*) clearly indicate the period covered by the report;

(*III*) clearly identify the specific licensee submitting the report and include the license number of the specific licensee;

(*IV*) identify each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the licensee shall be submitted along with the information on the actual location of use;

(*V*) identify an individual by name, position, and phone number who has knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(*VI*) the type, model and serial number of the device, and serial number of sealed source commercially distributed;

(*VII*) the quantity and type of radioactive material contained in the device; and

(*VIII*) date of receipt.

(*ii*) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall also include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(*iii*) If no commercial distributions have been made to persons in the agreement state or licensing state during the reporting period, the report shall so indicate.

(*iv*) For devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor; and

(D) keep records for three years following the date of the recorded event, showing the name, address, and the point of contact for each general licensee to whom the licensee directly or through an intermediate person commercially distributes radioactive material in devices for use in accordance with the general license provided in §289.251(f)(4)(H) of this title, or equivalent requirements of the NRC, an agreement state, or a licensing state.

(*i*) The records shall show the following:

(*I*) date of each commercial distribution;

(*II*) the isotope and the quantity of radioactivity in each device commercially distributed;

(*III*) the identity of any intermediate person; and

(*IV*) compliance with the reporting requirements of this subsection.

(*ii*) If no commercial distributions have been made to persons generally licensed in accordance with §289.251(f)(4)(H) of this title during the reporting period, the records shall so indicate.

(8) If a notification of bankruptcy has been made in accordance with subsection (x)(4) of this section or the license is to be terminated, each person licensed under this subsection shall provide, upon request to the NRC and to any appropriate agreement state or licensing state, records of final disposition required under subsection (y)(16)(A) of this section.

(9) Each device that is transferred after February 19, 2002, shall meet the labeling requirements in accordance with paragraph (1)(C)-(E) of this subsection.

(m) Specific licenses for the manufacture, assembly, or repair of luminous safety devices for use in aircraft for commercial distribution to persons generally licensed in accordance with §289.251(f)(4)(B) of this title. In addition to the requirements in subsection (e) of this section, a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for commercial distribution to persons generally licensed in accordance with §289.251(f)(4)(B) of this title, will be issued if the agency approves the information submitted by the applicant. The information shall satisfy the requirements of Title 10, CFR, §§32.53, 32.54, 32.55, 32.56, and 32.101 or their equivalent.

(n) Specific licenses for the manufacture of calibration sources containing americium-241, plutonium, or radium-226 for commercial distribution to persons generally licensed in accordance with §289.251(f)(4)(D) of this title. In addition to the requirements in subsection (e) of this section, a specific license to manufacture calibration sources containing americium-241, plutonium, or radium-226 to persons generally licensed in accordance with §289.251(f)(4)(D) of this title will be issued if the agency approves the information submitted by the applicant. The information shall satisfy the requirements of Title 10, CFR, §§32.57, 32.58, 32.59, and 32.102, and 10 CFR 70.39 or their equivalent.

(o) Specific licenses for the manufacture and commercial distribution of sealed sources or devices containing radioactive material for medical use. In addition to the requirements in subsection (e) of this section, a specific license to manufacture and commercially distribute sealed sources and devices containing radioactive material to persons licensed for use of sealed sources in the healing arts for use as a calibration or reference source will be issued if the agency approves the following information submitted by the applicant:

(1) an evaluation of the radiation safety of each type of sealed source or device including the following:

(A) the radioactive material contained, its chemical and physical form, and amount;

(B) details of design and construction of the sealed source or device;

(C) procedures for, and results of, prototype tests to demonstrate that the sealed source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(D) for devices containing radioactive material, the radiation profile of a prototype device;

(E) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(F) procedures and standards for calibrating sealed sources and devices;

(G) instructions for handling and storing the sealed source or device from the radiation safety standpoint. These instructions are to be included on a durable label attached to the sealed source or device or attached to a permanent storage container for the sealed source or device, provided that instructions that are too lengthy for the label may be summarized on the label and printed in detail on a brochure that is referenced on the label; and

(H) procedures for disposition of unwanted or unused radioactive material;

(2) documentation that the label affixed to the sealed source or device, or to the permanent storage container for the sealed source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the name of the sealed source or device is licensed by the agency for commercial distribution to persons licensed for use of sealed sources in the healing arts or by equivalent licenses of the NRC, an agreement state, or a licensing state, provided that the labeling for sealed sources that do not require long-term storage may be on a leaflet or brochure that accompanies the sealed source;

(3) documentation that in the event the applicant desires that the sealed source or device be required to be tested for radioactive material leakage at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the sealed source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of radioactive material leakage from the sealed source; and

(4) documentation that in determining the acceptable interval for testing radioactive material leakage, information will be considered that includes, but is not limited to the following:

(A) primary containment (sealed source capsule);

(B) protection of primary containment;

(C) method of sealing containment;

(D) containment construction materials;

(E) form of contained radioactive material;

(F) maximum temperature withstood during prototype tests;

(G) maximum pressure withstood during prototype tests;

(H) maximum quantity of contained radioactive material;

(I) radiotoxicity of contained radioactive material; and

(J) operating experience with identical sealed sources or devices or similarly designed and constructed sealed sources or devices.

(p) Specific licenses for the manufacture and commercial distribution of radioactive material for certain *in vitro* clinical or laboratory testing in accordance with the general license. In addition to the requirements in subsection (e) of this section, a specific license to manufacture or commercially distribute radioactive material for use in accordance with the general license in §289.251(f)(4)(G) of this title will be issued if the agency approves the following information submitted by the applicant:

(1) that the radioactive material will be prepared for distribution in prepackaged units of:

(A) iodine-125 in units not exceeding 10 microcuries (μCi) each;

(B) iodine-131 in units not exceeding 10 μCi each;

(C) carbon-14 in units not exceeding 10 μCi each;

(D) hydrogen-3 (tritium) in units not exceeding 50 μCi each;

(E) iron-59 in units not exceeding 20 μCi each;

(F) cobalt-57 in units not exceeding 10 μCi each;

(G) selenium-75 in units not exceeding 10 μCi each; or

(H) mock iodine-125 in units not exceeding 0.05 μCi of iodine-129 and 0.005 μCi of americium-241 each;

(2) that each prepackaged unit bears a durable, clearly visible label:

(A) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 μCi of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 μCi of hydrogen-3 (tritium); 20 μCi of iron-59; or mock iodine-125 in units not exceeding 0.05 μCi of iodine-129 and 0.005 μCi of americium-241; and

(B) displaying the radiation caution symbol in accordance with §289.202(z) of this title and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals";

(3) that one of the following statements, as appropriate, or a substantially similar statement appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

(A) option 1:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals, and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.

_____ ;or
Name of Manufacturer

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

(B) option 2:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.

_____ ; and
Name of Manufacturer

(4) that the label affixed to the unit, or the leaflet or brochure that accompanies the package, contains adequate information as to the precautions to be observed in handling and storing the radioactive material. In the case of a mock iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements of §289.202(ff) of this title.

(q) Specific licenses for the manufacture and commercial distribution of ice detection devices. In addition to the requirements of subsection (e) of this section, a specific license to manufacture and commercially distribute ice detection devices to persons generally licensed in accordance with §289.251(f)(4)(E) of this title will be issued if the agency approves the information submitted by the applicant. This information shall satisfy the requirements of Title 10, CFR, §§32.61, 32.62, and 32.103.

(r) Specific licenses for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive materials for medical use.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture, prepare, or transfer for commercial distribution, radioactive drugs containing radioactive material for use by persons authorized in accordance with §289.256 of this title will be issued if the agency approves the following information submitted by the applicant:

(A) evidence that the applicant is at least one of the following:

(*i*) registered or licensed with the United States Food and Drug Administration (FDA) as a drug manufacturer;

(*ii*) registered or licensed with a state agency as a drug manufacturer; or

(*iii*) licensed as a pharmacy by the Texas State Board of Pharmacy;

(B) radionuclide data relating to the following:

(*i*) chemical and physical form;

(*ii*) maximum activity per vial, syringe, generator, or other container of the radioactive drug;

(*iii*) shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(C) labeling requirements including the following:

(*i*) that each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution shall include the following:

(*I*) radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL;"

(*II*) name of the radioactive drug or its abbreviation;

(*III*) quantity of radioactivity at a specified date and time (the time may be omitted for radioactive drugs with a half life greater than 100 days); and

(*ii*) that each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution shall include the following:

(*I*) radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL;"

(*II*) name of the radioactive drug or its abbreviation;

(*III*) quantity of radioactivity at a specified date and time (the time may be omitted for radioactive drugs with a half life greater than 100 days); and

(*IV*) an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield.

(2) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs and shall have procedures for the use of the instrumentation. The licensee shall measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(A) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary;

(B) check each instrument for constancy and proper operation at the beginning of each day of use; and

(C) maintain records of the tests and checks in this paragraph for a minimum of three years for inspection by the agency.

(3) A licensee described in paragraph (1)(A)(*iii*) of this subsection shall prepare radioactive drugs for medical use as described in §289.256 of this title with the following provisions:

(A) radioactive drugs shall be prepared by a nuclear pharmacist(s) designated in the application as the individual user(s) who has completed the training and experience requirements specified in the rules of the Texas State Board of Pharmacy, contained in Title 22, Texas Administrative Code, §291.52;

(B) the radiopharmaceuticals for human use shall be processed and prepared according to instructions that are furnished by the manufacturer on the label attached to or in the FDA-accepted instructions in the leaflet or brochure that accompanies the generator or reagent kit;

(C) if the authorized nuclear pharmacist elutes generators or processes radioactive material with the reagent kit in a manner that deviates from instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit or in the accompanying leaflet or brochure, a complete description of the deviation shall be made and maintained for inspection by the agency for a period of three years; and

(D) provide to the agency a copy of each individual's certification by the Texas State Board of Pharmacy or the permit issued by a licensee of broad scope, and a copy of the state pharmacy license. If the licensee adds a nuclear pharmacist(s) to the license, this shall be completed no later than 30 days after the date that the licensee allows the individual(s) to work as a nuclear pharmacist.

(4) Nothing in this subsection relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

(s) Specific licenses for the manufacture and commercial distribution of products containing depleted uranium for mass-volume applications.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture products and devices containing depleted uranium for use in accordance with §289.251(f)(3)(D) of this title or equivalent regulations of the NRC or an agreement state, will be issued if the agency approves the following information submitted by the applicant:

(A) the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the product or device to provide reasonable assurance that possession, use, or commercial distribution of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one year a radiation dose in excess of 10% of the limits specified in §289.202(f) of this title; and

(B) reasonable assurance is provided that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of a product or device whose unique benefits are questionable, the agency will issue a specific license in accordance with paragraph (1) of this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The agency may deny any application for a specific license in accordance with this subsection if the end use(s) of the product or device cannot be reasonably foreseen.

(4) Each person licensed in accordance with paragraph (1) of this subsection shall:

(A) maintain the level of quality control required by the license in the manufacture of the product or device, and in the installation of the depleted uranium into the product or device;

(B) label or mark each unit to:

(*i*) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device, and

(*ii*) state that the receipt, possession, use, and commercial distribution of the product or device are subject to a general license or the equivalent and the requirements of the NRC or of an agreement state;

(C) assure that before being installed in each product or device, the depleted uranium has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(D) furnish a copy of the following:

(*i*) the general license in §289.251(f)(3)(D) of this title to each person to whom the licensee commercially distributes depleted uranium in a product or device for use in accordance with the general license in §289.251(f)(3)(D) of this title;

(*ii*) the NRC's or agreement state's requirements equivalent to the general license in §289.251(f)(3)(D) of this title and a copy of the NRC's or agreement state's certificate; or

(*iii*) alternately, a copy of the general license in §289.251(f)(3)(D) of this title to each person to whom the licensee commercially distributes depleted uranium in a product or device for use in accordance with the general license of the NRC or an agreement state;

(E) report to the agency all commercial distributions of products or devices to persons for use in accordance with the general license in §289.251(f)(3)(D) of this title.

(*i*) the report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is commercially distributed to the generally licensed person and shall include the following:

(*I*) identity of each general licensee by name and address;

(*II*) identity of an individual by name and/or position who may constitute a point of contact between the agency and the general licensee;

(*III*) the type and model number of devices commercially distributed; and

(*IV*) the quantity of depleted uranium contained in the product or device.

(*ii*) If no commercial distributions have been made to persons generally licensed in accordance with §289.251(f)(3)(D) of this title during the reporting period, the report shall so indicate;

(F) report to the NRC and each responsible agreement state agency all commercial distributions of industrial products or devices to persons for use in accordance with the general license in the NRC's or agreement state's equivalent requirements to §289.251(f)(3)(D) of this title. The report shall meet the provisions of subparagraph (E)(i) and (ii) of this paragraph; and

(G) keep records showing the name, address, and point of contact for each general licensee to whom the licensee commercially distributes depleted uranium in products or devices for use in accordance with the general license provided in §289.251(f)(3)(D) of this title or equivalent requirements of the NRC or of an agreement state. The records shall be maintained for a period of two years for inspection by the agency and shall show the date of each commercial distribution, the quantity of depleted uranium in each product or device commercially distributed, and compliance with the report requirements of this section.

(t) Specific licenses for the processing of loose radioactive material for manufacture and commercial distribution. In addition to the requirements in subsection (e) of this section, a license to process loose radioactive material for manufacture and commercial distribution of radioactive material to persons authorized to possess such radioactive material in accordance with this chapter will be issued if the agency approves the following information submitted by the applicant:

(1) radionuclides to be used, including the chemical and/or physical form and the maximum activity of each radionuclide;

(2) intended use of each radionuclide and the sealed sources and/or other products to be manufactured that includes:

(A) receipt of radioactive material;

(B) chemical or physical preparations;

(C) sealed source construction;

(D) final assembly or processing;

(E) quality assurance testing;

(F) quality control program;

(G) leak testing;

(H) American National Standards Institute (ANSI) testing procedures;

(I) transportation containers;

(J) shipping procedures; and

(K) disposition of unwanted or unused radioactive material;

(3) scaled drawings of the facility to include, but not be limited to:

(A) air filtration;

(B) ventilation system;

(C) plumbing; and

(D) radioactive material handling systems and, when applicable, remote handling hot cells;

(4) details of the environmental monitoring program; and

(5) documentation of training as specified in subsection (ii)(1) of this section for all personnel who will be handling radioactive materials.

(u) Specific licenses for other manufacture and commercial distribution of radioactive material. In addition to the requirements in subsection (e) of this section, a license to manufacture and commercially distribute radioactive material to persons authorized to possess such radioactive material in accordance with these requirements will be issued if the agency approves the following information submitted by the applicant:

(1) the radionuclides to be used, including the chemical and/or physical form and the maximum activity of each radionuclide;

(2) the intended use of each radionuclide and the sealed sources and/or other products to be manufactured that includes:

(A) receipt of radioactive material;

(B) chemical or physical preparations;

(C) sealed source construction;

(D) final assembly or processing;

(E) quality assurance testing;

(F) quality control program;

(G) leak testing;

(H) ANSI testing procedures;

(I) transportation containers;

(J) shipping procedures; and

(K) disposition of unwanted or unused radioactive material;

(3) scaled drawings of radioactive material handling systems and;

(4) documentation of training as specified in subsection (ii)(1) of this section for all personnel who will be handling radioactive material.

(v) Sealed source or device evaluation. Except as provided in paragraphs (7) and (8) of this subsection, sealed sources and devices shall only be authorized for use on radioactive material licenses in accordance with the information contained in the safety evaluation.

(1) An applicant shall submit a request to the agency for evaluation of radiation safety information on the sealed source or device containing a sealed source.

(2) The request for review shall be submitted in duplicate accompanied by the appropriate fee in §289.204 of this title.

(3) The request for review shall contain sufficient information about the sealed source or device to include the following:

(A) the radioactive material contained, its chemical and physical form, and amount;

(B) details of design and construction;

(C) procedures for, and results of, prototype tests to demonstrate that the sealed source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(D) details of quality control procedures to assure that production of sealed sources and devices meet the standards of the design and prototype tests;

(E) labeling;

(F) proposed uses; and

(G) procedures for leak testing.

(4) For a device containing radioactive material, the request shall also contain sufficient information about the device to include:

(A) the radiation profile of a prototype device;

(B) method of installation;

(C) service and maintenance requirements; and

(D) operating and safety instructions.

(5) After review of the request, the agency may issue an evaluation documenting the information in paragraphs (3) and (4) of this subsection.

(6) The applicant submitting the request for evaluation of the safety information about the product shall manufacture and distribute or cause the product to be manufactured or distributed in accordance with:

(A) the statements and representations contained in the request;

(B) documentation required to support the request;

(C) the provisions of the evaluation; and

(D) all applicable provisions contained in a radioactive material license.

(7) Custom (manufactured in accordance with the unique specifications of, and use by, a single licensee) sources and devices shall be evaluated using the criteria in paragraphs (1)-(6) of this subsection.

(8) Sealed sources or devices used for calibration and reference sources of 100 μCi or less for beta or gamma-emitting radionuclides and 10 μCi or less for alpha-emitting radionuclide do not require radiation safety evaluations.

(9) Sealed sources or devices used in research and development that have not had safety evaluations.

(A) For sealed sources or devices used in research and development, the following shall be submitted:

(*i*) the radioactive material contained, its chemical and physical form, and amount;

(*ii*) details of the design and construction sufficient to determine that no obvious mechanical flaws exist;

(*iii*) information that demonstrates that sealed sources meet ANSI/HPS N43.6-1997 criteria for the particular category of use and that devices will maintain their integrity during normal use and accident conditions; and

(*iv*) procedures for use that demonstrate a safe environment for users and others nearby.

(B) For custom (one-of-a-kind) sealed sources or devices used in research and development, the licensee shall be qualified by sufficient training and experience and have sufficient facilities and equipment to safely use the requested quantity of radioactive material in unsealed form.

(w) Issuance of specific licenses.

(1) When the agency determines that an application meets the requirements of the Act and the rules of the agency, the agency will issue a specific license authorizing the proposed activity in such form and containing the conditions and limitations as the agency deems appropriate or necessary.

(2) The agency may incorporate in any license at the time of issuance, or thereafter by amendment, additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this section as the agency deems appropriate or necessary in order to:

(A) minimize danger to occupational and public health and safety and the environment;

(B) require reports and the keeping of records, and to provide for inspections of activities in accordance with the license as may be appropriate or necessary; and

(C) prevent loss or theft of radioactive material subject to this chapter.

(3) The agency may request, and the licensee shall provide, additional information after the license has been issued to enable the agency to determine whether the license should be modified in accordance with subsection (dd) of this section.

(x) Specific terms and conditions of licenses.

(1) Each license issued in accordance with this section shall be subject to the applicable provisions of the Act and to applicable rules, now or hereafter in effect, and orders of the agency.

(2) No license issued or granted in accordance with this section and no right to possess or utilize radioactive material granted by any license issued in accordance with this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and to applicable rules, now or hereafter in effect, and orders of the agency, and shall give its consent in writing.

(3) Each person licensed by the agency in accordance with this section shall confine use and possession of the radioactive material licensed to the locations and purposes authorized in the license.

(4) Each licensee shall notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by the licensee or its parent company, if the parent company is involved in the bankruptcy.

(5) The notification in paragraph (4) of this subsection shall include:

(A) the bankruptcy court in which the petition for bankruptcy was filed; and

(B) the date of the filing of the petition.

(6) A copy of the petition for bankruptcy shall be submitted to the agency along with the written notification.

(7) In making a determination whether to grant, deny, amend, renew, revoke, suspend, or restrict a license, the agency may consider the technical competence and compliance history of an applicant or holder of a license. After an opportunity for a hearing, the agency shall deny an application for a license, an amendment to a license, or renewal of a license if the applicant's compliance history reveals that at least three agency actions have been issued against the applicant within the previous six years that assess administrative or civil penalties against the applicant, or that revoke or suspend the license.

(y) Expiration and termination of licenses, and administrative renewal; decommissioning of sites and separate buildings or outdoor areas.

(1) Effective September 1, 2004, the term of the specific license is two years. Except as provided in paragraph (3) of this subsection and subsection (z)(2) of this section, each specific license expires at the end of the day, in the month and year stated in the license. Except for subsection (z)(5) of this section, upon payment of the fee required by §289.204 of this title and if the agency does not deny the renewal in accordance with subsection (x)(7) of this section, the specific license will be administratively renewed. The requirements in this subsection are subject to the provisions of Government Code, §2001.054.

(2) If the fee is not paid and the license is not renewed in accordance with paragraph (1) of this subsection, the license expires, and the licensee is in violation of the rules and is subject to administrative penalties in accordance with §289.205 of this title.

(A) If the licensee pays the fee required by §289.204 of this title within 30 days after expiration of the license, the license will be reinstated and the licensee will not be required to file an application in accordance with subsection (d) of this section.

(B) If the licensee fails to pay the fee within 30 days after expiration of the license, the licensee shall file an application in accordance with subsection (d) of this section.

(3) Expiration of the specific license does not relieve the licensee of the requirements of this chapter.

(4) All license provisions continue in effect beyond the expiration date, with respect to possession of radioactive material until the agency notifies the former licensee in writing that the provisions of the license are no longer binding. During this time, the former licensee shall:

(A) be limited to actions involving radioactive material that are related to decommissioning; and

(B) continue to control entry to restricted areas until the location(s) is suitable for release for unrestricted use in accordance with the requirements in §289.202(ddd) of this title.

(5) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the agency in writing and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, so that the building and/or outdoor area is suitable for release in accordance with §289.202(eee) of this title, or submit within 12 months of notification a decommissioning plan, if required by paragraph (8) of this subsection, and begin decommissioning upon approval of that plan if:

(A) the license has expired or has been revoked in accordance with this subsection or subsection (dd) of this section;

(B) the licensee has decided to permanently cease principal activities, as defined in §289.201(b) of this title, at the entire site or in any separate building or outdoor area;

(C) no principal activities under the license have been conducted for a period of 24 months; or

(D) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with §289.202(eee) of this title.

(6) Coincident with the notification required by paragraph (5) of this subsection, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee in accordance with subsection (gg) of this section in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance shall be increased, or may be decreased, as appropriate, with agency approval, to cover the detailed cost estimate for decommissioning established in accordance with paragraph (11)(E) of this subsection.

(7) The agency may grant a request to delay or postpone initiation of the decommissioning process if the agency determines that such relief is not detrimental to the occupational and public health and safety and is otherwise in the public interest. The request shall be submitted no later than 30 days before notification in accordance with paragraph (5) of this subsection. The schedule for decommissioning set forth in paragraph (5) of this subsection may not commence until the agency has made a determination on the request.

[8] A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(A) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(B) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(C) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(D) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

[9] The agency may approve an alternate schedule for submittal of a decommissioning plan required in accordance with paragraph [5] of this subsection if the agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the occupational and public health and safety and is otherwise in the public interest.

[10] The procedures listed in paragraph [8] of this subsection may not be carried out prior to approval of the decommissioning plan.

[11] The proposed decommissioning plan for the site or separate building or outdoor area shall include the following:

(A) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(B) a description of planned decommissioning activities;

(C) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(D) a description of the planned final radiation survey;

(E) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning; and

(F) for decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in paragraph (15) of this subsection.

(12) The proposed decommissioning plan will be approved by the agency if the information in the plan demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(13) Except as provided in paragraph (15) of this subsection, licensees shall complete decommissioning of the site or separate building or outdoor areas as soon as practicable but no later than 24 months following the initiation of decommissioning.

(14) Except as provided in paragraph (15) of this subsection, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(15) The agency may approve a request for an alternate schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted by consideration of the following:

(A) whether it is technically feasible to complete decommissioning within the allotted 24 month period;

(B) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24 month period;

(C) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(D) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(E) other site-specific factors that the agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

[16] As the final step in decommissioning, the licensee shall do the following:

(A) certify the disposition of all licensed material, including accumulated wastes; and

(B) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in accordance with the radiological requirements for license termination specified in §289.202(ddd) of this title. The licensee shall do the following, as appropriate:

(*i*) report the following levels:

(*I*) gamma radiation in units of microroentgen per hour (μR/hr) (millisieverts per hour (mSv/hr)) at 1 meter (m) from surfaces;

(*II*) radioactivity, including alpha and beta, in units of disintegrations per minute (dpm) or microcuries (μCi) (megabecquerels (MBq)) per 100 square centimeters (cm^2) for surfaces;

(*III*) μCi (MBq) per milliliter for water; and

(*IV*) picocuries (pCi) (becquerels (Bq)) per gram (g) for solids such as soils or concrete; and

(*ii*) specify the manufacturer's name and model and serial number of survey instrument(s) used and certify that each instrument is properly calibrated and tested.

[17] The agency will provide written notification to specific licensees, including former licensees with provisions continued in effect beyond the expiration date in accordance with paragraph [4] of this subsection, that the provisions of the license are no longer binding. The agency will provide such notification when the agency determines that:

(A) radioactive material has been properly disposed;

(B) reasonable effort has been made to eliminate residual radioactive contamination, if present;

(C) a radiation survey has been performed that demonstrates that the premises are suitable for release in accordance with the radiological requirements for license termination specified in §289.202(ddd) of this title, or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the radiological requirements for license termination specified in §289.202(ddd) of this title; and

(D) any outstanding fees in accordance with §289.204 of this title are paid and any outstanding notices of violations of this chapter or of license conditions are resolved.

(18) Each licensee shall submit to the agency all records required by §289.202(nn)(2) of this title before the license is terminated.

(z) Technical renewal of licenses.

(1) An application for a technical renewal of specific licenses shall be filed in accordance with subsection (d)(1)-(3) and (5)-(7) of this section. An application for a technical renewal of a specific license shall be filed by the date specified in the license. If the licensee fails to apply and pay the fee required by §289.204 of this title, the license expires and the licensee shall comply with the requirements of subsection (y) of this section. In any application for renewal, the applicant may incorporate drawings by clear and specific reference (for example, title, date and unique number of drawing), if no modifications have been made since previously submitted.

(2) In any case in which a licensee, prior to expiration of an existing license, has filed a request in proper form for a technical renewal or for a new license authorizing the same activities, such existing license shall not expire until the request has been finally determined by the agency. In any case in which a licensee, not more than 30 days after the expiration of an existing license, has filed an application for technical renewal or for a new license authorizing the same activities and paid the fee required by §289.204 of this title, the agency may reinstate the license and extend the expiration until the request has been finally determined by the agency.

(3) An application for technical renewal of a license will be approved if the agency determines that the requirements of subsection (e) of this section have been satisfied.

(4) When the date for administrative renewal in accordance with subsection (y)(1) of this section and the date for the technical renewal in accordance with paragraph (1) of this subsection occur at the same time, the specific license will be renewed if the fee required by §289.204 of this title is paid, the technical renewal is approved by the agency in accordance with paragraph (3) of this subsection, and the agency does not deny the renewal in accordance with subsection (x)(7) of this section.

(5) When the date for the administrative renewal in accordance with subsection (y)(1) of this section and the date for the technical renewal in accordance with paragraph (1) of this subsection occur at the same time, the specific license renewal may be denied by the agency if any one of the following conditions apply:

(A) the fee required by §289.204 of this title is not paid;

(B) the agency denies the renewal in accordance with subsection (x)(7) of this section; or

(C) the agency does not approve the technical renewal in accordance with paragraph (3) of this subsection.

(6) Expiration of the specific license does not relieve the former licensee of the requirements of this chapter.

(7) The requirements in this subsection are subject to the provisions of Government Code, §2001.054.

(aa) Amendment of licenses at request of licensee.

(1) Requests for amendment of a license shall be filed in accordance with subsection (d)(1)-(3) of this section shall be signed by management or the RSO, and shall specify the respects in which the licensee desires a license to be amended and the grounds for the amendment.

(2) Requests for amendments to delete a subsite from a license shall be filed in accordance with subsections (d)(1) and (2) and (y)(3) and (15) of this section.

(bb) Agency action on requests to renew or amend. In considering a request by a licensee to renew or amend a license, the agency will apply the criteria in subsection (e) of this section as applicable.

(cc) Transfer of material.

(1) No licensee shall transfer radioactive material except as authorized in accordance with this chapter. This subsection does not include transfer for commercial distribution.

(2) Except as otherwise provided in a license and subject to the provisions of paragraphs (3) and (4) of this subsection, any licensee may transfer radioactive material:

(A) to the agency. (A licensee may transfer material to the agency only after receiving prior approval from the agency.);

(B) to the United States Department of Energy (DOE);

(C) to any person exempt from this section to the extent permitted in accordance with such exemption;

(D) to any person authorized to receive such material in accordance with the terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the NRC, any agreement state, or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency of the federal government, the agency, any agreement state, or any licensing state; or

(E) as otherwise authorized by the agency in writing.

(3) Before transferring radioactive material to a specific licensee of the agency, the NRC, an agreement state, or a licensing state, or to a general licensee who is required to register with the agency, the NRC, an agreement state, or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(4) The following methods for the verification required by paragraph (3) of this subsection are acceptable.

(A) The transferor may possess and have read a current copy of the transferee's specific license.

(B) When a current copy of the transferee's specific license described in subparagraph (A) of this paragraph is not readily available or when a transferor desires to verify that information received is correct or up-to-date, the transferor may obtain and record confirmation from the agency, the NRC, or the licensing agency of an agreement state or a licensing state that the transferee is licensed to receive the radioactive material.

(5) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of subsection (ff) of this section.

(dd) Modification, suspension, and revocation of licenses.

(1) The terms and conditions of all licenses shall be subject to revision or modification. A license may be modified, suspended or revoked by reason of amendments to the Act, by reason of rules in this chapter, or orders issued by the agency.

(2) Any license may be revoked, suspended, or modified, in whole or in part, for any of the following:

(A) any material false statement in the application or any statement of fact required under provisions of the Act;

(B) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a license on an original application;

(C) violation of, or failure to observe any of the terms and conditions of the Act, this chapter, the license, or order of the agency; or

(D) existing conditions that constitute a substantial threat to the public health or safety or the environment.

(3) Each specific license revoked by the agency ends at the end of the day on the date of the agency's final determination to revoke the license, or on the revocation date stated in the determination, or as otherwise provided by the agency order.

(4) Except in cases in which the occupational and public health or safety requires otherwise, no license shall be suspended or revoked unless, prior to the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

(ee) Reciprocal recognition of licenses.

(1) Subject to this section, any person who holds a specific license from NRC, any agreement state, or any licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is granted a general license to conduct the activities authorized in such licensing document within the State of Texas provided that:

(A) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(B) the out-of-state licensee notifies the agency in writing at least three working days prior to engaging in such activity. If, for a specific case, the three-working-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities in accordance with the general license provided in this subsection. Such notification shall include:

(*i*) the exact location, start date, duration, and type of activity to be conducted;

(*ii*) the identification of the radioactive material to be used;

(*iii*) the name(s) and in-state address(es) of the individual(s) performing the activity;

(*iv*) a copy of the applicant's pertinent license;

(*v*) a copy of the licensee's operating, safety, and emergency procedures; and

(*vi*) a fee as specified in §289.204 of this title.

(C) the out-of-state licensee complies with all applicable rules of the agency and with all the terms and conditions of the licensee's licensing document, except any such terms and conditions that may be inconsistent with applicable rules of the agency;

(D) the out-of-state licensee supplies such other information as the agency may request; and

(E) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used in accordance with the general license provided in this subsection except by transfer to a person:

(*i*) specifically licensed by the agency, the NRC, another agreement state, or another licensing state to receive such material, or

(*ii*) exempt from the requirements for a license for such material in accordance with §289.251(e)(1) of this title.

(2) In addition to the provisions of paragraph (1) of this subsection, any person who holds a specific license issued by NRC, an agreement state, or a licensing state authorizing the holder to manufacture, transfer, install, or service the device described in §289.251(f)(4)(H) of this title, within areas subject to the jurisdiction of the licensing body, is granted a general license to install, transfer, demonstrate, or service the device in the State of Texas provided that:

(A) the person files a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in the state of Texas. Each report shall identify by name and address, each general licensee to whom the device is transferred, the type of device transferred by manufacturer's name, model and serial number of the device, and serial number of the sealed source, and the quantity and type of radioactive material contained in the device;

(B) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to the person by the NRC, an agreement state, or a licensing state;

(C) the person assures that any labels required to be affixed to the device in accordance with requirements of the authority that licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(D) the holder of the specific license furnishes to each general licensee to whom the holder of the specific license transfers the device, or on whose premises the holder of the specific license installs the device, a copy of the general license contained in §289.251(f)(4)(H) of this title.

(3) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed in accordance with the licensing document, upon determining that the action is necessary in order to prevent undue hazard to occupational and public health and safety and the environment.

(ff) Preparation of radioactive material for transport. Requirements for the preparation of radioactive material for transport are specified in §289.257 of this title.

(gg) Financial assurance and record keeping for decommissioning.

(1) The applicant for a specific license or renewal of a specific license, or holder of a specific license, authorizing the possession and use of radioactive material shall submit and receive written authorization for a decommissioning funding plan as described in paragraph (4) of this subsection in an amount sufficient to allow the agency to engage a third party to decommission the site(s) specified on the license for the following situations:

(A) when unsealed radioactive material requested or authorized on the license, with a half-life greater than 120 days, is in quantities exceeding 10^5 times the applicable quantities set forth in subsection (ii)(2) of this section; or

(B) when a combination of the unsealed radionuclides requested or authorized on the license, with a half-life greater than 120 days, results in the R of the radionuclides divided by 10^5 being greater than 1 (unity rule), where R is defined as the sum of the ratios of the quantity of each radionuclide to the applicable value in subsection (ii)(2) of this section.

(2) The applicant for a specific license or renewal of a specific license or the holder of a specific license authorizing possession and use of radioactive material as specified in paragraph (3) of this subsection shall either:

(A) submit a decommissioning funding plan as described in paragraph (4) of this subsection in an amount sufficient to allow the agency to engage a third party to decommission the site(s) specified on the license; or

(B) submit financial assurance for decommissioning in the amount in accordance with paragraph (3) of this subsection using one of the methods described in paragraph (6) of this subsection in an amount sufficient to allow the agency to engage a third party to decommission the site(s) specified on the license.

(3) The required amount of financial assurance for decommissioning is determined by the quantity of material authorized by the license and is determined as follows:

(A) $850,000 for quantities of material greater than 10^4 but less than or equal to 10^5 times the applicable quantities in subsection (ii)(2) of this section in unsealed form. (For a combination of radionuclides, if R, as defined in paragraph (1) of this subsection, divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.);

(B) $170,000 for quantities of material greater than 10^3 but less than or equal to 10^4 times the applicable quantities in subsection (ii)(2) of this section in unsealed form. (For a combination of radionuclides, if R, as defined in paragraph (1) of this subsection, divided by 10^3 is greater than 1 but R divided by 10^4 if less than or equal to 1.); or

(C) $85,000 for quantities of material greater than 10^{10} times the applicable quantities in subsection (ii)(2) of this section in sealed sources or plated foils. (For a combination of radionuclides, if R, as defined in paragraph (1) of this subsection, divided by 10^{10} is greater than 1.)

(4) Each decommissioning funding plan shall contain a cost estimate for decommissioning in an amount sufficient to allow the agency to engage a third party to decommission the site(s) specified on the license and a description of the method of assuring funds for decommissioning from paragraph (6) of this subsection, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. The required amount of financial assurance for decommissioning is determined by the quantity of material authorized by the license. Upon approval of the decommissioning funding plan by the agency, the amount of financial assurance shall be adjusted and submitted in conformance with the agency approval.

(5) Financial assurance in conjunction with a decommissioning funding plan shall be submitted as follows:

(A) for an applicant for a specific license, financial assurance as described in paragraph (6) of this subsection, may be obtained after the application has been approved and the license issued by the agency, but shall be submitted to the agency prior to receipt of licensed material; or

(B) for an applicant for renewal of a specific license, or a holder of a specific license, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (6) of this subsection shall be submitted with the decommissioning funding plan.

(6) Financial assurance for decommissioning shall be provided by one or more of the following methods. The financial instrument obtained shall be continuous for the term of the license in a form prescribed by the agency. The applicant or licensee shall obtain written approval of the financial instrument or any amendment to it from the agency.

(A) Prepayment. Prepayment is the deposit into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

(B) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in subsection (ii)(3) of this section. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in subsection (ii)(4) of this section. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in subsection (ii)(5) of this section. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in subsection (ii)(6) of this section. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning shall contain the following conditions.

(*i*) The surety method or insurance shall be open-ended or, if written for a specified term, such as five years, shall be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance shall also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation.

(*ii*) The surety method or insurance shall be payable in the State of Texas to the Radiation and Perpetual Care Account.

(*iii*) The surety method or insurance shall remain in effect until the agency has terminated the license.

(C) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions shall be in accordance with subparagraph (B) of this paragraph.

(D) In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount in accordance with paragraph (4) of this subsection, and indicating that funds for decommissioning will be obtained when necessary.

(E) When a governmental entity is assuming custody and ownership of a site, there shall be an arrangement that is deemed acceptable by such governmental entity.

(7) Each person licensed in accordance with this section shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the agency. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency considers important to decommissioning consists of the following:

(A) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas, as in the case of possible seepage into porous materials such as concrete. These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(B) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations;

(C) except for areas containing only sealed sources (provided the sealed sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

(*i*) all areas designated and formerly designated as restricted areas as defined in §289.201(b) of this title;

(*ii*) all areas outside of restricted areas that require documentation under subparagraph (A) of this paragraph; and

(*iii*) all areas outside of restricted areas where current and previous wastes have been buried as documented in accordance with §289.202(tt) of this title; and

(D) records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds.

(8) Any licensee who has submitted an application before January 1, 1995, for renewal of license in accordance with this section shall provide financial assurance for decommissioning in accordance with paragraphs (1) and (2) of this subsection.

(hh) Emergency plan for responding to a release.

(1) A new or renewal application for each specific license to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in subsection (ii)(7) of this section shall contain either:

(A) an evaluation showing that the maximum dose to a person offsite due to a release of radioactive material would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

(B) an emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted in accordance with paragraph (1)(A) of this subsection:

(A) the radioactive material is physically separated so that only a portion could be involved in an accident;

(B) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(C) the release fraction in the respirable size range would be lower than the release fraction in subsection (ii)(7) of this section due to the chemical or physical form of the material;

(D) the solubility of the radioactive material would reduce the dose received;

(E) facility design or engineered safety features in the facility would cause the release fraction to be lower than that in subsection (ii)(7) of this section;

(F) operating restrictions or procedures would prevent a release fraction as large as that in subsection (ii)(7) of this section; or

(G) other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted in accordance with paragraph (1)(B) of this subsection shall include the following information.

(A) Facility description. A brief description of the licensee's facility and area near the site.

(B) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(C) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(D) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(E) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(F) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(G) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the agency; also, responsibilities for developing, maintaining, and updating the plan.

THIS PORTION OF THE PAGE LEFT INTENTIONLLY BLANK

(H) Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency. These reporting requirements do not supersede or release licensees from complying with the requirements in accordance with the Emergency Planning and Community Right-to-Know-Act of 1986, Title III, Publication L. 99-499 or other state or federal reporting requirements.

(I) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the agency.

(J) Training. A brief description of the frequency, performance objectives, and plans for the training that the licensee will provide workers on how to respond to an emergency, including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(K) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(L) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations at intervals not to exceed three months and biennial onsite exercises to test response to simulated emergencies. Communications checks with offsite response organizations shall include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises shall use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

(M) Hazardous chemicals. A certification that the applicant has met its responsibilities in accordance with the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Publication L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any comments received within the 60 days to the agency with the emergency plan.

(ii) Appendices.

(1) Subjects to be included in training courses:

(A) fundamentals of radiation safety:

(*i*) characteristics of radiation;

(*ii*) units of radiation dose (rem) and activity of radioactivity (curie);

(*iii*) significance of radiation dose;

(*I*) radiation protection standards; and

(*II*) biological effects of radiation;

(*iv*) levels of radiation from sources of radiation;

(*v*) methods of controlling radiation dose;

(*I*) time;

(*II*) distance; and

(*III*) shielding;

(*vi*) radiation safety practices, including prevention of contamination and methods of decontamination; and

(*vii*) discussion of internal exposure pathways;

(B) radiation detection instrumentation to be used:

(*i*) radiation survey instruments:

(*I*) operation;

(*II*) calibration; and

(*III*) limitations;

(*ii*) survey techniques;

(*iii*) individual monitoring devices;

(C) equipment to be used:

(*i*) handling equipment and remote handling tools;

(*ii*) sources of radiation;

(*iii*) storage, control, disposal, and transport of equipment and sources of radiation;

(*iv*) operation and control of equipment; and

(*v*) maintenance of equipment;

(D) the requirements of pertinent federal and state regulations;

(E) the licensee's written operating, safety, and emergency procedures; and

(F) the licensee's record keeping procedures.

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

(2) Isotope quantities (for use in subsection (gg) of this section).

Radionuclides	Limit	Unsealed Sources			Sealed Sources
		10^3	10^4	10^5	10^{10}
Ce-142, Pr-141, Nd-144, Nd-145, Sm-146, Sm-147, Sm-148, Gd-148, Gd-150, Gd-151, Gd-152, Tb-159, Dy-154, Dy-156, Ho-165, Hf-174, W-180, Pt-190, Pb-210, Bi-209, Bi-209m, Po-208, Po-209, Po-210, Ra-226, Ac-227, Th-228, Th-229, Th-230, Pa-231, U-232, U-233, U-234, U-235, U-236, Np-235, Np-237, Pu-236, Pu-238, Pu-239, Pu-240, Pu-241, Pu-242, Pu-244, Am-241, Am-242m, Am-243, Cm-242, Cm-243, Cm-244, Cm-245, Cm-246, Cm-247, Cm-248, Bk-247, Bk-249, Cf-248, Cf-249, Cf-250, Cf-251, Cf-252, Es-254, Any Alpha-emitting radionuclide not listed above or mixtures of unknown alpha emitters of unknown composition	0.01 μCi	.01 mCi	0.1 mCi	1.0 mCi	100 Ci
Be-10, Al-26, Si-32, Ar-39, Ar-42, K-40, Ca-45, Ca-48, Ti-44, V-49, V-50, Fe-60, Zn-70, Ge-68, Ge-76, Kr-81, Sr-90, Zr-96, Mo-100, Tc-98, Rh-101, Rh-102, Pd-107, Ag-108m, Cd-113m, Cd-116, Sn-121m, Sn-123, Sn-124, Sn-126 Te-121m, Te-123, Te-130, I-129, La-137, La-138, Ce-139, Nd-150, Pm-143, Pm-144, Pm-145, Pm-146, Sm-145, Eu-150, Tb-157, Tb-158, Dy-159, Ho-166m, Lu-173, Lu-174, Lu-174m, Lu-175, Lu-176, Lu-177m, Hf-172, Hf-182, Ta-179, Re-184m, Re-187, Re-189, Os-194, Ir-199m2, Pt-192, Pt-198, Hg-194, Pb-202, Pb-205, Bi-208, Ra-228, Np-236, Bk-248, Any radionuclide other than alpha-emitting radionuclides not listed above or mixtures of beta emitters of unknown composition	0.1 μCi	0.1 mCi	1.0 mCi	10 mCi	1.0 kCi
Na-22, Co-60, Ru-106, Ag-110m, Cs-134, Ce-144, Eu-152, Eu-154, Bi-210	1.0 μCi	1.0 mCi	10 mCi	100 mCi	10 kCi
Cl-36, Ca-45, Mn-54, Ni-63, Zn-65, Se-75, Rb-87, Zr-93, Nb-93m, Cd-109, In-115, Sb-125, Ba-133, Ba-135, Cs-137, Gd-153, Eu-155, Tm-170, Tm-171, W-181, Tl-204	10 μCi	10 mCi	100 mCi	1.0 Ci	100 kCi
C-14, Fe-55, Co-57, Ni-59, Kr-85, Tc-97, Tc-99, Pt-193, Ir-194, Th (natural), Th-232, U(natural), U-238	100 μCi	100 mCi	1.0 Ci	10 Ci	1.0 MCi
H-3	1.0 mCi	1 Ci	10 Ci	100 Ci	10 MCi

(3) Criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This paragraph establishes criteria for passing the financial test and for obtaining the parent company guarantee.

(B) Financial test.

(*i*) To pass the financial test, the parent company shall meet the criteria of either subclause (*I*) or (*II*) of this clause.

(*I*) The parent company shall have:

(-a-) two of the following three ratios:

(-1-) a ratio of total liabilities to net worth less than 2.0;

(-2-) a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and

(-3-) a ratio of current assets to current liabilities greater than 1.5;

(-b-) net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used);

(-c-) tangible net worth of at least $10 million; and

(-d-) assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used.)

(*II*) The parent company shall have:

(-a-) a current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's;

(-b-) tangible net worth each at least six times the current decommissioning cost estimate for the total of all facilities or parts thereof (or prescribed amount if a certification is used);

(-c-) tangible net worth of at least $10 million; and

(-d-) assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if certification is used).

(*ii*) The parent company's independent certified public accountant shall have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the auditor's attention that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(*iii*) After the initial financial test, the parent company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(*iv*) If the parent company no longer meets the requirements of clause (i) of this subparagraph, the licensee shall send notice to the agency of intent to establish alternate financial assurance as specified in the agency's regulations. The notice shall be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(C) Parent company guarantee. The terms of a parent company guarantee that an applicant or licensee obtains shall provide that:

(*i*) the parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the agency, as evidenced by the return receipts;

(*ii*) if the licensee fails to provide alternate financial assurance as specified in the agency's rules within 90 days after receipt by the licensee and the agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee;

(*iii*) the parent company guarantee and financial test provisions shall remain in effect until the agency has terminated the license; and

(*iv*) if a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the agency. An acceptable trustee includes an appropriate state or federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

(4) Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes a financial test of subparagraph (B) of this paragraph. Subparagraph (B) of this paragraph establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self guarantee.

(B) Financial test.

(*i*) To pass the financial test, a company shall meet all of the following criteria:

(*I*) tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used for all decommissioning activities for which the company is responsible as self guaranteeing licensee and as parent-guarantor);

(*II*) assets located in the United States amounting to at least 90% of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor); and

(*III*) a current rating for its most recent bond issuance of AAA, AA, A as issued by Standard and Poor's, or Aaa, Aa, A as issued by Moody's.

(*ii*) To pass the financial test, a company shall meet all of the following additional criteria:

(*I*) the company shall have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(*II*) the company's independent certified public accountant shall have compared the data used by the company in the financial test that is derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the auditor's attention that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test; and

(*III*) after the initial financial test, the company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(*iii*) If the licensee no longer meets the criteria of clause (*i*) of this subparagraph, the licensee shall send immediate notice to the agency of its intent to establish alternate financial assurance as specified in the agency's rules within 120 days of such notice.

(C) Company self guarantee. The terms of a self guarantee that an applicant or licensee furnishes shall provide that:

(*i*) the company guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the agency, as evidenced by the return receipt;

(*ii*) the licensee shall provide alternate financial assurance as specified in the agency's rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee;

(*iii*) the guarantee and financial test provisions shall remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee;

(*iv*) the licensee will promptly forward to the agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission in accordance with the requirements of the Securities and Exchange Act of 1934, §13;

(*v*) if, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee will provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the criteria of subparagraph (B)(i) of this paragraph; and

(*vi*) the applicant or licensee shall provide to the agency a written guarantee (a written commitment by a corporate officer) that states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(5) Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning by commercial companies that have no outstanding rated bonds.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of subparagraph (B) of this paragraph. The terms of the self-guarantee are in subparagraph (C) of this paragraph. This paragraph establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

(B) Financial test.

(*i*) To pass the financial test a company shall meet the following criteria:

(*I*) tangible net worth greater than $10 million, or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor;

(*II*) assets located in the United States amounting to at least 90% of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(*III*) a ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

(*ii*) In addition, to pass the financial test, a company shall meet all of the following requirements:

(*I*) the company's independent certified public accountant shall have compared the data used by the company in the financial test, that is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in the financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test;

(*II*) after the initial financial test, the company shall repeat passage of the test within 90 days after the close of each succeeding fiscal year; and

(*III*) if the licensee no longer meets the requirements of subparagraph (B)(i) of this paragraph, the licensee shall send notice to the agency of intent to establish alternative financial assurance as specified in the agency's rules. The notice shall be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee shall provide alternative financial assurance within 120 days after the end of such fiscal year.

(C) Company self-guarantee. The terms of a self-guarantee that an applicant or licensee furnishes shall provide the following.

(*i*) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

(*ii*) The licensee shall provide alternative financial assurance as specified in the agency rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

(*iii*) The guarantee and financial test provisions shall remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

(*iv*) The applicant or licensee shall provide to the agency a written guarantee (a written commitment by a corporate officer) that states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(6) Criteria relating to use of financial tests and self-guarantees for providing reasonable assurance of funds for decommissioning by nonprofit entities, such as colleges, universities, and nonprofit hospitals.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of subparagraph (B) of this paragraph. The terms of the self- guarantee are in subparagraph (C) of this paragraph. This paragraph establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

(B) Financial test.

(i) To pass the financial test, a college or university shall meet the criteria of subclause *(I)* or *(II)* of this clause. The college or university shall meet one of the following:

(I) for applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's or Aaa, Aa, or A as issued by Moody's .

(II) for applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

(ii) To pass the financial test, a hospital shall meet the criteria in subclause *(I)* or *(II)* of this clause. The hospital shall meet one of the following:

(I) for applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors or Aaa, Aa, or A as issued by Moodys;

(II) for applicants or licensees that do not issue bonds, all the following tests shall be met:

(-a-) (total revenues less total expenditures) divided by total revenues shall be equal to or greater than 0.04;

(-b-) long term debt divided by net fixed assets shall be less than or equal to 0.67;

(-c-) (current assets and depreciation fund) divided by current liabilities shall be greater than or equal to 2.55; and

(-d-) operating revenues shall be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing license.

(*iii*) In addition, to pass the financial test, a licensee shall meet all the following requirements:

(*I*) the licensee's independent certified public accountant shall have compared the data used by the licensee in the financial test that is required to be derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in the financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test;

(*II*) after the initial financial test, the licensee shall repeat passage of the test within 90 days after the close of each succeeding fiscal year;

(*III*) if the licensee no longer meets the requirements of subparagraph (A) of this paragraph, the licensee shall send notice to the agency of its intent to establish alternative financial assurance as specified in the agency's rules. The notice shall be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(C) Self-guarantee. The terms of a self-guarantee that an applicant or licensee furnishes shall provide the following:

(*i*) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

(*ii*) The licensee shall provide alternative financial assurance as specified in the agency's regulations within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

(*iii*) The guarantee and financial test provisions shall remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

(*iv*) The applicant or licensee shall provide to the agency a written guarantee (a written commitment by a corporate officer or officer of the institution) that states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(*v*) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of the fact to the agency within 20 days after publication of the change by the rating service.

(7) Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release. The following table contains quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

Radioactive Material*	Release Fraction	Quantity (curies)	Radioactive Material*	Release Fraction	Quantity (curies)	Radioactive Material*	Release Fraction	Quantity (curies)
Ac-228 (89)	0.001	4,000	In-114m (49)	0.01	1,000	Xe-133 (54)	1.0	900,000
Am-241 (95)	0.001	2	Ir-192 (77)	0.001	40,000	Y-91 (39)	0.01	2,000
Am-242 (95)	0.001	2	Fe-55 (26)	0.01	40,000	Zn-65 (30)	0.01	5,000
Am-243 (95)	0.001	2	Fe-59 (26)	0.01	7,000	Zr-93 (40)	0.01	400
Sb-124 (51)	0.01	4,000	Kr-85 (36)	1.0	6,000,000	Zr-95 (40)	0.01	5,000
Sb-126 (51)	0.01	6,000	Pb-210 (82)	0.01	8	Any other ß-γ emitter	0.01	10,000
Ba-133 (56)	0.01	10,000	Mn-56 (25)	0.01	60,000	Mixed fission products	0.01	1,000
Ba-140 (56)	0.01	30,000	Hg-203 (80)	0.01	10,000	Mixed corrosion products	0.01	10,000
Bi-207 (83)	0.01	5,000	Mo-99 (42)	0.01	30,000	Contaminated equipment, ß-γ	0.001	10,000
Bi-210 (83)	0.01	600	Np-237 (93)	0.001	2	Irradiated material, any form other than solid non-combustible	0.01	1,000
Cd-109 (48)	0.01	1,000	Ni-63 (28)	0.01	20,000	Irradiated material, solid non-combustible	0.001	10,000
Cd-113 (48)	0.01	80	Nb-94 (41)	0.01	300	Mixed radioactive waste, ß-γ	0.01	1,000
Ca-45 (20)	0.01	20,000	P-32 (15)	0.5	100	Packaged waste, ß-γ***	0.001	10,000
Cf-252 (98)	0.001	9(20mg)	P-33 (15)	0.5	1,000	Any other œ emitter	0.001	2
C-14 (6)**	0.01	50,000	Po-210 (84)	0.01	10	Contaminated equipment œ	0.0001	20
Ce-141 (58)	0.01	10,000	K-42 (19)	0.01	9,000	Packaged waste***	0.0001	20
Ce-144 (58)	0.01	300	Pm-145 (61)	0.01	4,000			
Cs-134 (55)	0.01	2,000	Pm-147 (61)	0.01	4,000			
Cs-137 (55)	0.01	2,000	Ru-106 (44)	0.01	200			
Cl-36 (17)	0.5	100	Sm-151 (62)	0.01	4,000			
Cr-51 (24)	0.01	300,000	Sc-46 (21)	0.01	3,000			
Co-60 (27)	0.001	5,000	Se-75 (34)	0.01	10,000			
Cu-64 (29)	0.01	200,000	Ag110m (47)	0.01	1,000			
Cm-242 (96)	0.001	60	Na-22 (11)	0.01	9,000			
Cm-243 (96)	0.001	3	Na-24 (11)	0.01	10,000			
Cm-244 (96)	0.001	4	Sr-89 (38)	0.01	3,000			
Cm-245 (96)	0.001	2	Sr-90 (38)	0.01	90			
Eu-152 (63)	0.01	500	Sr-35 (16)	0.5	900			
Eu-154 (63)	0.01	400	Tc-99 (43)	0.01	10,000			
Eu-155 (63)	0.01	3,000	Tc-99m (43)	0.01	400,000			
Ge-68 (32)	0.01	2,000	Te-127m(52)	0.01	5,000			
Gd-153 (64)	0.01	5,000	Te-129m(52)	0.01	5,000			
Au-198 (79)	0.01	30,000	Tb-160 (65)	0.01	4,000			
Hf-172 (72)	0.01	400	Tm-170 (69)	0.01	4,000			
Hf-181 (72)	0.01	7,000	Sn-113 (50)	0.01	10,000			
Ho-166 (67)	0.01	100	Sn-123 (50)	0.01	3,000			
H-3 (1)	0.5	20,000	Sn-126 (50)	0.01	1,000			
I-125 (53)	0.5	10	Ti-144 (22)	0.01	100			
I-131 (53)	0.5	10	V-48 (23)	0.01	7,000			

* For combinations of radionuclides, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radionuclide authorized to the quantity listed for that radionuclide in this paragraph exceeds one. ( ) indicates atomic number.

** Non CO forms only.

*** Waste packaged in Type B containers does not require an emergency plan.

(8) Requirements for demonstrating financial qualifications.

(A) If an applicant or licensee is not required to submit financial assurance in accordance with subsection (gg) of this section, that applicant or licensee shall demonstrate financial qualification by submitting attestation that the applicant or licensee is financially qualified to conduct the activity requested for licensure, including any required decontamination, decommissioning, reclamation, and disposal before the agency issues a license.

(B) If an applicant or licensee is required to submit financial assurance in accordance with subsection (gg) of this section, that applicant or licensee shall:

(*i*) submit one of the following:

(*I*) the bonding company report or equivalent (from which information can be obtained to calculate a ratios in clause (*ii*) of this subparagraph) that was used to obtain the financial assurance instrument used to meet the financial assurance requirement specified in subsection (gg) of this section. However, if the applicant or licensee posted collateral to obtain the financial instrument used to meet the requirement for financial assurance specified in subsection (gg) of this section, the applicant or licensee shall demonstrate financial qualification by one of the methods specified in subclause (*II*) or (*III*) of this clause;

(*II*) SEC documentation (from which information can be obtained to calculate a ratio as described in clause (*ii*) of this subparagraph, if the applicant or licensee is a publicly-held company; or

(*III*) a self-test (for example, an annual audit report certifying a company's assets and liabilities and resulting ratio as described in clause (*ii*) of this subparagraph or, in the case of a new company, a business plan specifying expected expenses versus capitalization and anticipated revenues).

(*ii*) declare its Standard Industry Classification (SIC) code. Several companies publish lists, on an annual basis, of acceptable assets-to liabilities (assets divided by liabilities) ratio ranges for each type of SIC code. If an applicant or licensee submits documentation of its current assets and current liabilities or, in the case of a new company, a business plan specifying expected expenses versus capitalization and anticipated revenues, and the resulting ratio falls within an acceptable range as published by generally recognized companies (for example, Almanac of Business and Industrial Financial Ratios, Industry NORM and Key Business Ratios, Dun & Bradstreet Industry publications, and Manufacturing USA: Industry Analyses, Statistics, and Leading Companies), the agency will consider that applicant or licensee financially qualified to conduct the requested or licensed activity.

(C) If the applicant or licensee is a state or local government entity, a statement of such will suffice as demonstration that the government entity is financially qualified to conduct the requested or licensed activities.

(D) The agency will consider other types of documentation if that documentation provides an equivalent measure of assurance of the applicant's or licensee's financial qualifications as found in subparagraphs (A) and (B) of this paragraph.

Appendix B

25 TEXAS ADMINISTRATIVE CODE

§289.254

Licensing of Radioactive Waste Processing and Storage Facilities

Texas Regulations for Control of Radiation

(revisions effective September 1, 2004
are shown as shaded text)

		Page
§289.254(a)	Purpose and Scope	254-1
§289.254(b)	Definitions	254-1
§289.254(c)	Activities Requiring License	254-4
§289.254(d)	Radioactive Waste Processing and Storage Facility Classification	254-4
§289.254(e)	Exemptions	254-4
§289.254(f)	Filing Application for a Specific License	254-5
§289.254(g)	Additional Environmental Requirements for Class III Facilities	254-10
§289.254(h)	Issuance of Licenses	254-11
§289.254(i)	Commencement of Major Construction	254-11
§289.254(j)	Commencement of Operations	254-11
289.254(k)	Specific Terms and Conditions of Licenses	254-12
§289.254(l)	Technical Renewal of Licenses	254-12
§289.254(m)	Amendment of License at Request of Licensee	254-12
§289.254(n)	Waste Processing and Packaging Requirements	254-12
§289.254(o)	Environmental Assessment	254-13
§289.254(p)	Waste Processing and Storage Categories of Radionuclides	254-13

§289.254. Licensing of Radioactive Waste Processing and Storage Facilities.

(a) Purpose and scope.

(1) This section establishes the requirements for management of commercial radioactive waste processing and storage facilities, the procedures and criteria for the issuance of licenses to receive, possess, transport, store, and process radioactive waste from other persons, and the terms and conditions upon which the agency will issue such licenses.

(2) Except as otherwise provided, this section applies to all persons who transport, receive, possess, store, or process radioactive waste from other persons. In addition to the requirements of this section, all licensees, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.252 of this title (relating to Licensing of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Commencement of major construction - Any major structural erection or major alterations to existing structures, or other substantial action that would change the facility design or site for the purpose of establishing a radioactive waste processing or storage facility. The term does not mean the acquisition of existing structures or minor changes thereto.

(2) Decommissioning - The final activities carried out at a radioactive waste processing or storage site after completion of processing operations to remove safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and/or termination of the license. Such activities shall include:

(A) disposing of all radioactive waste at a licensed radioactive waste disposal site;

(B) dismantling or decontaminating site structures;

(C) decontaminating site surfaces and remaining equipment; and

(D) conducting final closure surveys, decontamination, and reclamation of the site.

(3) Disposal - Isolation or removal of radioactive wastes from mankind and his environment. The term does not include emissions and discharges under rules of the agency.

(4) Engineered barriers - Man-made devices to contain or limit the potential movement of radioactive material, which might result from spills or other accidents.

(5) Floodplain - The lowland and relatively flat areas adjoining inland and coastal waters, including flood prone areas of off-shore islands.

(6) Local government - A county, an incorporated city or town, a special district, or other political subdivision of the state.

(7) Major aquifer - An aquifer that yields large quantities of water in a comparatively large area of the state. Major aquifers are located in the following formations: Ogallala, Alluvium and Bolsom Deposits, Edwards-Trinity (Plateau), Edwards (Balcones Fault Zone - San Antonio Region), Edwards (Balcones Fault Zone - Austin Region), Trinity Group, Carrizo-Wilcox, and Gulf Coast.

(8) Natural barriers - The natural characteristics of a site or surface and subsurface composition that serves to impede the movement of radioactive material. Natural barriers may include, for example, the location of a facility remote from an aquifer, or the sorptive capability of the soil surrounding a facility.

(9) Processing - The storage, extraction of materials, transfer, volume reduction, compaction, incineration, solidification, or other separation and preparation of radioactive waste from other persons for reuse or disposal, including any treatment or activity that renders the waste less hazardous, safer for transport, or amenable to recovery, storage, or disposal.

(10) Radioactive waste processing facility - A facility where radioactive waste received from other persons is processed and/or repackaged according to United States Department of Transportation (DOT) regulations.

(11) Radioactive waste storage facility - A facility where radioactive waste received from other persons is stored while awaiting shipment to a licensed radioactive waste processing or disposal facility.

(12) Reconnaissance level information - Any information or analysis that can be retrieved or generated without the performance of new comprehensive site-specific investigations. Reconnaissance level information includes, but is not limited to, relevant published scientific literature; drilling records required by state agencies, such as the Railroad Commission of Texas, the Texas Environmental Quality Commission (Commission), and the Texas Natural Resources Information System; and reports of governmental agencies.

(13) Site - The real property, including the buffer zone, on which a radioactive waste processing or storage facility may be located.

(14) Site monitoring - The procedures for the monitoring of the site and environment to assess quality of site operations and performance and to detect and quantify levels and types of radioactivity and chemicals in the environment. It includes preoperational, operational, and license termination phases.

(15) Site operations - The routine day-to-day activities carried out at the site for the receipt, processing, and storage of radioactive waste.

(16) Site suitability - The capability of the various characteristics of a processing or storage facility or site to safely contain the radioactive waste expected to be present at the site.

(17) Sole source aquifer - The aquifer that is the sole or principal source of drinking water for an area designated under the Safe Drinking Water Act of 1974, 42 United States Codes Annotated 300f, et seq.

(18) Waste processing and storage categories - Radionuclides classified as follows:

(A) any one of seven groups into which radionuclides in normal form are classified, according to their toxicity and their relative potential hazard in transport, as specified in subsection (p) of this section; and

(B) any radionuclide not specifically listed in one of the categories in subsection (p) of this section shall be assigned to one of the categories in accordance with subsection (p)(2) of this section.

(19) Wetlands - Areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support and that, under normal circumstances, do support a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include playa lakes, swamps, marshes, bogs, and similar areas.

(c) Activities requiring license. Except for persons exempted by this section, no person shall receive, possess, and store or process radioactive waste from another person except as authorized in a specific license issued in accordance with this section.

(d) Radioactive waste processing and storage facility classification.

(1) Classification of radioactive waste processing and storage facilities. Radioactive waste processing and storage facilities are classified according to the radionuclides, other than sealed sources, received, possessed, or processed in each of the waste processing and storage categories, as defined in subsection (b) of this section with all applicable provisions, except that, for the purposes of this section which apply to processing and storage of radioactive waste, Category IV shall include waste processing and storage categories IV-VII. The total possession limit of each category of unsealed (dispersible) radionuclides for each class of facility is as follows:

	Category I	Category II	Category III	Category IV
Class I Storage or Processing Facility	10 mCi	100 mCi	1 Ci	10 Ci
Class II Storage Facility	2 Ci	20 Ci	200 Ci	2000 Ci
Class II Processing Facility	1 Ci	10 Ci	100 Ci	1000 Ci

(2) Class III storage facilities are those in which the applicable possession limit of radioactive waste exceeds any limit of Class II storage facilities.

(3) Class III processing facilities are those in which the applicable possession limit of radioactive waste exceeds any limit of Class II processing facilities.

(e) Exemptions.

(1) Sealed sources. Persons who receive, possess, or process sealed sources of radioactive material as radioactive waste from other persons are exempt from this section, provided that:

(A) encapsulated sources are tested upon receipt and determined to have less than 0.005 microcurie of removable contamination; and

(B) sealed sources of radioactive material remain in sealed form after receipt.

(2) Unsealed sources.

(A) Persons who receive, possess, or process sources of radioactive material in unsealed form as radioactive waste from other persons are exempt from this section provided that:

(*i*) the total radioactivity of all radioactive waste possessed at any one time does not exceed the applicable limits for Class I processing or storage facilities as described in subsection (d) of this section; and

(*ii*) the total volume of radioactive waste processed in any one year does not exceed 50 cubic feet.

(B) Persons who receive, possess, and store radioactive material in unsealed form as radioactive waste from other persons are exempt from this section provided that:

(*i*) the radioactive waste consists only of radiopharmaceutical residues resulting from radiopharmaceuticals manufactured, compounded, and supplied by those persons receiving the radiopharmaceutical residues as radioactive waste;

(*ii*) the radioactive waste is held in storage for decay to background radiation levels; and

(*iii*) the radioactive waste is not shipped to a radioactive waste processing or disposal facility.

(3) Radioactive material. A person who receives, possesses, and stores radioactive material as radioactive waste from sites owned and controlled by that same person is not considered to have received waste from other persons.

(f) Filing application for a specific license. Unless otherwise specified, an applicant for a license to receive, possess, or process radioactive waste from other persons is subject to the requirements in §289.252(d) of this title. The applicant shall also comply with the following additional filing requirements.

(1) The applicant for a license to receive, possess, or process radioactive waste from other persons shall submit seven copies of each license application or application for amendment and any supporting documents in a manner specified by the agency. Applications for issuance of licenses shall include all general and specific technical requirements, financial information, and environmental requirements, if applicable, described in this section.

(2) Each application shall clearly demonstrate how the requirements of this subsection and subsections (g), (h), and (i) of this section have been addressed.

(3) Applications for licenses shall be processed in accordance with the following time periods.

(A) The first period is the time from receipt of an application by the Division of Licensing, Registration and Standards to the date of issuance or denial of the license or a written notice outlining why the application is incomplete or unacceptable. This time period is 90 days.

(B) The second period is the time from receipt of the last item necessary to complete the application to the date of issuance or denial of the license. This time period is 90 days.

(C) These time periods are exclusive of any time period incident to hearings and post-hearing activities required by Government Code, Chapters 2001 and 2002.

(4) Notwithstanding the provisions of §289.204(d)(1) of this title, reimbursement of application fees may be granted in the following manner.

(A) In the event the application is not processed in the time periods as stated in paragraph (3) of this subsection, the applicant has the right to request of the director of the Radiation Control Program full reimbursement of all application fees paid in that particular application process. If the director does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request will be denied.

(B) Good cause for exceeding the period established is considered to exist if:

(*i*) the number of applications for licenses to be processed exceeds by 15% or more the number processed in the same calendar quarter the preceding year;

(*ii*) another public or private entity utilized in the application process caused the delay; or

(*iii*) other conditions existed giving good cause for exceeding the established periods.

(C) If the request for full reimbursement authorized by subparagraph (A) of this paragraph is denied, the applicant may then request a hearing by appeal to the Commissioner of Health for a resolution of the dispute. The appeal will be processed in accordance with Title 1, Texas Administrative Code, Chapter 155 (relating to Rules of Procedure) and the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title.

(5) An applicant for a license under this section shall include the following additional information in the application to the agency:

(A) identity of the applicant including the full name, address, telephone number, and description of the business(es) or occupation(s) of the applicant;

(B) the organizational structure of the applicant, both off-site and on-site, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;

(C) a description of past operations that the applicant has been involved in including any license limitations, suspensions or revocations of such licenses, and any other information that will allow the agency to assess the applicant's past operating history;

(D) the technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities; and minimum training and experience requirements for personnel;

(E) a description of the personnel training and retraining program;

(F) a statement of need and a description of the proposed activities identifying:

(*i*) the location of the proposed site;

(*ii*) the character of the proposed activities;

(*iii*) the types, chemical and/or physical forms and quantities of radioactive waste to be received, possessed, and processed; and

(*iv*) the plans for use of the facility for purposes other than processing of radioactive waste;

(G) proposed time schedules for construction and receipt and processing of radioactive waste at the proposed facility;

(H) description of the site and accurate drawings of the facility including, but not limited to:

(*i*) construction;

(*ii*) foundation details;

(*iii*) ventilation;

(*iv*) plumbing and fire suppression systems;

(*v*) physical security system;

(*vi*) storage areas;

(*vii*) radioactive waste handling or processing areas;

(*viii*) proximity to creeks or culverts; and

(*ix*) soil types under the facility with respect to compatibility with foundation and structural design;

(I) a description that demonstrates that the site suitability characteristics will meet the following requirements:

(*i*) the overall hydrogeologic environment of the site, in combination with engineering design, shall act to minimize and control potential radioactive waste migration into surface water and groundwaters;

(*ii*) no new site shall be located in a 100-year floodplain, as designated by the Commission, or a wetland; and

(*iii*) no new site shall be located in the recharge area of a sole source aquifer or a major aquifer unless it can be demonstrated with reasonable assurance that the new site will be designed, constructed, operated, and closed without an unreasonable risk to the aquifer.

(J) minimum criteria for facility design and operation to include:

(*i*) the building used for processing radioactive wastes shall have a minimum classification of Type II (111) in accordance with National Fire Protection Association 220 titled, "Standard Types of Building Construction;"

(*I*) buildings used for processing or storage of radioactive wastes shall have ventilation and fire protection systems to minimize the release of radioactive materials into the soils, waters, and the atmosphere; and

(*II*) facilities and equipment for repackaging leaking and/or damaged containers shall be provided.

(*ii*) the design and operation of the radioactive waste processing or storage facility shall be such that:

(*I*) releases of non-radiological noxious materials from the facility are minimized; and

(*II*) radiation levels, concentrations, and potential exposures off-site due to airborne releases during operations are within the limits established in §289.202 of this title and are maintained as low as reasonably achievable.

(*iii*) the design and operation of the radioactive waste processing or storage facility shall be compatible with the objectives of the site closure and decommissioning plan;

(*iv*) the facility shall be designed to confine spills. Independent and diverse engineered barriers shall be provided, as necessary, to complement natural barriers in minimizing potential releases from the facility and in complying with this section;

(*v*) the location and construction of any new radioactive waste processing facility shall have a buffer zone adequate to permit emergency measures to be implemented following accidents and to address airborne plume dispersions and, as a minimum, shall be such that:

(*I*) the active components of a Class II facility are located at least 30 meters from the nearest residence as of the date of the license application; and

(*II*) the active components of a Class III facility are located at least 30 meters from the nearest property not owned or occupied by the licensee.

(K) a flow diagram of radioactive waste processing operations;

(L) a description and accurate drawings of processing equipment and any required special handling techniques to be employed;

(M) a description of personnel monitoring methods, training, and procedures to be followed to keep employees from ingesting and inhaling radioactive materials, including a description of methods to keep the radiation exposure to levels as low as reasonably achievable;

(N) a description of the site monitoring program to include prelicense data and proposed operational monitoring programs for direct gamma radiation measurements and radioactive and chemical characteristics of the soils, groundwater, surface waters, and vegetation, as applicable;

(*i*) for radioactive waste storage facilities, the applicant shall address on-site air quality; and

(*ii*) for radioactive waste processing facilities, the applicant shall address on-site and off-site air quality;

(O) spill detection and cleanup plans for the licensed site and for associated transportation of radioactive material;

(P) an operating, safety, and emergency procedures manual that shall provide detailed procedures for receiving, handling, storing, processing, and shipping radioactive waste;

(Q) for radioactive waste processing facilities, a description of the equipment to be installed to maintain control over maximum concentrations of radioactive materials in gaseous and liquid effluents produced during normal operations and the means to be employed for keeping levels of radioactive material in effluents to unrestricted areas as low as reasonably achievable and within the limits listed in §289.202 of this title;

(R) methods of ultimate disposal and decommissioning; and

(S) the system for maintaining inventory of receipt, storage, and transfer of radioactive waste.

(g) Additional environmental requirements for Class III facilities. An application for a license for a class III processing or storage facility shall include environmental information that may be based on reconnaissance level information when appropriate and addresses the following:

(1) description of present land uses and population distribution in the vicinity of the site:

(A) for radioactive waste storage facilities, the description shall address properties adjacent to the site; and

(B) for radioactive waste processing facilities, the description shall address properties adjacent to the site and shall include population distribution within a one-mile radius of the site;

(2) area/site suitability including geology, hydrology, and natural hazards. For radioactive waste processing facilities, area meteorology also shall be addressed;

(3) site and project alternatives including alternative siting analysis;

(4) socioeconomic effects on surrounding communities of operation of the licensed activity and of associated transportation of radioactive material; and

(5) environmental effects of postulated accidents

(h) Issuance of licenses.

(1) A license for a radioactive waste processing or storage facility will be issued if the agency finds reasonable assurance that:

(A) an application meets the requirements of the Act and the rules of the agency;

(B) the proposed radioactive waste facility will be sited, designed, operated, decommissioned, and closed in accordance with this section;

(C) the issuance of the license will not be inimical to the health and safety of the public or the environment; and

(D) there is no reason to deny the license as specified in §289.252(d)(10) of this title.

(2) The agency may request, and the licensee shall provide, additional information after the license has been issued to enable the agency to determine whether the license should be modified in accordance with §289.202(dd) of this title.

(i) Commencement of major construction. Commencement of major construction is prohibited until 30 days after the agency has given notice that a license is proposed to be granted, and the environmental analysis is available. If a hearing is requested, the commencement of major construction is prohibited until notice of the contested case hearing is noticed in accordance with the Act. Commencement of major construction subsequent to issuance of the notices is at the economic risk of the applicant.

(j) Commencement of operations. No licensee issued a license under this section may commence operations until the licensee has obtained licenses or permits from other agencies as required by law

(k) Specific terms and conditions of licenses. Unless otherwise specified, each license issued in accordance with this section is subject to the requirements in §289.252(x) of this title. A license issued under this section shall include license conditions derived from the evaluations of the application and analyses performed by the agency, including amendments and changes made before a license is issued. License conditions may include, but are not limited to, the following:

(1) restrictions as to the total radioactive inventory of radioactive waste to be received;

(2) restrictions as to size, shape, and materials and methods of construction of radioactive waste packaging and maximum number of package units stored, at any one time;

(3) restrictions as to the physical and chemical form and radioisotopic content and concentration of radioactive waste;

(4) controls to be applied to restrict access to the site;

(5) controls to be applied to maintain and protect the health and safety of the public and site employees and the environment;

(6) administrative controls, which are the provisions relating to organization, management, and operating procedures; record-keeping, review and audit; and reporting necessary to assure that activities at the facility are conducted in a safe manner and in conformity with agency rules and license conditions; and

(7) maximum retention time for radioactive waste received at the facility.

(l) Technical renewal of licenses.

(1) Technical renewal of licenses shall be filed in accordance with §289.252(z) of this title.

(2) The licensee is responsible for decommissioning the facility and continued safe storage of any radioactive waste whether an application for continued receipt of wastes is filed or not.

(m) Amendment of license at request of licensee. Applications for amendment of a license shall be filed in accordance with subsection (f) of this section and §289.252(d)(1) and (3) of this title. Such applications shall be signed by the RSO and specify how the licensee desires his license to be amended and the basis for such amendment.

(n) Waste processing and packaging requirements. All processed radioactive waste offered for transport or disposal shall meet:

(1) all applicable transportation requirements of the agency, the United States Nuclear Regulatory Commission, and of the DOT; and

(2) all applicable disposal facility license conditions.

[o] Environmental assessment. A written analysis of the impact on the human environment will be prepared or secured by the agency for any license for a class III processing or storage facility and shall be available to the public for written comment at least 30 days prior to the beginning of a hearing, if any, on the issuance or renewal of the license.

[p] Waste processing and storage categories of radionuclides.

(1) The following table contains waste processing and storage categories of radionuclides.

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

Element*	Radionuclide**	Category
Actinium (89)	Ac-227	I
	Ac-228	I
Americium (95)	Am-241	I
	Am-243	I
Antimony (51)	Sb-122	IV
	Sb-124	III
	Sb-125	III
Argon (18)	Ar-37	VI
	Ar-41	II
	Ar-41 (uncompressed)†	V
Arsenic (33)	As-73	IV
	As-74	IV
	As-76	IV
	As-77	IV
Astatine (85)	Ar-211	III
Barium (56)	Ba-131	IV
	Ba-133	II
	Ba-140	III
Berkelium (97)	Bk-249	I
Beryllium (4)	Be-7	IV
Bismuth (83)	Bi-206	IV
	Bi-207	III
	Bi-210	II
	Bi-212	III
Bromine (35)	Br-82	IV
Cadmium (48)	Cd-109	IV
	Cd-115m	III
	Cd-115	IV
Calcium (20)	Ca-45	IV
	Ca-47	IV
Californium (98)	Cf-249	I
	Cf-250	I
	Cf-252	I
Carbon (6)	C-14	IV

* Atomic number shown in parentheses.
** Atomic mass number shown after the element symbol.
† Uncompressed means at a pressure not exceeding 1 atmosphere.
m Metastable state.

Element*	Radionuclide**	Category
Cerium (58)	Ce-141	IV
	Ce-143	IV
	Ce-144	III
Cesium (55)	Cs-131	IV
	Cs-134m	III
	Cs-134	III
	Cs-135	IV
	Cs-136	IV
	Cs-137	III
Chlorine (17)	Cl-36	III
	Cl-38	IV
Chromium (24)	Cr-51	IV
Cobalt (27)	Co-56	III
	Co-57	IV
	Co-58m	IV
	Co-58	IV
	Co-60	III
Copper (29)	Cu-64	IV
Curium (96)	Cm-242	I
	Cm-243	I
	Cm-244	I
	Cm-245	I
	Cm-246	I
Dysprosium (66)	Dy-154	III
	Dy-165	IV
	Dy-166	IV
Erbium (68)	Er-169	IV
	Er-171	IV
Europium (63)	Eu-150	III
	Eu-152m	IV
	Eu-152	III
	Eu-154	II
	Eu-155	IV
Florine (9)	F-18	IV
Gadolinium (64)	Gd-153	IV
	Gd-159	IV

* Atomic number shown in parentheses.

** Atomic mass number shown after the element symbol.

m Metastable state.

Element*	Radionuclide**	Category
Galium (31)	Ga-67	III
	Ga-72	IV
Germanium (32)	Ge-71	IV
Gold (79)	Au-193	III
	Au-194	III
	Au-195	III
	Au-196	IV
	Au-198	IV
	Au-199	IV
Hafnium (72)	Hf-181	IV
Holmium (67)	Ho-166	IV
Hydrogen (1)	H-3 (see tritium)	
Indium (49)	In-113m	IV
	In-114m	III
	In-115m	IV
	In-115	IV
Iodine (53)	I-124	III
	I-125	III
	I-126	III
	I-129	III
	I-131	III
	I-132	IV
	I-133	III
	I-134	IV
	I-135	IV
Iridium (77)	Ir-190	IV
	Ir-192	III
	Ir-194	IV
Iron (26)	Fe-55	IV
	Fe-59	IV
Krypton (36)	Kr-85m	III
	Kr-85m (uncompresssed)†	V
	Kr-85	III
	Kr-85 (uncompressed)†	VI
	Kr-87	II
	Kr-87 (uncompressed)†	V

* Atomic number shown in parentheses.
** Atomic mass number shown after the element symbol.
m Metastable state.
† Uncompressed means at a pressure not exceeding 1 atmosphere.

Element*	Radionuclide**	Category
Lanthanum (57)	La-140	IV
Lead (82)	Pb-203	IV
	Pb-210	II
	Pb-212	II
Lutetium (71)	Lu-172	III
	Lu-177	IV
Magnesium (12)	Mg-28	III
Manganese (25)	Mn-52	IV
	Mn-54	IV
	Mn-56	IV
Mercury (80)	Hg-197m	IV
	Hg-197	IV
	Hg-203	IV
Mixed fission products (MFP)		II
Molybdenum (42)	Mo-99	IV
Neodymium (60)	Nd-147	IV
	Nd-149	IV
Neptunium (93)	Np-237	I
	Np-239	I
Nickel (28)	Ni-56	III
	Ni-59	IV
	Ni-63	IV
	Ni-65	IV
Niobium (41)	Nb-93m	IV
	Nb-95	IV
	Nb-97	IV
Osmium (76)	Os-185	IV
	Os-191m	IV
	Os-191	IV
	Os-193	IV
Palladium (46)	Pd-103	IV
	Pd-109	IV
Phosphorus (15)	P-32	IV

* Atomic number shown in parentheses.
** Atomic mass number shown after the element symbol.
m Metastable state.

Element*	Radionuclide**	Category
Platinum (73)	Pt-191	IV
	Pt-193	IV
	Pt-193m	IV
	Pt-197m	IV
	Pt-197	IV
Plutonium (94)	Pu-238 F	I
	Pu-239 F	I
	Pu-240	I
	Pu-241 F	I
	Pu-242	I
Polonium (84)	Po-210	I
Potassium (19)	K-42	IV
	K-43	III
Praseodymium (59)	Pr-142	IV
	Pr-143	IV
Promethium (61)	Pm-147	IV
	Pm-149	IV
Protactinium (91)	Pa-230	I
	Pa-231	I
	Pa-233	II
Radium (88)	Ra-223	II
	Ra-224	II
	Ra-226	I
	Ra-228	I
Radon (86)	Rn-220	IV
	Rn-222	II
Rhenium (75)	Re-183	IV
	Re-186	IV
	Re-187	IV
	Re-188	IV
	Re-Natural	IV
Rhodium (45)	Rh-103m	IV
	Rh-105	IV
Rubidium (37)	Rb-86	IV
	Rb-87	IV
	Rb-Natural	IV

* Atomic number shown in parentheses.
** Atomic mass number shown after the element symbol.
m Metastable state.
F Fissile material.

Element*	Radionuclide**	Category
Ruthenium (44)	Ru-97	IV
	Ru-103	IV
	Ru-105	IV
	Ru-106	III
Samarium (62)	Sm-145	III
	Sm-147	III
	Sm-151	IV
	Sm-153	IV
Scandium (21)	Sc-46	III
	Sc-47	IV
	Sc-48	IV
Selenium (34)	Se-75	IV
Silicon (14)	Si-31	IV
Silver (47)	Ag-105	IV
	Ag-110m	III
	Ag-111	IV
Sodium (11)	Na-22	III
	Na-24	IV
Strontium (38)	Sr-85m	IV
	Sr-85	IV
	Sr-89	III
	Sr-90	II
	Sr-91	III
	Sr-92	IV
Sulfur (16)	S-35	IV
Tantalum (73)	Ta-182	III
Technetium (43)	Tc-96m	IV
	Tc-96	IV
	Tc-97m	IV
	Tc-97	IV
	Tc-99m	IV
	Tc-99	IV

* Atomic number shown in parentheses.
** Atomic mass number shown after the element symbol.
m Metastable state.

Element*	Radionuclide**	Category
Tellurium (52)	Te-125m	IV
	Te-127m	IV
	Te-127	IV
	Te-129m	III
	Te-129	IV
	Te-131m	III
	Te-132	IV
Terbium (65)	Tb-160	III
Thallium (81)	Tl-200	IV
	Tl-201	IV
	Tl-202	IV
	Tl-204	III
Thorium (90)	Th-227	II
	Th-228	I
	Th-230	I
	Th-231	I
	Th-232	III
	Th-234	II
	Th-Natural	III
Thulium (69)	Tm-168	III
	Tm-170	III
	Tm-171	IV
Tin (50)	Sn-113	IV
	Sn-117m	III
	Sn-121	III
	Sn-125	IV
Tritium (1)	H-3	IV
	H-3 (as a gas, as luminous paint, or adsorbed on solid material.)	VII
Tungsten (74)	W-181	IV
	W-185	IV
	W-187	IV

* Atomic number shown in parentheses.

** Atomic mass number shown after the element symbol.

m Metastable state.

Element*	Radionuclide**	Category
Uranium (92)	U-230	II
	U-232	I
	U-233 F	II
	U-234	II
	U-235 F	III
	U-236	II
	U-238	III
	U-Natural	III
	U-Enriched F	III
	U-Depleted	III
Vanadium (23)	V-48	IV
	V-49	III
Xenon (54)	Xe-125	III
	Xe-131m	III
	Xe-131m (uncompressed)†	V
	Xe-133	III
	Xe-133 (uncompressed)†	VI
	Xe-135	II
	Xe-135 (uncompressed)†	V
Ytterbium (70)	Yb-175	IV
Yttrium (39)	Y-88	III
	Y-90	IV
	Y-91m	III
	Y-91	III
	Y-92	IV
	Y-93	IV
Zinc (30)	Zn-65	IV
	Zn-69m	IV
	Zn-69	IV
Zirconium (40)	Zr-93	IV
	Zr-95	III
	Zr-97	IV

NOTE: For mixtures of radionuclides and for radionuclides not included in this subsection, see subsection (b) of this section, waste processing and storage categories.

* Atomic number shown in parentheses.
** Atomic mass number shown after the element symbol.
F Fissile material.
m Metastable state.
† Uncompressed means at a pressure not exceeding 1 atmosphere.

(2) Any radionuclide not specifically listed in paragraph (1) of this section shall be assigned to one of the categories in accordance with the following table.

	RADIOACTIVE HALF-LIFE		
Radionuclide	0 to 1000 days	1000 days to 10^6 years	Over 10^6 years
Atomic No. 1-81	Category III	Category II	Category III
Atomic No. 82 and over	Category I	Category I	Category III

(3) For mixtures of radionuclides, the following shall apply.

(A) If the identity and respective activity of each radionuclide are known, the permissible activity of each radionuclide shall be such that the sum, for all categories present, of the ratio between the total activity for each category to the permissible activity for each category will not be greater than unity.

(B) If the categories of the radionuclides are known but the amount in each category cannot be reasonably determined, the mixture shall be assigned to the most restrictive category present.

(C) If the identity of all or some of the radionuclides cannot be reasonably determined, each of those unidentified radionuclides shall be considered as belonging to the most restrictive category that cannot be positively excluded.

(D) Mixtures consisting of a single radioactive decay chain where the radionuclides are in the naturally occurring proportions shall be considered as consisting of a single radionuclide. The category and activity shall be that of the first member present in the chain, except that if radionuclide "X" has a half-life longer than that of that first member and an activity greater than that of any other member, including the first, at any time during processing, the waste processing and storage category shall be that of nuclide "X" and the activity of the mixture shall be the maximum activity of nuclide "X" during processing.

25 TEXAS ADMINISTRATIVE CODE

§289.260

Licensing of Uranium Recovery and Byproduct Material Disposal Facilities

Texas Regulations for Control of Radiation

(revisions effective September 1, 2004 are shown as shaded text)

		Page
§289.260(a)	Purpose	260-1
§289.260(b)	Scope	260-1
§289.260(c)	Definitions	260-1
§289.260(d)	Filing Application for Specific Licenses	260-6
§289.260(e)	General Requirements for the Issuance of Specific Licenses	260-9
§289.260(f)	Special Requirements for a License Application for Uranium Recovery and Byproduct Material Disposal Facilities	260-9
§289.260(g)	Specific Terms and Conditions of Licenses	260-10
§289.260(h)	Expiration and Termination of Licenses and Administrative Renewal; Decommissioning of Sites, Separate Buildings, or Outdoor Areas	260-11
§289.260(i)	Technical Renewal of Licenses	260-17
§289.260(j)	Amendment of Licenses at Request of Licensee	260-18
§289.260(k)	Agency Action on Applications to Renew or Amend	260-19
§289.260(l)	Transfer of Material	260-19
§289.260(m)	Financial Security Requirements	260-20
§289.260(n)	Long-term Care and Maintenance Requirements	260-22
§289.260(o)	Technical Requirements	260-23
§289.260(p)	Land Ownership of Byproduct Material Disposal Sites	260-37
§289.260(q)	Maximum Values for Use in Groundwater Protection	260-38

§289.260. Licensing of Uranium Recovery and Byproduct Material Disposal Facilities.

(a) Purpose. This section provides for the specific licensing of the receipt, possession, use, or disposal of radioactive material in uranium recovery facilities and other operations that accept byproduct material for disposal. No person shall engage in such activities except as authorized in a specific license issued in accordance with this section unless otherwise provided for in §289.252 of this title (relating to Licensing of Radioactive Material).

(b) Scope. In addition to the requirements of this section, all licensees, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.251 of this title (relating to Exemptions, General Licenses, and General License Acknowledgements), §289.252 of this title, and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(c) Definitions. The following words and terms when used in this section shall have the following meaning unless the context clearly indicates otherwise.

(1) Aquifer - A geologic formation, group of formations, or part of a formation capable of yielding a significant amount of groundwater to wells or springs. Any saturated zone created by uranium or thorium recovery operations would not be considered an aquifer unless the zone is or potentially is:

(A) hydraulically interconnected to a natural aquifer;

(B) capable of discharge to surface water; or

(C) reasonably accessible because of migration beyond the vertical projection of the boundary of the land transferred for long-term government ownership and care in accordance with subsection (p) of this section.

(2) As expeditiously as practicable considering technological feasibility - As quickly as possible considering the physical characteristics of the byproduct material and the site, the limits of "available technology" (as defined in this subsection), the need for consistency with mandatory requirements of other regulatory programs, and "factors beyond the control of the licensee" (as defined in this subsection). The phrase permits consideration of the cost of compliance only to the extent specifically provided for by use of the term "available technology."

(3) Available technology - Technologies and methods for emplacing a final radon barrier on byproduct material piles or impoundments. This term shall not be construed to include extraordinary measures or techniques that would impose costs that are grossly excessive as measured by practice within the industry (or one that is reasonably analogous), (for example, by way of illustration only, unreasonable overtime, staffing, or transportation requirements, etc., considering normal practice in the industry; laser fusion of soils; etc.), provided there is reasonable progress toward emplacement of the final radon barrier. To determine grossly excessive costs, the relevant baseline against which costs shall be compared is the cost estimate for tailings impoundment closure contained in the licensee's approved reclamation plan, but costs beyond these estimates shall not automatically be considered grossly excessive.

(4) Byproduct material - Tailings or wastes produced by or resulting from the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by such solution extraction operations do not constitute "byproduct material" within this definition.

(5) Capable fault - As used in this section, "capable fault" has the same meaning as defined in Section III(g) of Appendix A of Title 10 Code of Federal Regulations (CFR) Part 100.

(6) Closure - The post-operational activities to decontaminate and decommission the buildings and site used to produce byproduct materials and reclaim the tailings and/or disposal area, including groundwater restoration, if needed.

(7) Closure plan - The plan approved by the agency to accomplish closure. The closure plan consists of a decommissioning plan and may also include a reclamation plan.

(8) Commencement of construction - Any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site, but does not include necessary borings to determine site characteristics or other preconstruction monitoring to establish background information related to the suitability of a site, or to the protection of the environment.

(9) Compliance period - The period of time that begins when the agency sets secondary groundwater protection standards and ends when the owner or operator's license is terminated and the site is transferred to the state or federal government for long-term care, if applicable.

(10) Dike - An embankment or ridge of either natural or man-made materials used to prevent the movement of liquids, sludges, solids, or other materials.

(11) Disposal area - The area containing byproduct materials to which the requirements of subsection (o)(16)-(27) of this section apply.

(12) Existing portion - As used in subsection (o)(9)(A) of this section, "existing portion" is that land surface area of an existing surface impoundment on which significant quantities of byproduct materials had been placed prior to September 30, 1983.

(13) Factors beyond the control of the licensee - Factors proximately causing delay in meeting the schedule in the applicable reclamation plan for the timely emplacement of the final radon barrier notwithstanding the good faith efforts of the licensee to complete the barrier in compliance with subsection (o)(24) of this section. These factors may include but are not limited to:

(A) physical conditions at the site;

(B) inclement weather or climatic conditions;

(C) an act of God;

(D) an act of war;

(E) a judicial or administrative order or decision, or change to the statutory, regulatory, or other legal requirements applicable to the licensee's facility that would preclude or delay the performance of activities required for compliance;

(F) labor disturbances;

(G) any modifications, cessation or delay ordered by state, federal, or local agencies;

(H) delays beyond the time reasonably required in obtaining necessary government permits, licenses, approvals, or consent for activities described in the reclamation plan proposed by the licensee that result from government agency failure to take final action after the licensee has made a good faith, timely effort to submit legally sufficient applications, responses to requests (including relevant data requested by the agencies), or other information, including approval of the reclamation plan; and

(I) an act or omission of any third party over whom the licensee has no control.

(14) Final radon barrier - The earthen cover (or approved alternative cover) over byproduct material constructed to comply with subsection (6)(16)-(27) of this section (excluding erosion protection features).

(15) Groundwater - Water below the land surface in a zone of saturation. For purposes of this section, groundwater is the water contained within an aquifer as defined in paragraph (1) of this subsection.

(16) Hazardous constituent - Subject to subsection (6)(10)(E) of this section, "hazardous constituent" is a constituent that meets all three of the following tests:

(A) the constituent is reasonably expected to be in or derived from the byproduct material in the disposal area;

(B) the constituent has been detected in the groundwater in the uppermost aquifer; and

(C) the constituent is listed in 10 CFR Part 40, Appendix A, Criterion 13.

(17) Leachate - Any liquid, including any suspended or dissolved components in the liquid, that has percolated through or drained from the byproduct material.

(18) Licensed site - The area contained within the boundary of a location under the control of persons generating or storing byproduct materials under a license.

(19) Liner - A continuous layer of natural or man-made materials, beneath or on the sides of a surface impoundment that restricts the downward or lateral escape of byproduct material, hazardous constituents, or leachate.

(20) Maximum credible earthquake - That earthquake that would cause the maximum vibratory ground motion based upon an evaluation of earthquake potential considering the regional and local geology and seismology and specific characteristics of local subsurface material.

(21) Milestone - An action or event that is required to occur by an enforceable date.

(22) Operation - The period of time during which a byproduct material disposal area is being used for the continued placement of byproduct material or is in standby status for such placement. A disposal area is in operation from the day that byproduct material is first placed in it until the day final closure begins.

(23) Point of compliance - The site-specific location in the uppermost aquifer where the groundwater protection standard shall be met. The objective in selecting the point of compliance is to provide the earliest practicable warning that an impoundment is releasing hazardous constituents to the groundwater. The point of compliance is selected to provide prompt indication of groundwater contamination on the hydraulically downgradient edge of the disposal area.

(24) Principal activities - Activities authorized by the license that are essential to achieving the purpose(s) for which the license is issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(25) Reclamation plan - For the purposes of subsection (6)(16)-(27) of this section, "reclamation plan" is the plan detailing activities to accomplish reclamation of the byproduct material disposal area in accordance with the technical criteria of this section. The reclamation plan shall include a schedule for reclamation milestones that are key to the completion of the final radon barrier, including as appropriate, but not limited to, wind blown tailings retrieval and placement on the pile, interim stabilization (including dewatering or the removal of freestanding liquids and recontouring), and final radon barrier construction. Reclamation of byproduct material shall also be addressed in the closure plan. The detailed reclamation plan may be incorporated into the closure plan.

(26) Security (surety) - The following are examples of security:

(A) cash deposits;

(B) surety bonds;

(C) certificates of deposit;

(D) deposits of government securities;

(E) irrevocable letters of credit; or

(F) other security acceptable to the agency.

(27) Surface impoundment - A natural topographic depression, man-made excavation, or diked area, which is designed to hold an accumulation of liquid wastes or wastes containing free liquids, and which is not an injection well.

(28) Unrefined and unprocessed ore - Ore in its natural form before any processing, such as grinding, roasting, beneficiating, solution extracting, or refining.

(29) Uppermost aquifer - The geologic formation nearest the natural ground surface that is an aquifer, as well as lower aquifers that are hydraulically interconnected with this aquifer within the facility's property boundary.

(30) Uranium recovery - Any uranium extraction or concentration activity that results in the production of "byproduct material" as it is defined in this subsection. As used in this definition, "uranium recovery" has the same meaning as "uranium milling" in 10 CFR 40.4.

(d) Filing application for specific licenses. Unless otherwise specified, an applicant for a license is subject to the requirements in §289.252(d) of this title. The applicant shall also comply with the following additional filing requirements.

(1) Applications for specific licenses shall be filed in seven copies in a manner specified by the agency.

(2) Each applicant shall demonstrate to the agency that the applicant is financially qualified to conduct the licensed activity, including any required decontamination, decommissioning, reclamation, and disposal, before the agency issues or renews a license. The requirement is different from those in subsection (m) of this section for financial security.

(A) An applicant or licensee shall show financial qualification by submitting one of the following:

(*i*) the bonding company report or equivalent (from which information can be obtained to calculate a ratio as described in subparagraph (B) of this paragraph) that was used to obtain the financial security instrument used to meet the financial security requirement specified in subsection (m) of this section. However, if the applicant or licensee posted collateral to obtain the financial instrument used to meet the requirement for financial security specified in subsection (m) of this section, the applicant or licensee shall demonstrate financial qualification by one of the methods specified in clause (*ii*) or (*iii*) of this subparagraph;

(*ii*) SEC documentation (from which information can be obtained to calculate a ratio as described in subparagraph (B) of this paragraph), if the applicant or licensee is a publicly-held company; or

(*iii*) a self-test (for example, an annual audit report, certifying a company's assets and liabilities and resulting ratio (as described in subparagraph (B) of this paragraph) or, in the case of a new company, a business plan specifying expected expenses versus capitalization and anticipated revenues).

(B) Each applicant or licensee must declare its Standard Industry Classification (SIC) code. Several companies publish lists, on an annual basis, of acceptable assets-to-liabilities (assets divided by liabilities) ratio ranges for each type of SIC code. If an applicant or licensee submits documentation of its current assets and current liabilities or, in the case of a new company, a business plan specifying expected expenses versus capitalization and anticipated revenues, and the resulting ratio falls within an acceptable range as published by generally recognized companies (for example, Almanac of Business and Industrial Financial Ratios, Industry NORM and Key Business Ratios, Dun & Bradstreet Industry publications, and Manufacturing USA: Industry Analyses, Statistics, and Leading Companies), the agency will consider that applicant or licensee financially qualified to conduct the requested or licensed activity.

(C) The agency will consider other types of documentation if that documentation provides an equivalent measure of assurance of the applicant's or licensee's financial qualifications as found in subparagraphs (A) and (B) of this paragraph.

(3) An application for a license shall contain written specifications relating to the uranium recovery facility operations and the disposition of the byproduct material.

(4) Each application shall clearly demonstrate how the requirements of subsections (d)-(g) and (m)-(p) of this section have been addressed.

(5) Applications for new licenses shall be processed in accordance with the following time periods.

(A) The first period is the time from receipt of an application by the Division of Licensing, Registration and Standards to the date of issuance or denial of the license or a written notice outlining why the application is incomplete or unacceptable. This time period is 180 days.

(B) The second period is the time from receipt of the last item necessary to complete the application to the date of issuance or denial of the license. This time period is 180 days.

(C) These time periods are exclusive of any time period incident to hearings and post-hearing activities required by Government Code, Chapters 2001 and 2002.

(6) Notwithstanding the provisions of §289.204(d)(1) of this title, reimbursement of application fees may be granted in the following manner.

(A) In the event the application is not processed in the time periods as stated in paragraph (10) of this subsection, the applicant has the right to request of the Director of the Radiation Control Program full reimbursement of all application fees paid in that particular application process. If the director does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request will be denied.

(B) Good cause for exceeding the period established is considered to exist if:

(*i*) the number of applications for licenses to be processed exceeds by 15% or more the number processed in the same calendar quarter the preceding year;

(*ii*) another public or private entity utilized in the application process caused the delay; or

(*iii*) other conditions existed giving good cause for exceeding the established periods.

(C) If the request for full reimbursement authorized by subparagraph (A) of this paragraph is denied, the applicant may then request a hearing by appeal to the Commissioner of Health for a resolution of the dispute. The appeal will be processed in accordance with Title 1, Texas Administrative Code, Chapter 155 (relating to Rules of Procedure) and the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title.

(e) General requirements for the issuance of specific licenses. A license application will be approved if the agency determines that the applicant has met the requirements of §289.252(e) of this title and the following:

(1) qualifications of the designated radiation safety officer (RSO) are adequate for the purpose requested in the application and include as a minimum:

(A) possession of a high school diploma or a certificate of high school equivalency based on the GED test; and

(B) training and experience necessary to supervise the radiation safety aspects of the licensed activity;

(2) the applicant satisfies all applicable special requirements in this section.

(f) Special requirements for a license application for uranium recovery and byproduct material disposal facilities. In addition to the requirements in subsection (e) of this section, a license will be issued if the applicant submits the items in paragraph (1) of this subsection for agency approval and meets the conditions in paragraphs (2) and (3) of this subsection.

(1) An application for a license shall include the following:

(A) for new licenses, an environmental report that includes the results of a one-year preoperational monitoring program and for renewal of licenses, an environmental report containing the results of the operational monitoring program. Both shall also include the following:

(*i*) description of the proposed project or action;

(*ii*) area/site characteristics including ecology, geology, topography, hydrology, meteorology, historical and cultural landmarks, and archaeology;

(*iii*) radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts and any long-term impacts;

(*iv*) environmental effects of accidents;

(*v*) byproduct material disposal, decommissioning, decontamination, and reclamation and impacts of these activities; and

(*vi*) site and project alternative;

(B) a closure plan for decontamination, decommissioning, restoration, and reclamation of buildings and the site to levels that would allow unrestricted use and for reclamation of the byproduct material disposal areas in accordance with the technical requirements of subsection (o) of this section;

(C) proposal of an acceptable form and amount of financial security consistent with the requirements of subsection (m) of this section;

(D) procedures describing the means employed to meet the requirements of subsections (g)(1) and (2) and (o)(15) of this section during the operational phase of any project;

(E) specifications for the emissions control and disposition of the byproduct material; and

(F) for disposal of byproduct material received from others, information on the chemical and radioactive characteristics of the wastes to be received, detailed procedures for receiving and documenting incoming waste shipments, and detailed waste acceptance criteria.

(2) Unless otherwise exempted, the applicant shall not commence construction at the site until the agency has issued the license. Commencement of construction prior to issuance of the license shall be grounds for denial of a license.

(3) Facility drawings submitted in conjunction with the application for a license shall be prepared by a professional engineer or engineering firm. Those drawings shall be final and shall be signed, sealed and dated in accordance with the requirements of the Texas Board of Professional Engineers, 22 Texas Administrative Code, Chapter 131.

(g) Specific terms and conditions of licenses. Unless otherwise specified, each license issued in accordance with this section is subject to the requirements of §289.252(x) of this title and the following:

(1) Daily inspection of any byproduct material retention systems shall be conducted by the licensee. General qualifications for individuals conducting inspections shall be approved by the agency. Records of the inspections shall be maintained for review by the agency.

(2) In addition to the applicable requirements of §289.202(ww)-(yy) of this title, the licensee shall immediately notify the agency of the following:

(A) any failure in a byproduct material retention system that results in a release of byproduct material into unrestricted areas;

(B) any release of radioactive material that exceeds the concentrations for water listed in Table II, Column 2, of §289.202(ggg)(2) of this title and that extends beyond the licensed boundary;

(C) any spill that exceeds 20,000 gallons and that exceeds the concentrations for water listed in Table II, Column 2, of §289.202(ggg)(2) of this title; or

(D) any release of solids that exceeds the limits in subsection (h)(6) of this section and that extends beyond the licensed boundary.

(3) In addition to the applicable requirements of §289.202(ww)-(yy) of this title, the licensee shall notify the agency within 24 hours of the following:

(A) any spill that extends:

(*i*) beyond the wellfield monitor well ring;

(*ii*) more than 400 feet from an injection or production well pipe artery to or from a recovery plant; or

(*iii*) more than 200 feet from a recovery plant; or

(B) any spill that exceeds 2,000 gallons and that exceeds the concentrations for water listed in Table II, Column 2, of §289.202(ggg)(2) of this title.

(4) A licensee shall submit to the agency at five year intervals from the issuance of the license or at the time of technical renewal, if renewal and re-evaluation occur in the same year, continued proof of the licensee's financial qualifications.

(h) Expiration and termination of licenses and administrative renewal; decommissioning of sites, separate buildings or outdoor areas.

(1) Effective September 1, 2004, the term of the specific license is two years. Except as provided in paragraph (4) of this subsection and subsection (i)(2) of this section, each specific license expires at the end of the day, in the month and year stated in the license. Except for subsection (i)(5) of this section, upon payment of the fee required by §289.204 of this title and if the agency does not deny the renewal in accordance with §289.252(x)(7) of this title, the specific license will be administratively renewed. The requirements in this subsection are subject to the provisions of Government Code §2001.054.

(2) If the fee is not paid and the license is not renewed in accordance with paragraph (1) of this subsection, the license expires, and the licensee is in violation of the rules and is subject to administrative penalties in accordance with §289.205 of this title.

(A) If the licensee pays the fee required by §289.204 of this title within 30 days after expiration of the license, the license will be reinstated and the licensee will not be required to file an application in accordance with subsection (d) of this section.

(B) If the licensee fails to pay the fee within 30 days after expiration of the license, the licensee shall file an application in accordance with subsection (d) of this section.

(3) Expiration of the specific license does not relieve the licensee of the requirements of this chapter.

(4) All license provisions continue in effect beyond the expiration date with respect to possession of radioactive material until the agency notifies the former licensee in writing that the provisions of the license are no longer binding. During this time, the former licensee shall:

(A) be limited to actions involving radioactive material that are related to decommissioning; and

(B) continue to control entry to restricted areas until the location(s) is suitable for release for unrestricted use in accordance with the requirements of paragraph (6) of this subsection.

(5) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the agency in writing and either begin decommissioning its site, or any separate buildings or outdoor areas that contain residual radioactivity in accordance with the closure plan in subsection (f)(1)(B) of this section, so that the buildings or outdoor areas are suitable for release in accordance with paragraph (6) of this subsection if:

(A) the license has expired in accordance with paragraph (1) of this subsection; or

(B) the licensee has decided to permanently cease principal activities, as defined in subsection (c)(24) of this section, at the entire site or in any separate building or outdoor area; or

(C) no principal activities have been conducted for a period of 24 months in any building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with agency requirements.

(6) Outdoor areas are considered suitable for release for unrestricted use if the following limits are not exceeded.

(A) The concentration of radium-226 or radium-228 in soil, averaged over any 100 square meters (m^2), shall not exceed the background level by more than:

(*i*) 5 picocuries per gram (pCi/g) (0.185 becquerel per gram (Bq/g)), averaged over the first 15 cm of soil below the surface; and

(*ii*) 15 pCi/g (0.555 Bq/g), averaged over 15 cm thick layers of soil more than 15 cm below the surface.

(B) The contamination of vegetation shall not exceed 5 pCi/g (0.185 Bq/g), based on dry weight, for radium-226 or radium-228.

(C) The concentration of natural uranium in soil, with no daughters present, averaged over any 100 m^2, shall not exceed the background level by more than:

(*i*) 30 pCi/g (1.11 Bq/g), averaged over the top 15 cm of soil below the surface; and

(*ii*) 150 pCi/g (5.55 Bq/g), average concentration at depths greater than 15 centimeters below the surface so that no individual member of the public will receive an effective dose equivalent in excess of 100 mrem (1 mSv) per year.

(7) Coincident with the notification required by paragraph (5) of this subsection, the licensee shall maintain in effect all decommissioning financial security established by the licensee in accordance with subsection (m) of this section in conjunction with a license issuance or renewal or as required by this section. The amount of the financial security shall be increased, or may be decreased, as appropriate, with agency approval, to cover the detailed cost estimate for decommissioning established in accordance with paragraph (13)(E) of this subsection.

(8) In addition to the provisions of paragraph (7) of this subsection, each licensee shall submit an updated closure plan to the agency within 12 months of the notification required by paragraph (5) of this subsection. The updated closure plan shall meet the requirements of subsections (f)(1)(B) and (m) of this section. The updated closure plan shall describe the actual conditions of the facilities and site and the proposed closure activities and procedures.

(9) The agency may grant a request to delay or postpone initiation of the decommissioning process if the agency determines that such relief is not detrimental to the occupational and public health and safety and is otherwise in the public interest. The request shall be submitted no later than 30 days before notification in accordance with paragraph (5) of this subsection. The schedule for decommissioning in paragraph (5) of this subsection may not begin until the agency has made a determination on the request.

(10) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(A) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(B) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(C) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(D) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(11) The agency may approve an alternate schedule for submittal of a decommissioning plan required in accordance with paragraph (5) of this subsection if the agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the occupational and public health and safety and is otherwise in the public interest.

(12) The procedures listed in paragraph (10) of this subsection may not be carried out prior to approval of the decommissioning plan.

(13) The proposed decommissioning plan for the site or separate building or outdoor area shall include:

(A) a description of the conditions of the site, separate buildings, or outdoor area sufficient to evaluate the acceptability of the plan;

(B) a description of planned decommissioning activities;

(C) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(D) a description of the planned final radiation survey;

(E) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate decommissioning; and

(F) for decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in paragraph (17) of this subsection.

(14) The proposed decommissioning plan will be approved by the agency if the information in the plan demonstrates that the decommissioning will be completed as soon as practicable and that the occupational health and safety of workers and the public will be adequately protected.

(15) Except as provided in paragraph (17) of this subsection, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(16) Except as provided in paragraph (17) of this subsection, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(17) The agency may approve a request for an alternate schedule for completion of decommissioning of the site or separate buildings or outdoor areas and the license termination if appropriate, if the agency determines that the alternative is warranted by the consideration of the following:

(A) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(B) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period; and

(C) other site-specific factors that the agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural groundwater restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(18) As the final step in decommissioning, the licensee shall:

(A) certify the disposition of all radioactive material, including accumulated byproduct material;

(B) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in accordance with paragraph [6] of this subsection. The licensee shall, as appropriate:

(*i*) report the following levels:

(*I*) gamma radiation in units of microroentgen per hour (μR/hr) (millisieverts per hour (mSv/hr)) at 1 meter (m) from surfaces;

(*II*) radioactivity, including alpha and beta, in units of disintegrations per minute (dpm) or microcuries (μCi) (megabecquerels (MBq)) per 100 square centimeters (cm^2) for surfaces;

(*III*) μCi (MBq) per milliliter for water; and

(*IV*) picocuries (pCi) (becquerels (Bq)) per gram (g) for solids such as soils or concrete; and

(*ii*) specify the manufacturer's name, and model and serial number of survey instrument(s) used and certify that each instrument is properly calibrated and tested.

[19] The agency will provide written notification to specific licensees, including former licensees with license provisions continued in effect beyond the expiration date in accordance with paragraph [4] of this subsection, that the provisions of the license are no longer binding. The agency will provide such notification when the agency determines that:

(A) radioactive material has been properly disposed;

(B) reasonable effort has been made to eliminate residual radioactive contamination, if present;

(C) a radiation survey has been performed that demonstrates that the premises are suitable for release in accordance with agency requirements;

(D) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the requirements of paragraph [6] of this subsection;

(E) all records required by §289.202(nn)(2) of this title have been submitted to the agency;

(F) the licensee has paid any outstanding fees required by §289.204 of this title and has resolved any outstanding notice(s) of violation issued to the licensee;

(G) the licensee has met the applicable technical and other requirements for closure and reclamation of a byproduct material disposal site; and

(H) the United States Nuclear Regulatory Commission (NRC) has made a determination that all applicable standards and requirements have been met.

(20) Licenses for uranium recovery and/or byproduct material disposal are exempt from paragraphs (5)(C), (8), and (9) of this subsection with respect to reclamation of byproduct material impoundments and/or disposal areas. Timely reclamation plans for byproduct material disposal areas shall be submitted and approved in accordance with subsection (o)(16)-(27) of this section.

(21) A licensee may request that a subsite or a portion of a licensed site be released for unrestricted use before full license termination as long as release of the area of concern will not adversely impact the remaining unaffected areas and will not be recontaminated by ongoing authorized activities. When the licensee is confident that the area of concern will be acceptable to the agency for release for unrestricted use, a written request for release for unrestricted use and agency confirmation of closeout work performed shall be submitted to the agency. The request should include a comprehensive report, accompanied by survey and sample results that show contamination is less than the limits specified in paragraph (6) of this subsection and an explanation of how ongoing authorized activities will not adversely affect the area proposed to be released. Upon confirmation by the agency that the area of concern is releasable for unrestricted use, the licensee may apply for a license amendment, if required.

(i) Technical renewal of licenses.

(1) Application for a technical renewal of specific licenses shall be filed in accordance with subsections (d)(1)-(5) and (f)(1) of this section. Application for a technical renewal of a specific license shall be filed by the date specified on the license. If the licensee fails to apply for a technical renewal and fails to pay the fee required by §289.204 of this title, the license expires and the licensee shall comply with the requirements of subsection (h) of this section. In any application for renewal, the applicant may incorporate drawings by clear and specific reference (for example, title, date and unique number of drawing), if no modifications have been made since previously submitted.

(2) In any case in which a licensee, prior to expiration of the existing license, has filed a request in proper form for a technical renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the agency. In any case in which a licensee, not more than 30 days after the expiration of an existing license, has filed an application for technical renewal or for a new license authorizing the same activities and paid the fee required by §289.204 of this title, the agency may reinstate the license and extend the expiration until the request has been finally determined by the agency.

(3) An application for technical renewal of a license will be approved if the agency determines that the requirements of subsection (e) of this section have been satisfied.

(4) When the date for administrative renewal in accordance with subsection (h)(1) of this section and the date for the technical renewal in accordance with paragraph (1) of this subsection occur at the same time, the license will be renewed if the fee required by §289.204 of this title is paid, the technical renewal is approved by the agency in accordance with paragraph (3) of this subsection, and the agency does not deny the renewal in accordance with §289.252(x)(7) of this title.

(5) When the date for the administrative renewal in accordance with subsection (h)(1) of this section and the date for the technical renewal in accordance with paragraph (1) of this subsection occur at the same time, the specific license renewal may be denied by the agency if any one of the following conditions apply:

(A) the fee required by §289.204 of this title is not paid;

(B) the agency denies the renewal in accordance with §289.252(x)(7) of this title; or

(C) the agency does not approve the technical renewal in accordance with paragraph (3) of this subsection.

(6) Expiration of the specific license does not relieve the former licensee of the requirements of this chapter.

(7) The requirements in this subsection are subject to the provisions of Government Code, §2001.054.

(j) Amendment of licenses at request of licensee. Requests for amendment of a license shall be filed in accordance with subsection (d) of this section and §289.252(d)(1)-(3) of this title. Such requests shall be signed by the RSO and specify how the licensee desires the license to be amended and the basis for such amendment.

(k) Agency action on applications to renew or amend. In considering a request by a licensee to renew or amend a license, the agency will apply the appropriate criteria in subsections (e) and (f) of this section.

(l) Transfer of material.

(1) No licensee shall transfer radioactive material except as authorized in accordance with this chapter.

(2) Except as otherwise provided in a license and subject to the provisions of paragraphs (3) and (4) of this subsection, any licensee may transfer radioactive material:

(A) to the agency after receiving prior approval from the agency;

(B) to the United States Department of Energy;

(C) to any person exempt from the licensing requirements of the Act and these requirements or exempt from the licensing requirements of the NRC or an agreement state, to the extent permitted by these exemptions;

(D) to any person authorized to receive such material in accordance with terms of a general license or its equivalent, a specific license or equivalent licensing document issued by the agency, NRC, any agreement state, any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency of the federal government, or the agency;

(E) to any person abroad pursuant to an export license issued under Title 10, Chapter 1, CFR Part 110; or

(F) as otherwise authorized by the agency in writing.

(3) Before transferring radioactive material to a specific licensee of the agency, NRC, an agreement state, a licensing state, or to a general licensee who is required to register with the agency, the licensee transferring the radioactive material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(4) The following methods for the verification of paragraph (3) of this subsection are acceptable:

(A) the transferor may possess and have read a current copy of the transferee's specific license or registration certificate;

(B) the transferor may possess a written certification by the transferee that the transferee is authorized by the license or certificate of registration to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(C) for emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed in writing within ten days; or

(D) when none of the methods of verification described in subparagraphs (A)-(C) of this paragraph are readily available or when a transferor desires to verify that information received by one of these methods is correct or up-to-date, the transferor may obtain and record confirmation from the agency, or the NRC, that the transferee is licensed to receive the radioactive material.

(5) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of §289.257 of this title.

(m) Financial security requirements.

(1) Financial security for decontamination, decommissioning, reclamation, restoration, disposal, and any other requirements of the agency shall be established by each licensee prior to the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of buildings and the site and for the reclamation of any byproduct material disposal areas. The amount of funds to be ensured by such security arrangements shall be based on agency-approved cost estimates in an agency-approved closure plan for:

(A) decontamination and decommissioning of buildings and the site to levels that allow unrestricted use of these areas upon decommissioning; and

(B) the reclamation of byproduct material disposal areas in accordance with technical criteria delineated in subsection (o) of this section.

(2) The licensee shall submit this closure plan in conjunction with an environmental report that addresses the expected environmental impacts of the licensee's operation, decommissioning and reclamation, and evaluates alternatives for mitigating these impacts.

(3) The security shall also cover the payment of the charge for long-term surveillance and control for byproduct material disposal areas required by subsection (n)(3) of this section.

(4) In establishing specific security arrangements, the licensee's cost estimates must take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the agency may accept financial securities that have been consolidated with financial or security arrangements established to meet requirements of other federal or state agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance and control, provided such arrangements are considered adequate to satisfy these requirements and that the portion of the security that covers the decommissioning and reclamation of the buildings, site, and byproduct material disposal areas, and the long-term funding charge is clearly identified and committed for use in accomplishing these activities.

(5) The security shall be continuous for the term of the license and shall be payable in the State of Texas to the Radiation and Perpetual Care Account.

(6) The licensee's security mechanism will be reviewed annually by the agency to assure that sufficient funds would be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of security liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs.

(7) Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of security liability shall be retained until final compliance with the reclamation plan is determined. This will yield a security that is at least sufficient at all times to cover the costs of decommissioning and reclamation of the areas that are expected to be disturbed before the next license technical renewal. The term of the security mechanism shall be open ended. This assurance would be provided with a security instrument that is written for a specified period of time (for example, five years) yet which shall be automatically renewed unless the security notifies the agency and the licensee some reasonable time (for example, 90 days) prior to the renewal date of their intention not to renew. In such a situation, the security requirement still exists and the licensee would be required to submit an acceptable replacement security within a brief period of time to allow at least 60 days for the agency to collect.

(8) Proof of forfeiture shall not be necessary to collect the security so that in the event that the licensee could not provide an acceptable replacement security within the required time, the security shall be automatically collected prior to its expiration. The conditions described above would have to be clearly stated on any security instrument, and shall be agreed upon by all parties.

(9) Self-insurance, or any arrangement that essentially constitutes self insurance (for example, a contract with a state or federal agency), will not satisfy the security requirement since this provides no additional assurance other than that which already exists through license requirements.

(n) Long-term care and maintenance requirements.

(1) Unless otherwise provided by the agency, each licensee licensed in accordance with this part for disposal of byproduct material shall make payments into the Radiation and Perpetual Care Account in amounts specified by the agency. The agency shall make such determinations on a case-by-case basis.

(2) The final disposition of byproduct material should be such that the need for ongoing active maintenance is eliminated to the maximum extent practicable.

(3) A minimum charge of $250,000 (1978 dollars) or more, if demonstrated as necessary by the agency, shall be paid into the Radiation and Perpetual Care Account to cover the costs of long-term care and maintenance. The total charge shall be paid prior to the termination of a license. With agency approval, the charge may be paid in installments. The total or unpaid portion of the charge shall be covered during the term of the license by additional security meeting the requirements of subsection (m) of this section. If site surveillance, control, or maintenance requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater (for example, if fencing or monitoring is determined to be necessary), the agency may specify a higher charge. The total charge shall be such that, with an assumed 1.0% annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site care, surveillance, and where necessary, maintenance. Prior to actual payment, the total charge will be adjusted annually for inflation. The inflation rate to be used is that indicated by the change in the Consumer Price Index published by the United States Department of Labor, Bureau of Labor Statistics.

(4) The requirements of this subsection shall apply only to those sites whose ownership is subject to being transferred to the state or the federal government. The total amount of funds collected by the agency in accordance with this subsection shall be transferred to the federal government if title and custody of the byproduct material disposal site is transferred to the federal government upon termination of the license.

(o) Technical requirements.

(1) Byproduct material handling and disposal systems shall be designed to accommodate full-capacity production over the lifetime of the facility. When later expansion of systems or operations may be likely, capability of the disposal system to be modified to accommodate increased quantities without degradation in long-term stability and other performance factors shall be evaluated.

(2) In selecting among alternative byproduct material disposal sites or judging the adequacy of existing sites, the following site features which would assure meeting the broad objective of isolating the tailings and associated contaminants without ongoing active maintenance shall be considered:

(A) remoteness from populated areas;

(B) hydrogeologic and other environmental conditions conducive to continued immobilization and isolation of contaminants from usable groundwater sources; and

(C) potential for minimizing erosion, disturbance, and dispersion by natural forces over the long term.

(3) The site selection process shall be an optimization to the maximum extent reasonably achievable in terms of these site features.

(4) In the selection of disposal sites, primary emphasis shall be given to isolation of the byproduct material, a matter having long-term impacts, as opposed to consideration only of short-term convenience or benefits (e.g., minimization of transportation of land acquisition costs). While isolation of byproduct material will also be a function of both site and engineering design, overriding consideration shall be given to siting features.

(5) Byproduct material should be disposed of in a manner such that no active maintenance is required to preserve conditions of the site.

(6) The applicant's environmental report shall evaluate alternative sites and disposal methods and shall consider disposal of byproduct material by placement below grade. Where full below grade burial is not practicable, the size of retention structures, and size and steepness of slopes associated with exposed embankments shall be minimized by excavation to the maximum extent reasonably achievable or appropriate given the geologic and hydrologic conditions at a site. In these cases, it shall be demonstrated that an above grade disposal program will provide reasonably equivalent isolation of the byproduct material from natural erosional forces.

(7) To avoid proliferation of small waste disposal sites and thereby reduce perpetual surveillance obligations, byproduct material from in situ extraction operations, such as residues from solution evaporation or contaminated control processes, and wastes from small remote above ground extraction operations shall be disposed of at existing large mill tailings disposal sites; unless, considering the nature of the wastes, such as their volume and specific activity, and the costs and environmental impacts of transporting the wastes to a large disposal site, such offsite disposal is demonstrated to be impracticable or the advantages of onsite burial clearly outweigh the benefits of reducing the perpetual surveillance obligations.

(8) The following site and design requirements shall be adhered to whether byproduct material is disposed of above or below grade:

(A) the upstream rainfall catchment areas shall be minimized to decrease erosion potential by flooding that could erode or wash out sections of the byproduct material disposal area;

(B) the topographic features shall provide good wind protection;

(C) the embankment and cover slopes shall be relatively flat after final stabilization to minimize erosion potential and to provide conservative factors of safety assuring long term stability. The objective should be to contour final slopes to grades that are as close as possible to those that would be provided if byproduct material was disposed of below grade. Slopes shall not be steeper than 5 horizontal to 1 vertical (5h:1v), except as specifically authorized by the agency. Where steeper slopes are proposed, reasons why a slope steeper than 5h:1v would be as equally resistant to erosion shall be provided, and compensating factors and conditions that make such slopes acceptable shall be identified;

(D) a full self-sustaining vegetative cover shall be established or rock cover employed to reduce wind and water erosion to negligible levels;

(E) where a full vegetative cover is not likely to be self-sustaining due to climatic conditions, such as in semi-arid and arid regions, rock cover shall be employed on slopes of the impoundment system. The agency will consider relaxing this requirement for extremely gentle slopes, such as those that may exist on the top of the pile;

(F) the following factors shall be considered in establishing the final rock cover design to avoid displacement of rock particles by human and animal traffic or by natural processes, and to preclude undercutting and piping:

(*i*) shape, size, composition, gradation of rock particles (excepting bedding material, average particles size shall be at least cobble size or greater);

(*ii*) rock cover thickness and zoning of particles by size; and

(*iii*) steepness of underlying slopes.

(G) individual rock fragments shall be dense, sound, and resistant to abrasion, and shall be free from cracks, seams, and other defects that would tend to unduly increase their destruction by erosion and weathering action. Local rock materials are permissible provided the characteristics under local climatic conditions indicate similar long-term performance as a protective layer. Weak, friable, or laminated aggregate may not be used;

(H) rock covering of slopes may not be required where top covers are very thick (on the order of 10 m or greater); impoundment slopes are very gentle (on the order of 10h:1v or less); bulk cover materials have inherently favorable erosion resistance characteristics; there is negligible drainage catchment area upstream of the pile; and there is good wind protection;

(I) all impoundment surfaces shall be contoured to avoid areas of concentrated surface runoff or abrupt or sharp changes in slope gradient. In addition to rock cover on slopes, areas toward which surface runoff might be directed shall be well protected with substantial rock cover (riprap). In addition to providing for stability of the impoundment system itself, overall stability, erosion potential, and geomorphology of surrounding terrain shall be evaluated to assure that there are no ongoing or potential processes, such as gully erosion, which would lead to impoundment instability;

(J) the impoundment shall not be located near a capable fault that could cause a maximum credible earthquake larger than that which the impoundment could reasonably be expected to withstand; and

(K) the impoundment should be designed to incorporate features that will promote deposition. Design features that promote deposition of sediment suspended in any runoff which flows into the impoundment area might be utilized. The object of such a design feature would be to enhance the thickness of cover over time.

(9) Groundwater protection. The following groundwater protection requirements and those in paragraphs (10) and (11) of this subsection and subsection (g) of this section apply during operations and until closure is completed. Groundwater monitoring to comply with these standards is required by paragraphs (28) and (29) of this subsection.

(A) The primary groundwater protection standard is a design standard for surface impoundments used to manage byproduct material. Unless exempted under paragraph (9)(C) of this subsection, surface impoundments (except for an existing portion) shall have a liner that is designed, constructed, and installed to prevent any migration of wastes out of the impoundment to the adjacent subsurface soil, groundwater, or surface water at any time during the active life (including the closure period) of the impoundment. If the liner is constructed of materials that may allow wastes to migrate into the liner during the active life of the facility, impoundment closure shall include removal or decontamination of all waste residues, contaminated containment system components (liners, etc.), contaminated subsoils, and structures and equipment contaminated with waste and leachate. For impoundments that will be closed with the liner material left in place, the liner shall be constructed of materials that can prevent wastes from migrating into the liner during the active life of the facility.

(B) The liner required by subparagraph (A) of this paragraph shall be:

(*i*) constructed of materials that have appropriate chemical properties and sufficient strength and thickness to prevent failure due to pressure gradients (including static head and external hydrogeologic forces), physical contact with the waste or leachate to which they are exposed, climatic conditions, the stress of installation, and the stress of daily operation;

(*ii*) placed upon a foundation or base capable of providing support to the liner and resistance to pressure gradients above and below the liner to prevent failure of the liner due to settlement, compression, or uplift; and

(*iii*) installed to cover all surrounding earth likely to be in contact with the wastes or leachate.

(C) The applicant or licensee will be exempted from the requirements of subparagraph (A) of this paragraph if the agency finds, based on a demonstration by the applicant or licensee, that alternate design and operating practices, including the closure plan, together with site characteristics will prevent the migration of any hazardous constituents into groundwater or surface water at any future time. In deciding whether to grant an exemption, the agency will consider:

(*i*) the nature and quantity of the wastes;

(*ii*) the proposed alternate design and operation;

(*iii*) the hydrogeologic setting of the facility, including the attenuative capacity and thickness of the liners and soils present between the impoundment and groundwater or surface water; and

(*iv*) all other factors that would influence the quality and mobility of the leachate produced and the potential for it to migrate to groundwater or surface water.

(D) A surface impoundment shall be designed, constructed, maintained, and operated to prevent overtopping resulting from normal or abnormal operations, overfilling, wind and wave actions, rainfall, or run-off; from malfunctions of level controllers, alarms, and other equipment; and from human error.

(E) When dikes are used to form the surface impoundment, the dikes shall be designed, constructed, and maintained with sufficient structural integrity to prevent massive failure of the dikes. In ensuring structural integrity, it shall not be presumed that the liner system will function without leakage during the active life of the impoundment.

(10) Byproduct materials shall be managed to conform to the following secondary groundwater protection requirements.

(A) Hazardous constituents, as defined in subsection (c)(16) of this section, entering the groundwater from a licensed site shall not exceed the specified concentration limits in the uppermost aquifer beyond the point of compliance during the compliance period.

(B) Specified concentration limits are those limits established by the agency as indicated in subparagraph (G) of this paragraph.

(C) The agency will also establish the point of compliance and compliance period on a site-specific basis through license conditions and orders.

(D) When the detection monitoring established under paragraphs (28) and (29) of this section indicates leakage of hazardous constituents from the disposal area, the agency will perform the following:

(*i*) identify hazardous constituents;

(*ii*) establish concentration limits;

(*iii*) set the compliance period; and

(*iv*) may adjust the point of compliance if needed in accordance with developed data and site information regarding the flow of groundwater or contaminants.

(E) Even when constituents meet all three tests in the definition of hazardous constituent, the agency may exclude a detected constituent from the set of hazardous constituents on a site-specific basis if it finds that the constituent is not capable of posing a substantial present or potential hazard to human health or the environment. In deciding whether to exclude constituents, the agency will consider the following:

(*i*) potential adverse effects on groundwater quality, considering the following:

(*I*) physical and chemical characteristics of the waste in the licensed site, including its potential for migration;

(*II*) hydrogeological characteristics of the licensed site and surrounding land;

(*III*) quantity of groundwater and the direction of groundwater flow;

(*IV*) proximity of groundwater users and groundwater withdrawal rates;

(*V*) current and future uses of groundwater in the area;

(*VI*) existing quality of groundwater, including other sources of contamination and cumulative impact on the groundwater quality;

(*VII*) potential for human health risks caused by human exposure to waste constituents;

(*VIII*) potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and

(*IX*) persistence and permanence of potential adverse effects; and

(*ii*) potential adverse effects on quality of hydraulically-connected surface water, considering the:

(*I*) volume and physical and chemical characteristics of the byproduct material in the licensed site;

(*II*) hydrogeological characteristics of the licensed site and surrounding land;

(*III*) quantity and quality of groundwater and the direction of groundwater flow;

(*IV*) patterns of rainfall in the region;

(*V*) proximity of the licensed site to surface waters;

(*VI*) current and future uses of surface waters in the area and any water quality standards established for those surface waters;

(*VII*) existing quality of surface water, including potential impacts from other sources of contamination and the cumulative impact on surface water quality;

(*VIII*) potential for human health risks caused by human exposure to waste constituents;

(*IX*) potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and

(*X*) persistence and permanence of the potential adverse effects.

(F) In making any determinations under subparagraphs (E) and (H) of this paragraph about the use of groundwater in the area around the facility, the agency will consider any identification of underground sources of drinking water and exempted aquifers made by the United States Environmental Protection Agency (EPA) and the Texas Commission on Environmental Quality.

(G) At the point of compliance, the concentration of a hazardous constituent shall not exceed the following:

(*i*) the agency approved background concentration in the groundwater of the constituents listed in 10 CFR 40, Appendix A, Criterion 13;

(*ii*) the respective value given in subsection (q) of this section if the constituent is listed in the table and if the background level of the constituent is below the value listed; or

(*iii*) an alternate concentration limit established by the agency.

(H) Alternate concentration limits to background concentration or to the drinking water limits in subsection (q) of this section that present no significant hazard may be proposed by licensees for agency consideration. Licensees shall provide the basis for any proposed limits including consideration of practicable corrective actions, evidence that limits are as low as reasonably achievable, and information on the factors the agency shall consider. The agency will establish a site-specific alternate concentration limit for a hazardous constituent, as provided in subparagraph (G) of this paragraph, if it finds that the proposed limit is as low as reasonably achievable, after considering practicable corrective actions, and that the constituent will not pose a substantial present or potential hazard to human health or the environment as long as the alternate concentration limit is not exceeded. In making the present and potential hazard finding, the agency will consider the factors listed in subparagraph (D) of this paragraph.

(11) If the groundwater protection standards established under subparagraph (D) of this paragraph are exceeded at a licensed site, a corrective action program shall be put into operation as soon as is practicable, and in no event later than 18 months after the agency finds that the standards have been exceeded. The licensee shall submit the proposed corrective action program and supporting rationale for agency approval prior to putting the program into operation, unless otherwise directed by the agency. The licensee's proposed program shall address removing or treating in place any hazardous constituents that exceed concentration limits in groundwater between the point of compliance and downgradient licensed site boundary. The licensee shall continue corrective action measures to the extent necessary to achieve and maintain compliance with the groundwater protection standard. The agency will determine when the licensee may terminate corrective action measures based on data from the groundwater monitoring program and other information that provides reasonable assurance that the groundwater protection standard will not be exceeded.

(12) In developing and conducting groundwater protection programs, applicants and licensees shall also consider the following:

(A) installation of bottom liners. Where synthetic liners are used, a leakage-detection system shall be installed immediately below the liner to ensure detection of any major failures. This is in addition to the groundwater monitoring program conducted as provided in paragraph (29) of this subsection. Where clay liners are proposed or relatively thin, in situ clay soils are to be relied upon for seepage control, tests shall be conducted with representative tailings solutions and clay materials to confirm that no significant deterioration of permeability or stability properties will occur with continuous exposure of clay to byproduct material solutions. Tests shall be run for a sufficient period of time to reveal any effects that may occur;

(B) mill process designs that provide the maximum practicable recycle of solutions and conservation of water to reduce the net input of liquid to the byproduct material impoundment;

(C) dewatering of byproduct material solutions by process devices and/or in situ drainage systems. At new sites, byproduct material solutions shall be dewatered by a drainage system installed at the bottom of the impoundment to lower the phreatic surface and reduce the driving head of seepage, unless tests show byproduct material solutions are not amenable to such a system. Where in situ dewatering is to be conducted, the impoundment bottom shall be graded to assure that the drains are at a low point. The drains shall be protected by suitable filter materials to assure that drains remain free-running. The drainage system shall also be adequately sized to assure good drainage; and

(D) neutralization to promote immobilization of hazardous constituents.

(13) Technical specifications shall be prepared for installation of seepage control systems. A quality assurance, testing, and inspection program, which includes supervision by a qualified engineer or scientist, shall be established to assure that specifications are met. If adverse groundwater impacts or conditions conducive to adverse groundwater impacts occur due to seepage, action shall be taken to alleviate the impacts or conditions and restore groundwater quality to levels consistent with those before operations began. The specific seepage control and groundwater protection method, or combination of methods, to be used shall be worked out on a site-specific basis.

(14) In support of a byproduct material disposal system proposal, the applicant/licensee shall supply the following information:

(A) the chemical and radioactive characteristics of the waste solutions;

(B) the characteristics of the underlying soil and geologic formations particularly as they will control transport of contaminants and solutions. This shall include detailed information concerning extent, thickness, uniformity, shape, and orientation of underlying strata. Hydraulic gradients and conductivities of the various formations shall be determined. This information shall be gathered by borings and field survey methods taken within the proposed impoundment area and in surrounding areas where contaminants might migrate to groundwater. The information gathered on boreholes shall include both geologic and geophysical logs in sufficient number and degree of sophistication to allow determining significant discontinuities, fractures, and channeled deposits of high hydraulic conductivity. If field survey methods are used, they should be in addition to and calibrated with borehole logging. Hydrologic parameters such as permeability shall not be determined on the basis of laboratory analysis of samples alone. A sufficient amount of field testing (e.g., pump tests) shall be conducted to assure actual field properties are adequately understood. Testing shall be conducted to make possible estimates of chemisorption attenuation properties of underlying soil and rock; and

(C) location, extent, quality, capacity, and current uses of any groundwater at and near the site.

(15) If ore is stockpiled, methods shall be used to minimize penetration of radionuclides and other substances into underlying soils.

(16) In disposing of byproduct material, licensees shall place an earthen cover over the byproduct material at the end of the facility's operations and shall close the waste disposal area in accordance with a design that provides reasonable assurance of control of radiological hazards to the following:

(A) be effective for 1,000 years to the extent reasonably achievable and, in any case, for at least 200 years; and

(B) limit releases of radon-222 from uranium byproduct materials and radon-220 from thorium byproduct materials to the atmosphere so as not to exceed an average release rate of 20 picocuries per square meter per second (pCi/m^{2}s) to the extent practicable throughout the effective design life determined in accordance with subparagraph (A) of this paragraph. This average applies to the entire surface of each disposal area over a period of at least one year, but a period short compared to 100 years. Radon will come from both byproduct materials and cover materials. Radon emissions from cover materials should be estimated as part of developing a closure plan for each site. The standard, however, applies only to emissions from byproduct materials to the atmosphere.

(17) In computing required byproduct material cover thicknesses, moisture in soils in excess of amounts found normally in similar soils in similar circumstances shall not be considered. Direct gamma exposure from the byproduct material should be reduced to background levels. The effects of any thin synthetic layer shall not be taken into account in determining the calculated radon exhalation level. Cover shall not include materials that contain elevated levels of radium. Soils used for near-surface cover shall be essentially the same, as far as radioactivity is concerned, as that of surrounding surface soils. If non-soil materials are proposed as cover materials, the licensee shall demonstrate that such materials will not crack or degrade by differential settlement, weathering, or other mechanisms over the long term.

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

(18) As soon as reasonably achievable after emplacement of the final cover to limit releases of radon-222 from uranium byproduct material and prior to placement of erosion protection barriers of other features necessary for long-term control of the tailings, the licensee shall verify through appropriate testing and analysis that the design and construction of the final radon barrier is effective in limiting releases of radon-222 to a level not exceeding 20pCi/m^{2}s averaged over the entire pile or impoundment using the procedures described in Appendix B, method 115 of 40 CFR Part 61, or another method of verification approved by the agency as being at least as effective in demonstrating the effectiveness of the final radon barrier.

(19) When phased emplacement of the final radon barrier is included in the applicable reclamation plan, as defined in subsection c(25) of this section, the verification of radon-222 release rates required in paragraph (30) of this subsection shall be conducted for each portion of the pile or impoundment as the final radon barrier for that portion is emplaced.

(20) Within 90 days of the completion of all testing and analysis relevant to the required verification in paragraphs (30)(C) and (30)(D) of this subsection, the uranium recovery licensee shall report to the agency the results detailing the actions taken to verify that levels of release of radon-222 do not exceed 20 pCi/m^{2}s when averaged over the entire pile or impoundment. The licensee shall maintain records documenting the source of input parameters, including the results of all measurements on which they are based, the calculations and/or analytical methods used to derive values for input parameters, and the procedure used to determine compliance. These records shall be maintained until termination of the license and shall be kept in a form suitable for transfer to the custodial agency at the time of transfer of the site to the state or federal government in accordance with subsection p of this section.

(21) Near-surface cover materials may not include waste, rock, or other materials that contain elevated levels of radium. Soils used for near-surface cover shall be essentially the same, as far as radioactivity is concerned, as surrounding surface soils. This is to ensure that surface radon exhalation is not significantly above background because of the cover material itself.

(22) The design requirements for longevity and control of radon releases apply to any portion of a licensed and/or disposal site unless such portion contains a concentration of radium in land averaged over areas of 100 square meters (m^2), that, as a result of byproduct material, does not exceed the background level by more than:

(A) 5 picocuries per gram (pCi/g) of radium-226, or in the case of thorium byproduct material, radium-228, averaged over the first 15 centimeters (cm) below the surface; and

(B) 15 pCi/g of radium-226, or in the case of thorium byproduct material, radium-228, averaged over 15-cm thick layers more than 15 cm below surface.

(23) The licensee shall also address the nonradiological hazards associated with the waste in planning and implementing closure. The licensee shall ensure that disposal areas are closed in a manner that minimizes the need for further maintenance. To the extent necessary to prevent threats to human health and the environment, the licensee shall control, minimize, or eliminate post-closure escape of nonradiological hazardous constituents, leachate, contaminated rainwater, or waste decomposition products to groundwater or surface waters or to the atmosphere.

(24) For impoundments containing uranium byproduct materials, the final radon barrier shall be completed as expeditiously as practicable considering technological feasibility after the pile or impoundment ceases operation in accordance with a written reclamation plan, as defined in subsection (c)(25) of this section, approved by the agency, by license amendment. (The term "as expeditiously as practicable considering technological feasibility" includes "factors beyond the control of the licensee.") Deadlines for completion of the final radon barrier and applicable interim milestones shall be established as license conditions. Applicable interim milestones may include, but are not limited to, the retrieval of windblown byproduct material and placement on the pile and the interim stabilization of the byproduct material (including dewatering or the removal of freestanding liquids and recontouring). The placement of erosion protection barriers or other features necessary for long-term control of the byproduct material shall also be completed in a timely manner in accordance with a written reclamation plan approved by the agency by license amendment.

(25) The agency may approve by license amendment a licensee's request to extend the time for performance of milestones related to emplacement of the final radon barrier if, after providing an opportunity for public participation, the agency finds that the licensee has adequately demonstrated in the manner required in paragraph (18) of this subsection that releases of radon-222 do not exceed an average of 20 pCi/m^2s. If the delay is approved on the basis that the radon releases do not exceed 20 pCi/m^2s, a verification of radon levels, as required by paragraph (18) of this subsection, shall be made annually during the period of delay. In addition, once the agency has established the date in the reclamation plan for the milestone for completion of the final radon barrier, the agency may by license amendment extend that date based on cost if, after providing an opportunity for public participation, the agency finds that the licensee is making good faith efforts to emplace the final radon barrier, the delay is consistent with the definition of "available technology," and the radon releases caused by the delay will not result in a significant incremental risk to the public health.

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

(26) The agency may authorize by license amendment, upon licensee request, a portion of the impoundment to accept uranium byproduct material, or such materials that are similar in physical, chemical, and radiological characteristics to the uranium mill tailings and associated wastes already in the pile or impoundment, from other sources during the closure process. No such authorization will be made if it results in a delay or impediment to emplacement of the final radon barrier over the remainder of the impoundment in a manner that will achieve levels of radon-222 releases not exceeding 20 pCi/m^{2}s averaged over the entire impoundment. The verification required in paragraph (18) of this subsection may be completed with a portion of the impoundment being used for further disposal if the agency makes a final finding that the impoundment will continue to achieve a level of radon-222 release not exceeding 20 pCi/m^{2}s averaged over the entire impoundment. After the final radon barrier is complete except for the continuing disposal area, only byproduct material will be authorized for disposal, and the disposal will be limited to the specified existing disposal area. This authorization by license amendment will only be made after providing opportunity for public participation. Reclamation of the disposal area, as appropriate, shall be completed in a timely manner after disposal operations cease in accordance with paragraph (16) of this subsection. These actions are not required to be complete as part of meeting the deadline for final radon barrier construction.

(27) The licensee's closure plan shall provide reasonable assurance that institutional control will be provided for the length of time found necessary by the agency to ensure the requirements of paragraph (16) of this subsection are met.

(28) Prior to any major site construction, a preoperational monitoring program shall be conducted for one full year to provide complete baseline data on the site and its environs. Throughout the construction and operating phases of the project, an operational monitoring program shall be conducted to measure or evaluate compliance with applicable standards and rules; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

(29) The licensee shall establish a detection monitoring program needed for the agency to set the site-specific groundwater protection standards in paragraph (10)(D) of this subsection. For all monitoring under this paragraph, the licensee or applicant will propose, as license conditions for agency approval, which constituents are to be monitored on a site-specific basis. The data and information shall provide a sufficient basis to identify those hazardous constituents that require concentration limit standards and to enable the agency to set the limits for those constituents and compliance period. They may provide the basis for adjustments to the point of compliance. The detection monitoring program shall be in place when specified by the agency in orders or license conditions. Once groundwater protection standards have been established in accordance with paragraph (10)(D) of this subsection, the licensee shall establish and implement a compliance monitoring program. In conjunction with a corrective action program, the licensee shall establish and implement a corrective action monitoring program to demonstrate the effectiveness of the corrective actions. Any monitoring program required by this paragraph may be based on existing monitoring programs to the extent the existing programs can meet the stated objective for the program.

(30) Systems shall be designed and operated so that all airborne effluent releases are as low as is reasonably achievable. The primary means of accomplishing this shall be by means of emission controls. Institutional controls, such as extending the site boundary and exclusion area, may be employed to ensure that offsite exposure limits are met, but only after all practicable measures have been taken to control emissions at the source.

(A) During operations and prior to closure, radiation doses from radon emissions from surface impoundments of byproduct materials shall be kept as low as is reasonably achievable.

(B) Checks shall be made and logged hourly of all parameters which determine the efficiency of emission control equipment operation. It shall be determined whether or not conditions are within a range prescribed to ensure that the equipment is operating consistently near peak efficiency. Corrective action shall be taken when performance is outside of prescribed ranges. Effluent control devices shall be operative at all times during drying and packaging operations and whenever air is exhausting from the uranium dryer stack. Drying and packaging operations shall terminate when controls are inoperative. When checks indicate the equipment is not operating within the range prescribed for peak efficiency, actions shall be taken to restore parameters to the prescribed range. When this cannot be done without shutdown and repairs, drying and packaging operations shall cease as soon as practicable. Operations may not be restarted after cessation due to off-normal performance until needed corrective actions have been identified and implemented. All such cessations, corrective actions, and re-starts shall be reported to the agency in writing within ten days of the subsequent restart.

(C) To control dusting from byproduct material, that portion not covered by standing liquids shall be wetted or chemically stabilized to prevent or minimize blowing and dusting to the maximum extent reasonably achievable. This requirement may be relaxed if byproduct material are effectively sheltered from wind, as in the case of below-grade disposal. Consideration shall be given in planning byproduct material disposal programs to methods for phased covering and reclamation of byproduct material impoundments. To control dusting from diffuse sources, applicants/licensees shall develop written operating procedures specifying the methods of control that will be utilized.

(D) Uranium recovery facility operations producing or involving thorium byproduct material shall be conducted in such a manner as to provide reasonable assurance that the annual dose equivalent does not exceed 25 millirems (mrem) to the whole body, 75 mrem to the thyroid, and 25 mrem to any other organ of any member of the public as a result of exposures to the planned discharge of radioactive materials to the general environment, radon-220 and its daughters excepted.

(E) Byproduct materials shall be managed so as to conform to the applicable provisions of 40 CFR 440, as codified on January 1, 1983.

(31) Licensees/applicants may propose alternatives to the specific requirements in subsections (m)-(p) of this section. The alternative proposals may take into account local or regional conditions including geology, topography, hydrology, and meteorology.

(32) The agency may find that the proposed alternatives meet the agency's requirements if the alternatives will achieve a level of stabilization and containment of the sites concerned and a level of protection for the public health and safety and the environment from radiological and nonradiological hazards associated with the sites, which is equivalent to, to the extent practicable, or more stringent than the level that would be achieved by the requirements of subsections (m)-(p) of this section and the standards promulgated by EPA in 40 CFR Part 192, Subparts D and E.

(33) All site-specific licensing decisions based on the criteria in subsections (m)-(p) of this section, or alternatives proposed by licensees/applicants shall take into account the risk to the public health and safety and the environment with due consideration to the economic costs involved and any other factors the agency determines to be appropriate.

(34) Any proposed alternatives to the specific requirements in subsections (m)-(p) of this section shall meet the requirements of 10 CFR 150.31(d).

(35) No new site shall be located in a 100-year floodplain or wetland as defined in "Floodplain Management Guidelines for Implementing Executive Order 11988."

(p) Land ownership of byproduct material disposal sites.

(1) These criteria relating to ownership of byproduct material and their disposal sites apply to all licenses terminated, issued, or renewed after November 8, 1981.

(2) Unless exempted by NRC, title to land (including any affected interests therein) that is used for the disposal of byproduct material or that is essential to ensure the long-term stability of the disposal site and title to the byproduct material shall be transferred to the State of Texas or the United States prior to the termination of the license. Material and land transferred shall be transferred without cost to the State of Texas or the United States. In cases where no ongoing site surveillance will be required, surface land ownership transfer requirements may be waived. For licenses issued before November 8, 1981, NRC may take into account the status of the ownership of the land and interests therein, and the ability of a licensee to transfer title and custody thereof to the State.

(3) Any uranium recovery facility license shall contain terms and conditions as the agency determines necessary to assure that, prior to termination of the license, the licensee will comply with ownership requirements of this subsection for sites used for tailings disposal.

(4) For surface impoundments only, the applicant/licensee shall demonstrate a serious effort to obtain severed mineral rights and shall, in the event that fee simple title including all mineral rights cannot be obtained, provide notification in local public land records of the fact that the land is being used for the disposal of radioactive material and is subject to a NRC license prohibiting the disruption and disturbance of the tailings.

(5) If NRC, subsequent to title transfer, determines that use of the surface or subsurface estates, or both, of the land transferred to the state or federal government will not endanger the public health and safety or the environment, NRC may permit the use of the surface or subsurface estates, or both, of such land in a manner consistent with the provisions of this section. If NRC permits the use of such land, it will provide the person who transferred the land with the first refusal with respect to the use of such land.

(q) Maximum values for use in groundwater protection. The following is a list of the maximum concentration values to be used for groundwater protection.

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

Constituent or Property	Maximum (mg/l)	Concentration (pCi/l)
Arsenic	0.05	
Barium	1.0	
Cadmium	0.01	
Chromium	0.05	
Lead	0.05	
Mercury	0.002	
Selenium	0.01	
Silver	0.05	
Endrin 1,2,3,4,10,10-hexachloro-6, 7-expoxy-1,4,4a,5,6,7,8, 8a-octahydro-endo, endo-1,4:5,8-dimethanonaphthalene	0.0002	
Lindane 1,2,3,4,5, 6-hexachlorocyclohexane	0.004	
Methoxychlor 1,1,1-trichloro-2,2-bis-(p-methoxyphenyl) ethane	0.1	
Toxaphene Chlorinated camphene	0.005	
2,4-D (2,4, 5-Trichlorophenoxy) acetic acid	0.1	
Silvex 2-(2,4,5-Trichlorophenoxy) propionic acid	0.01	
Combined radium-226 and radium-228		5
Gross alpha-particle activity (excluding radon and uranium when producing uranium byproduct material or radon and thorium when producing thorium byproduct material)		15

Appendix C

TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • http://www.dshs.state.tx.us

May 27, 2005

Mr. Dennis Rathbun
Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Rathbun:

Enclosed is a copy of the final revision to the Texas Regulations for Control of Radiation, 25 Texas Administrative Code, §289.253 relating to Radiation Safety Requirements for Well Logging Service Operation and Tracer Studies that became effective April 29, 2003.

Please see the following table that identifies the specific items noted as a result of NRC's review of the proposed regulation per the NRC letter dated January 9, 2003, and the agency's responses.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

If you have any questions, please feel free to contact me at 512-834-6688, ext. 2239 or Cindy.Cardwell@dshs.state.tx.us.

Sincerely,

Cynthia C. Cardwell

Cynthia C. Cardwell, Manager
Radiation Policy, Standards, and Quality Assurance Group
Policy, Standards, and Quality Assurance Unit
Department of State Health Services

Final Revisions of Texas Regulations that
Incorporate Equivalent NRC Amendments into State Regulations

NRC Regulation	FR Notice (State Due Date)	RATS ID	Texas Regulation*	Final Texas Regulation (Effective Date)**
39.35(d)(1)	65 FR 20337 (05/17/03)	2000-1	289.253(i)(3) and 289.201(g)(5) and (6) Meets compatibility	04/29/03
39.41(f)	65 FR 20337 (05/17/03)	2000-1	289.253(l)(3) and 289.252(a)(2), ECS sources are included on specific licenses Meets compatibility	
39.53(b)	65 FR 20337 (05/17/03)	2000-1	289.253(y) The Railroad Commission of Texas (RRC) regulates oil and gas exploration/production including wells. RRC rules do not allow for uncased wells in Texas; therefore, it is not necessary to adopt this rule in Dept. of State Health Services requirements.	04/29/03
39.55(b)	65 FR 20337 (05/17/03)	2000-1	289.253(z) The RRC regulates oil and gas exploration/production including wells. RRC rules do not allow for uncased wells in Texas; therefore, it is not necessary to adopt this rule in Dept. of State Health Services requirements.	04/29/03
39.77(c)(1)(i)	65 FR 20337 (05/17/03)	2000-1	289.253(cc)(5)(A) Meets compatibility	04/29/03

* For generic legally binding requirements, mark Legally Binding Requirements with the effective date.
** The last column is used only when the regulations are final.

25 TEXAS ADMINISTRATIVE CODE

§289.201

General Provisions for Radioactive Material

Texas Regulations for Control of Radiation

(revisions effective April 29, 2003
and shown as shaded text)

		Page
§289.201(a)	Scope	201-1
§289.201(b)	Definitions	201-1
§289.201(c)	Exemptions	201-15
§289.201(d)	Records	201-16
§289.201(e)	Inspections	201-17
§289.201(f)	Tests	201-18
§289.201(g)	Tests for Leakage and/or Contamination of Sealed Sources	201-18
§289.201(h)	Additional Requirements	201-20
§289.201(i)	Violations	201-21
§289.201(j)	Impounding	201-21
§289.201(k)	Communications	201-21
§289.201(l)	Interpretations	201-21
§289.201(m)	Open Records	201-21
§289.201(n)	Mean Quality Factors and Absorbed Dose Equivalencies	201-23
§289.201(o)	Units of Activity	201-26

§289.201. General Provisions for Radioactive Material.

(a) Scope. Except as otherwise specifically provided, this section applies to all persons who receive, possess, use, transfer, or acquire any radioactive material, provided, however, that nothing in this section shall apply to any person to the extent such person is subject to regulation by the United States Nuclear Regulatory Commission (NRC) or to radioactive material in the possession of federal agencies. Attention is directed to the fact that regulation by the state of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and NRC and to Part 150 of NRC regulations (Title 10, Code of Federal Regulations (CFR), Part 150). A person who receives, possesses, uses, owns, transfers, or acquires radioactive material prior to receiving a license is subject to the requirements of this chapter.

(b) Definitions. The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

(1) Absorbed dose - The energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) Accelerator-produced material - Any material made radioactive by exposing it to the radiation from a particle accelerator.

(3) Act - Texas Radiation Control Act, Health and Safety Code, Chapter 401.

(4) Activity - The rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

(5) Adult - An individual 18 or more years of age.

(6) Agency - The Texas Department of Health.

(7) Agreement state - Any state with which NRC has entered into an effective agreement under §274b of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

(8) Airborne radioactive material - Any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(9) Airborne radioactivity area - A room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(A) in excess of the derived air concentrations (DACs) specified in Table I, Column 1 of §289.202(ggg)(2)(F) of this title (relating to Standards for Protection Against Radiation from Radioactive Material); or

(B) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC-hours.

(10) As low as is reasonably achievable (ALARA) - Making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of ionizing radiation and licensed sources of radiation in the public interest.

(11) Background radiation - Radiation from cosmic sources; non-technologically enhanced naturally occurring radioactive material, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents, such as Chernobyl, that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from sources of radiation regulated by the agency.

(12) Becquerel (Bq) - The SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

(13) Bioassay - The determination of kinds, quantities, or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of this chapter, "radiobioassay" is an equivalent term.

(14) Brachytherapy - A method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

(15) Byproduct material - Byproduct material is defined as:

(A) any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(B) the tailings or wastes produced by or resulting from the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes.

(16) Certificate of registration - A form of permission given by the agency to an applicant who has met the requirements for registration or mammography system certification set out in the Act and this chapter.

(17) Certification of mammography systems (state certification) - A form of permission given by the agency to an applicant who has met the requirements for mammography system certification set out in the Act and this chapter.

(18) Collective dose - The sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(19) Commercial - Having financial profit as the primary aim.

(20) Committed dose equivalent ($H_{T,50}$) - The dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(21) Committed effective dose equivalent ($H_{E,50}$) - The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum w_T, H_{T,50}$).

(22) Constraint (dose constraint) - A value above which specified licensee actions are required.

(23) Critical group - The group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(24) Curie (Ci) - A unit of measurement of radioactivity. One curie (Ci) is that quantity of radioactive material that decays at the rate of 3.7×10^{10} disintegrations per second (dps). Commonly used submultiples of the curie are the millicurie (mCi) and the microcurie (μCi). One mCi = 1×10^{-3} Ci = 3.7×10^{7} dps. One μCi = 1×10^{-6} Ci = 3.7×10^{4} dps. One nanocurie (nCi) = 1×10^{-9} Ci = 3.7×10^{1} dps. One picocurie (pCi) = 1×10^{-12} Ci = 3.7×10^{-2} dps.

(25) Decommission - To remove a facility or site safely from service and reduce residual radioactivity to a level that permits the following:

(A) release of the property for unrestricted use and/or termination of license; or

(B) release of the property under alternate requirements for license termination.

(26) Deep dose equivalent (H_d), that applies to external whole body exposure - The dose equivalent at a tissue depth of 1 centimeter (cm) (1,000 milligrams per square centimeter (mg/cm^2)).

(27) Depleted uranium - The source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(28) Distinguishable from background - The detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site, or, in the case of structures or equipment, in similar materials using adequate measurement technology, survey, and statistical techniques.

(29) Distribution - The physical conveyance and authorized transfer of commodities from producers to consumers and any intermediate persons involved in that conveyance.

(30) Dose - A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of this chapter, "radiation dose" is an equivalent term.

(31) Dose equivalent (H_T) - The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

(32) Dose limits - The permissible upper bounds of radiation doses established in accordance with this chapter. For purposes of this chapter, "limits" is an equivalent term.

(33) Effective dose equivalent (H_E) - The sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).

(34) Embryo/fetus - The developing human organism from conception until the time of birth.

(35) Entrance or access point - Any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed sources of radiation. This includes portals of sufficient size to permit human access, irrespective of their intended use.

(36) Exposure - The quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). The roentgen is the special unit of exposure. For purposes of this chapter, this term is used as a noun.

(37) Exposure rate - The exposure per unit of time.

(38) External dose - That portion of the dose equivalent received from any source of radiation outside the body.

(39) Extremity - Hand, elbow, arm below the elbow, foot, knee, and leg below the knee. The arm above the elbow and the leg above the knee are considered part of the whole body.

(40) Generally applicable environmental radiation standards - Standards issued by the United States Environmental Protection Agency (EPA) under the authority of the Atomic energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(41) Gray (Gy) - The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (J/kg) or 100 rad.

(42) High radiation area - An area, accessible to individuals, in which radiation levels from sources of radiation external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 millisievert (mSv)) in one hour at 30 cm from any source of radiation or from any surface that the radiation penetrates.

(43) Human use - The internal or external administration of radiation or radioactive material to human beings for healing arts purposes or research and/or development specifically authorized by the agency.

(44) Individual - Any human being.

(45) Individual monitoring - The assessment of:

(A) dose equivalent to an individual by the use of individual monitoring devices; or

(B) committed effective dose equivalent to an individual by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. (See the definition for DAC-hours in §289.202(c) of this title); or

(C) dose equivalent to an individual by the use of survey data.

(46) Individual monitoring devices - Devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this chapter, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices include, but are not limited to, film badges, thermoluminescence dosimeters (TLDs), optically stimulated luminescence dosimeters (OSLs), pocket ionization chambers (pocket dosimeters), electronic personal dosimeters, and personal air sampling devices.

(47) Inspection - An official examination and/or observation including, but not limited to, records, tests, surveys, and monitoring to determine compliance with the Act and rules, orders, requirements, and conditions of the agency.

(48) Internal dose - That portion of the dose equivalent received from radioactive material taken into the body.

(49) Ionizing radiation - Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. Ionizing radiation includes gamma rays and x rays, alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles.

(50) Land disposal facility - The land, buildings, and equipment that are intended to be used for the disposal of low-level radioactive waste (LLRW) into the subsurface of the land.

(51) Lens dose equivalent - The external dose equivalent to the lens of the eye at a tissue depth of 0.3 cm (300 mg/cm 2).

(52) License - A form of permission given by the agency to an applicant who has met the requirements for licensing set out in the Act and this chapter.

(53) Licensed material - Radioactive material received, possessed, used, or transferred under a general or specific license issued by the agency.

(54) Licensee - Any person who is licensed by the agency in accordance with the Act and this chapter.

(55) Licensing state - Any state with rules equivalent to the Suggested State Regulations for Control of Radiation relating to, and having an effective program for, the regulatory control of naturally occurring or accelerator-produced radioactive material (NARM) and has been designated as such by the Conference of Radiation Control Program Directors, Inc. For the purposes of evaluation and/or distribution of sealed sources, this includes Licensing State Status: Product Review Only.

(56) Lost or missing radioactive material - Radioactive material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(57) Low-level radioactive waste (LLRW) - Radioactive material that meets the following criteria:

(A) LLRW is radioactive material that is:

(*i*) discarded or unwanted and is not exempt by rule adopted under the Texas Radiation Control Act (Act), Health and Safety Code, §401.106;

(*ii*) waste, as that term is defined in Title 10, CFR, Part 61.2; and

(*iii*) subject to:

(*I*) concentration limits established in Title 10, CFR, Part 61.55, or compatible rules adopted by the agency or the Texas Commission on Environmental Quality (TCEQ), as applicable; and

(*II*) disposal criteria established in Title 10, CFR, or established by the agency or TCEQ, as applicable.

(B) LLRW does not include:

(*i*) high-level radioactive waste as defined by Title 10, CFR, Part 60.2;

(*ii*) spent nuclear fuel as defined by Title 10, CFR, Part 72.3;

(*iii*) byproduct material defined in the Act, Health and Safety Code, §401.003(3)(B);

(*iv*) naturally occurring radioactive material (NORM) waste that is not oil and gas NORM waste;

(*v*) oil and gas NORM waste; or

(*vi*) transuranics greater than 100 nanocuries per gram.

(58) Manufacture - To fabricate or mechanically produce.

(59) Member of the public - Any individual, except when that individual is receiving an occupational dose.

(60) Minor - An individual less than 18 years of age.

(61) Monitoring - The measurement of radiation, radioactive material concentrations, surface area activities, or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this chapter, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(62) NARM - Any naturally occurring or accelerator-produced radioactive material except source material or special nuclear material.

(63) Natural radioactivity - Radioactivity of naturally occurring nuclides whose location and chemical and physical form have not been altered by man.

(64) NRC - The United States Nuclear Regulatory Commission (NRC) or its duly authorized representatives.

(65) Occupational dose - The dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation from licensed/registered and unlicensed/unregistered sources of radiation, whether in the possession of the licensee/registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this chapter, from voluntary participation in medical research programs, or as a member of the public.

(66) Particle accelerator - Any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and designed to discharge the resultant particulate or other associated radiation at energies usually in excess of 1 MeV.

(67) Person - Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, local government, any other state or political subdivision or agency thereof, or any other legal entity, and any legal successor, representative, agent, or agency of the foregoing, other than NRC, and other than federal government agencies licensed or exempted by NRC.

(68) Personnel monitoring equipment (See definition for individual monitoring devices.)

(69) Pharmacist - An individual licensed by the Texas State Board of Pharmacy to compound and dispense drugs, prescriptions, and poisons.

(70) Physician - An individual licensed by the Texas State Board of Medical Examiners.

(71) Principal activities - Activities authorized by the license that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(72) Public dose - The dose received by a member of the public from exposure to sources of radiation released by a licensee, or to any other source of radiation under the control of a licensee/registrant. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this chapter, or from voluntary participation in medical research programs.

(73) Quality factor (Q) - The modifying factor listed in subsection (n)(1) and (2) of this section that is used to derive dose equivalent from absorbed dose.

(74) Quarter (calendar quarter) - A period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(75) Rad - The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram (erg/g) or 0.01 J/kg (0.01 gray).

(76) Radiation - One or more of the following:

(A) gamma and x rays; alpha and beta particles and other atomic or nuclear particles or rays;

(B) emission of radiation from any electronic device to such energy density levels as to reasonably cause bodily harm; or

(C) sonic, ultrasonic, or infrasonic waves from any electronic device or resulting from the operation of an electronic circuit in an electronic device in the energy range to reasonably cause detectable bodily harm.

(77) Radiation area - Any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 cm from the source of radiation or from any surface that the radiation penetrates.

(78) Radiation machine - Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(79) Radiation safety officer (RSO) - An individual who has a knowledge of and the authority and responsibility to apply appropriate radiation protection rules, standards, and practices, who must be specifically authorized on a radioactive material license, and who is the primary contact with the agency.

(80) Radioactive material - Any material (solid, liquid, or gas) that emits radiation spontaneously.

(81) Radioactive waste - As used in §289.254 of this title (relating to Licensing of Radioactive Waste Processing and Storage Facilities), this term is equivalent to LLRW.

(82) Radioactivity - The disintegration of unstable atomic nuclei with the emission of radiation.

(83) Radiobioassay (See definition for bioassay.)

(84) Registrant - Any person issued a certificate of registration by the agency in accordance with the Act and this chapter.

(85) Regulation (See definition for rule.)

(86) Regulations of the United States Department of Transportation (DOT) - The requirements in Title 49 CFR Parts 100-189.

(87) Rem - The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert (Sv)).

(88) Research and development - Research and development is defined as:

(A) theoretical analysis, exploration, or experimentation; or

(B) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

(89) Residual radioactivity - The radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Title 30, Texas Administrative Code, §336.334.

(90) Restricted area - An area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(91) Roentgen (R) - The special unit of exposure. One roentgen (R) equals 2.58×10^{-4}C/kg of air. (See definition for exposure.)

(92) Rule (as defined in the Government Code, Chapters 2001 and 2002, as amended) - Any agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedure or practice requirements of an agency. The term includes the amendment or repeal of a prior section but does not include statements concerning only the internal management or organization of any agency and not affecting private rights or procedures. The word "rule" was formerly referred to as "regulation."

(93) Sealed source - Radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions that are likely to be encountered in normal use and handling.

(94) Shallow dose equivalent (H_s) (that applies to the external exposure of the skin or an extremity) - The dose equivalent at a tissue depth of 0.007 cm (7 mg/cm^2) averaged over an area of 1 square centimeter (cm^2).

(95) SI - The abbreviation for the International System of Units.

(96) Sievert - The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(97) Site boundary - That line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

(98) Source material - Source material is defined as:

(A) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(B) ores that contain by right 0.05% or more of uranium, thorium, or any combination thereof; and

(C) does not include special nuclear material.

(99) Source of radiation - Any radioactive material, or any device or equipment emitting or capable of producing radiation.

(100) Special form radioactive material - Radioactive material that satisfies the following conditions.

(A) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(B) The piece or capsule has at least one dimension not less than 5 millimeters (mm) (0.2 inch); and

(C) It satisfies the requirements specified by NRC. A special form encapsulation designed in accordance with NRC requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with NRC requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet the requirements of this definition applicable at the time of its design or construction.

(101) Special nuclear material - Special nuclear material is defined as:

(A) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that NRC, in accordance with the provisions of the Atomic Energy Act of 1954, §51 as amended, determines to be special nuclear material, but does not include source material; or

(B) any material artificially enriched by any of the foregoing, but does not include source material.

(102) Special nuclear material in quantities not sufficient to form a critical mass--Uranium enriched in the isotope 235 in quantities not exceeding 350 grams (g) of contained uranium-235; uranium-233 in quantities not exceeding 200 g; plutonium in quantities not exceeding 200 g; or any combination of them in accordance with the following formula.

(A) For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity).

(B) For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175\,(\text{grams contained U}-235)}{350}+\frac{50\,(\text{grams U}-233)}{200}+\frac{50\,(\text{grams Pu})}{200}=1$$

(103) Special units - The conventional units historically used by licensees, for example, curie (activity), rad (absorbed dose), and rem (dose equivalent).

(104) Survey - An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and/or presence of sources of radiation. When appropriate, such survey includes, but is not limited to, tests, physical examination of location of materials and equipment, measurements of levels of radiation or concentration of radioactive material present, and evaluation of administrative and/or engineered controls.

(105) Termination - A release by the agency of the obligations and authorizations of the licensee under the terms of the license. It does not relieve a person of duties and responsibilities imposed by law.

(106) Test - A method of determining the characteristics or condition of sources of radiation or components thereof.

(107) Texas Regulations for Control of Radiation (TRCR) - All sections of Title 25 Texas Administrative Code (TAC), Chapter 289.

(108) Total effective dose equivalent (TEDE) - The sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(109) Total organ dose equivalent (TODE) - The sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in §289.202(rr)(1)(F) of this title.

(110) Transport index - The dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows:

(A) For non-fissile material packages, the number determined by multiplying the maximum radiation level in millisievert per hour (mSv/hr) at 1 meter (m) (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour (mrem/hr) at 1 m (3.3 feet); or

(B) For fissile material packages, the number determined by multiplying the maximum radiation level in mSv/hr at 1 m (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in mrem/hr at 1 m (3.3 feet), or, for criticality control purposes, the number obtained as described in 10 CFR 71.59, whichever is larger.

(111) Type A quantity - A quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in §289.257(s)(2) of this title (relating to Packaging and Transportation of Radioactive Material) or may be determined by procedures described in §289.257(s)(1)-(4) of this title.

(112) Type B quantity - A quantity of radioactive material greater than a type A quantity.

(113) Unrefined and unprocessed ore - Ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

(114) Unrestricted area (uncontrolled area) - An area, or access to which is neither limited nor controlled by the licensee. For purposes of this chapter, "uncontrolled area" is an equivalent term.

(115) Very high radiation area - An area, accessible to individuals, in which radiation levels from sources of radiation external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at 1 meter (m) from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, Sv and rem.

(116) Veterinarian - An individual licensed by the Texas Board of Veterinary Medical Examiners.

(117) Week - Seven consecutive days starting on Sunday.

(118) Whole body - For purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(119) Worker - An individual engaged in work under a license or certificate of registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

(120) Working level (WL) - Any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3 x 10^5 million electron volts (MeV) of potential alpha particle energy. The short-lived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

(121) Working level month (WLM) - An exposure to one working level for 170 hours -- 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

(122) Year - The period of time beginning in January used to determine compliance with the provisions of this chapter. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

(c) Exemptions.

(1) General provision. The agency may, upon application therefor or upon its own initiative, exempt a source of radiation or a kind of use or user from the requirements of this chapter if the agency determines that the exemption is not prohibited by law and will not result in a significant risk to public health and safety and the environment. In determining such exemptions, the agency will consider:

(A) state of technology;

(B) economic considerations in relation to benefits to the public health and safety; and

(C) other societal, socioeconomic, or public health and safety considerations.

(2) United States Department of Energy (DOE) contractors and NRC contractors. Any DOE contractor or subcontractor and any NRC contractor or subcontractor of the following categories operating within Texas is exempt from this chapter, with the exception of §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), to the extent that such contractor or subcontractor under that individual's contract receives, possesses, uses, transfers, or acquires sources of radiation:

(A) prime contractors performing work for DOE at United States government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(B) prime contractors of DOE performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

(C) prime contractors of DOE using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

(D) any other prime contractor or subcontractor of DOE or of NRC when the state and NRC jointly determine that:

(*i*) the exemption of the prime contractor or subcontractor is authorized by law; and

(*ii*) in accordance with the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and the environment.

(d) Records.

(1) Each licensee shall maintain records showing the receipt, transfer, and disposal of all non-exempt sources of radiation.

(A) Records of receipt, transfer, and disposal of sources of radiation shall include as a minimum, the following information:

(*i*) a unique identification of each source of radiation including:

(*I*) manufacturer's name;

(*II*) isotope;

(*III*) activity; and

(*IV*) if available, sealed source serial number;

(*ii*) the date of receipt, transfer, or disposal of each source of radiation;

(*iii*) for the person transferring the source of radiation, the name of the transferee, the number of the transferee's radioactive material license authorizing possession of the material, and the regulatory agency issuing the license to the transferee; and

(*iv*) for the person receiving the source of radiation, the name of the transferor, the number of the transferor's radioactive material license authorizing possession of the material, and the regulatory agency issuing the license to the transferor.

(B) Records of receipt, transfer, and disposal shall be maintained by the licensee until disposal is authorized by the agency.

(2) Additional record requirements and retention periods are specified elsewhere in this chapter.

(3) All records required by this chapter shall be accurate and factual.

(4) Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

(5) Each record required by this chapter must be legible throughout the retention period specified by the agency. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, or specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(e) Inspections.

(1) The agency may enter public or private property at reasonable times to determine whether, in a matter under the agency's jurisdiction, there is compliance with the Act, the agency's rules, license conditions, and orders issued by the agency.

(2) Each licensee shall afford the agency, at all reasonable times, opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

(3) Each licensee shall make available to the agency for inspection, upon reasonable notice, records maintained in accordance with this chapter.

(f) Tests.

(1) Each licensee shall perform, upon instructions from the agency, or shall permit the agency to perform such reasonable tests as the agency deems appropriate or necessary including, but not limited to, tests of:

(A) sources of radiation;

(B) facilities wherein sources of radiation are used or stored;

(C) radiation detection and monitoring instruments; and

(D) other equipment and devices used in connection with utilization or storage of licensed sources of radiation.

(2) Each licensee is required to accept from the agency, samples collected from its facility(ies) or from areas that are radioactive as a result of its licensed activities.

(g) Tests for leakage and/or contamination of sealed sources.

(1) The licensee in possession of any sealed source shall assure that:

(A) each sealed source, except as specified in paragraph (2) of this subsection and §289.253(i) of this title (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee;

(B) each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the agency, or by NRC, an agreement state, or a licensing state after evaluation of information specified in §289.252(v) of this title (relating to Licensing of Radioactive Material);

(C) each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the agency, after evaluation of information specified in §289.252(v) of this title, or by NRC, an agreement state, or a licensing state;

(D) for each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee shall assure that the sealed source is tested for leakage or contamination before further use;

(E) tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 0.005 μCi (185 Bq) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted and at the nearest accessible point to the sealed source where contamination might accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position;

(F) the test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 0.001 μCi (37 Bq) of radon-222 in a 24-hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume, and time;

(G) tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 0.005 μCi (185 Bq) of a radium daughter that has a half-life greater than four days; and

(H) tests for leakage or contamination shall be performed using a leak test kit or method approved by the agency, NRC, an agreement state, or a licensing state;

(2) A licensee need not perform tests for leakage or contamination on the following sealed sources:

(A) sealed sources containing only radioactive material with a half-life of less than 30 days;

(B) sealed sources containing only radioactive material as a gas;

(C) sealed sources containing 100 μCi (3.7 megabecquerels (MBq)) or less of beta or gamma-emitting material or 10 μCi (370 kilobecquerels (kBq)) or less of alpha or neutron-emitting material;

(D) sealed sources containing only hydrogen-3 (tritium);

(E) seeds of iridium-192 encased in nylon ribbon; and

(F) sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used, and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.

(3) Analysis of tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the agency, NRC, an agreement state, or a licensing state, to perform such services.

(4) Test results shall be kept in units of microcurie or becquerel and maintained for inspection by the agency.

(5) The following shall be considered evidence that a sealed source is leaking:

(A) the presence of 0.005 μCi (185 becquerels Bq) or more of removable contamination on any test sample;

(B) leakage of 0.001 μCi (37 Bq) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium; or

(C) the presence of removable contamination resulting from the decay of 0.005 μCi (185 Bq) or more of radium.

(6) The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or transferred for disposal in accordance with §289.202 of this title.

(7) Reports of test results for leaking or contaminated sealed sources shall be made in accordance with §289.202(bbb) of this title.

(h) Additional requirements. The agency may, by rule, order, or condition of license or general license acknowledgment, impose upon any licensee such requirements in addition to those established in this chapter as it deems appropriate or necessary to minimize danger to public health and safety or property or the environment.

(i) Violations. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a misdemeanor and upon conviction, may be punished by fine or imprisonment or both, as provided by law.

(j) Impounding. Sources of radiation shall be subject to impounding in accordance with §401.068 of the Act and §289.205 of this title (relating to Hearing and Enforcement Procedures).

(k) Communications.

(1) Except where otherwise specified, all communications and reports concerning this chapter and applications filed under them should be addressed to the Bureau of Radiation Control, Texas Department of Health, 1100 West 49th Street, Austin, Texas, 78756-3189. Communications, reports, and applications may be delivered in person to the agency's office located at 8407 Wall Street, Austin, Texas.

(2) Documents transmitted to the agency will be deemed submitted on the date of the postmark, telegram, telefacsimile, or electronic media transmission.

(l) Interpretations. Except as specifically authorized by the agency in writing, no interpretation of the meaning of this chapter by any officer or employee of the agency other than a written interpretation by the Office of General Counsel, Texas Department of Health, will be considered binding upon the agency.

(m) Open records.

(1) Subject to the limitations provided in the Texas Public Information Act, Government Code, Chapter 552, all information and data collected, assembled, or maintained by the agency are public records open to inspection and copying during regular office hours.

(2) Any person who submits written information or data to the agency and requests that the information be considered confidential, privileged, or otherwise not available to the public under the Texas Public Information Act, shall justify such request in writing, including statutes and cases where applicable, addressed to the agency.

(A) Documents containing information that is claimed to fall within an exception to the Texas Public Information Act shall be marked to indicate that fact. Markings shall be placed on the document on origination or submission.

(*i*) The words "NOT AN OPEN RECORD" shall be placed conspicuously at the top and bottom of each page containing information claimed to fall within one of the exceptions.

(*ii*) The following wording shall be placed at the bottom of the front cover and title page, or first page of text if there is no front cover or title page:

"INFORMATION FALLING WITHIN EXCEPTION OF THE TEXAS PUBLIC INFORMATION ACT, GOVERNMENT CODE, CHAPTER 552 ---- CONFIDENTIAL

This document contains information submitted to the Texas Department of Health, Bureau of Radiation Control by

_____

(Name of Company)(Name of Submitter)

that is claimed to fall within the following exception to the Texas Public Information Act, Government Code, Chapter 552, Subchapter C _____

(Appropriate Subsection)

WITHHOLD FROM PUBLIC DISCLOSURE

_____

(Signature and Title)(Office)(Date)"

(B) The agency requests, whenever possible, that all information submitted under the claim of an exception to the Texas Public Information Act be extracted from the main body of the application and submitted as a separate annex or appendix to the application.

(C) Failure to comply with any of the procedures described in subparagraphs (A) and (B) of this paragraph may result in all information in the agency file being disclosed upon an open records request.

(3) The agency will determine whether information falls within one of the exceptions to the Texas Public Information Act. The Office of General Counsel will be queried as to whether or not there has been a previous determination that the information falls within one of the exceptions to the Texas Public Information Act. If there has been no previous determination and the agency believes that the information falls within one of the exceptions, an opinion of the Attorney General will be requested. If the agency agrees in writing to the request, the information shall not be open for public inspection unless the Attorney General's office subsequently determines that it does not fall within an exception.

(4) Requests for information.

(A) All requests for open records information must be in writing and refer to documents currently in possession of the agency.

(B) The agency will ascertain whether the information may be released or whether it falls within an exception to the Texas Public Information Act.

(*i*) The agency may take a reasonable period of time to determine whether information falls within one of the exceptions to the Texas Public Information Act.

(*ii*) If the information is determined to be public, it will be presented for inspection and/or copies of documents will be furnished within a reasonable period of time. A fee will be charged to recover agency costs for copies.

(C) Original copies of public records may not be removed from the agency. Under no circumstances shall material be removed from existing records.

(n) Mean quality factors and absorbed dose equivalencies.

(1) As used in this chapter, the quality factors for converting absorbed dose to dose equivalent are shown in the following table:

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

MEAN QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

*Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

(2) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in paragraph (1) of this subsection, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of this section, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from the following table to convert a measured tissue dose in rad (gray) to dose equivalent in rem (Sv).

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor** (Q)	Fluence per Unit Dose Equivalent* (neutrons $cm^{-2}rem^{-1}$)	Fluence per Unit Dose Equivalent* (neutrons $cm^{-2}Sv^{-1}$)
(thermal)	2.5×10^{-8}	2	980×10^{6}	980×10^{8}
	1.0×10^{-7}	2	980×10^{6}	980×10^{8}
	1.0×10^{-6}	2	810×10^{6}	810×10^{8}
	1.0×10^{-5}	2	810×10^{6}	810×10^{8}
	1.0×10^{-4}	2	840×10^{6}	840×10^{8}
	1.0×10^{-3}	2	980×10^{6}	980×10^{8}
	1.0×10^{-2}	2.5	$1,010 \times 10^{6}$	$1,010 \times 10^{8}$
	1.0×10^{-1}	7.5	170×10^{6}	170×10^{8}
	5.0×10^{-1}	11	39×10^{6}	39×10^{8}
	1.0	11	27×10^{6}	27×10^{8}
	2.5	9	29×10^{6}	29×10^{8}
	5.0	8	23×10^{6}	23×10^{8}
	7.0	7	24×10^{6}	24×10^{8}
	10	6.5	24×10^{6}	24×10^{8}
	14	7.5	17×10^{6}	17×10^{8}
	20	8	16×10^{6}	16×10^{8}
	40	7	14×10^{6}	14×10^{8}
	60	5.5	16×10^{6}	16×10^{8}
	1.0×10^{2}	4	20×10^{6}	20×10^{8}
	2.0×10^{2}	3.5	19×10^{6}	19×10^{8}
	3.0×10^{2}	3.5	16×10^{6}	16×10^{8}
	4.0×10^{2}	3.5	14×10^{6}	14×10^{8}

*Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

**Value of quality factor (Q) at the point where the DE is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

(o) Units of activity. For purposes of this chapter, activity is expressed in the special unit of curie (Ci) (Bq), or its multiples, or disintegrations or transformations per second (dps or tps).

(1) 1 Ci = 3.7×10^{10} dps or tps = 3.7×10^{10} (Bq) = 2.22×10^{12} disintegrations or transformations per minute (dpm or tpm).

(2) 1 Bq = 1 dps or tps.

25 TEXAS ADMINISTRATIVE CODE

§289.253

Radiation Safety Requirements for Well Logging Service Operation and Tracer Studies

Texas Regulations for Control of Radiation

(revisions effective April 29, 2003
and shown as shaded text)

		Page
§289.253(a)	Purpose	253-1
§289.253(b)	Scope	253-1
§289.253(c)	Definitions	253-1
§289.253(d)	Prohibitions	253-3
§289.253(e)	Limits on Levels of Radiation	253-4
§289.253(f)	Storage Precautions	253-5
§289.253(g)	Transport Precautions	253-5
§289.253(h)	Radiation Survey Instruments	253-5
§289.253(i)	Leak Testing of Sealed Sources	253-6
§289.253(j)	Quarterly Inventory	253-6
§289.253(k)	Utilization Records	253-7
§289.253(l)	Design and Performance Criteria for Sealed Sources Used in Well Logging Operations	253-7
§289.253(m)	Labeling	253-8
§289.253(n)	Inspection and Maintenance	253-9
§289.253(o)	Training Requirements	253-9
§289.253(p)	Operating, Safety, and Emergency Procedures	253-11
§289.253(q)	Personnel Monitoring	253-11
§289.253(r)	Radiation Safety Officer	253-11
§289.253(s)	Security	253-13
§289.253(t)	Handling Tools	253-13
§289.253(u)	Tracer Studies	253-13
§289.253(v)	Particle Accelerators	253-13
§289.253(w)	Radioactive Markers	253-13
§289.253(x)	Uranium Sinker Bars	253-13
§289.253(y)	Energy Compensation Source	253-13
§289.253(z)	Tritium Neutron Generator Target Source	253-14

25 TAC §289.253

Radiation Safety Requirements for Well Logging Service Operation and Tracer Studies (Continued)

		Page
§289.253(aa)	Radiation Surveys	253-14
§289.253(bb)	Records/Documents for Inspection by the Agency	253-15
§289.253(cc)	Notification of Incidents and Lost Sources; Abandoment Procedures for Irretrievable Sources	253-15
§289.253(dd)	Appendices	253-18
§289.253(dd)(1)	Subjects to be Included in Training Courses for Well Logging Service Operations and/or Tracer Studies	253-18
§289.253(dd)(2)	Additional Training for Individuals Performing Tracer Studies	253-20
§289.253(dd)(3)	Example of a Plaque for Identifying Wells Containing Sealed Sources of Radioactive Material Abandoned Downhole	253-20
§289.253(dd)(4)	Operating, Safety, and Emergency Procedures	253-22
§289.253(dd)(5)	Time Requirements for Record Keeping	253-23

§289.253. Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies.

(a) Purpose. This section establishes radiation safety requirements for persons using sources of radiation for well logging service operations, including radioactive markers, mineral exploration and tracer studies.

(b) Scope. This section applies to all licensees or registrants who use sources of radiation for well logging service operations, radioactive markers, mineral exploration and tracer studies. In addition to the requirements of this section, licensees and registrants are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Material), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.226 of this title (relating to Registration of Radiation Machine Use and Services), §289.229 of this title (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, and Simulators), §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation), §289.252 of this title (relating to Licensing of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(c) Definitions. The following words and terms when used in this section shall have the following meaning unless the context clearly indicates otherwise.

(1) Energy compensation source (ECS) - A small sealed source with an activity not exceeding 100 microcurie (μCi) (3.7 megabecquerel (MBq)) used within a logging tool or other tool components to provide a reference standard to maintain the tools calibration when in use.

(2) Field station (additional authorized use/storage location) - A facility where sources of radiation may be stored or used and from which equipment is dispatched to temporary job sites.

(3) Injection tool - A device used for subsurface or downhole controlled injection of radioactive tracer material.

(4) Logging assistant (equipment operator) - Any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by subsection (aa) of this section.

(5) Logging supervisor (field engineer) - The individual who provides personal supervision of the use of sources of radiation at temporary job sites.

(6) Logging tool - A device used subsurface to perform well logging.

(7) Mineral logging - Any logging performed for the purpose of mineral exploration other than oil or gas.

(8) Personal supervision - Guidance and instruction by the supervisor, who is physically present at the job site and in such proximity that visual contact can be maintained and immediate assistance given as required.

(9) Radiation safety officer - An individual named by the licensee or registrant and listed on the license or certificate of registration who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee and/or registrant; and who meets the requirements of subsection (r) of this section.

(10) Radioactive marker - Radioactive material placed subsurface or upon a structure intended for subsurface use for the purpose of depth determination or direction orientation.

(11) Residential location - Any area where structures in which people lodge or live are located, and the grounds on which these structures are located including, but not limited to, houses, apartments, condominiums, and garages.

(12) Service company - Any contracted or subcontracted company that is present at the temporary job site, specifically, that company to which the licensee's equipment is connected and that is exposed to radioactive material.

(13) Source holder - A housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source.

(14) Storage container - A container designed to provide radiation safety and security when sources of radiation are being stored.

(15) Temporary job site - A location where well logging or tracer studies are performed other than the specific location(s) listed on a license or certificate of registration.

(16) Tracer study - The release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the wellbore, at the wellhead, or adjacent formation.

(17) Transport container - A container that meets the requirements of the United States Department of Transportation (DOT) and is designed to provide radiation safety and security when sources of radiation are being transported.

(18) Tritium neutron generator target source - A tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

(19) Uranium sinker bar - A weight containing depleted uranium used to aid in the descent of a logging tool down toward the bottom of a wellbore.

(20) Wellbore - A drilled hole in which wireline service operations are performed.

(21) Well logging - All operations involving the lowering and raising of measuring devices or logging tools (that may or may not contain sources of radiation) into wellbores or cavities for the purpose of obtaining information about the well and/or adjacent formations.

(22) Wireline - An armored steel cable containing one or more electrical conductors used to lower and raise logging tools in the wellbore.

(23) Wireline service operation - Any mechanical service that is performed in the wellbore using devices that are lowered into the well on a wireline for purposes of evaluation.

(d) Prohibitions.

(1) No licensee shall perform well logging service operations with a sealed source(s) in any well or wellbore unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or land owner that specifies who will be responsible for ensuring the following requirements are met:

(A) a reasonable effort at recovery will be made in the event a sealed source is lost or lodged downhole;

(B) a person shall not attempt to recover a sealed source in a manner that, in the licensee's opinion, could result in a source rupture;

(C) in the event the environment, any equipment, or personnel are contaminated with radioactive material, decontamination to levels specified in §289.202(f), (n), and (eee) of this title shall be performed; and

(D) the requirements of subsection (cc)(4) of this section shall be met in the event a decision is made to abandon the sealed source downhole.

(2) No licensee shall perform tracer study operations with a substance tagged with radioactive material in any well or wellbore unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor or land owner, and the service company to which the licensee's equipment is connected, as applicable, that specifies who will be responsible for ensuring the following requirements are met:

(A) in the event the service company's personnel or equipment are contaminated with radioactive material, they shall be decontaminated in accordance with §289.202(n) or (eee) of this title before release from the job site or release for unrestricted use;

(B) in the event the well head or job site is contaminated with radioactive material, it shall be decontaminated in accordance with §289.202(eee) of this title; and

(C) in the event radioactive material is to be reversed from the well or the well screens out, the licensee shall have established procedures and equipment or facilities to do the following:

(*i*) reverse material into a preconstructed pit that is specifically established in the event of a screen out; or

(*ii*) reverse material into suitable transport container(s) in the event of a screen out.

(3) The licensee shall maintain, in accordance with subsection (dd)(5) of this section, a copy of the written agreement specified in paragraphs (1) or (2) of this subsection.

(e) Limits on levels of radiation. Sources of radiation shall be used, stored, and transported in such a manner that the requirements of §289.202 of this title, §289.231 of this title, and §289.257 of this title, as applicable, are met.

(f) Storage precautions.

(1) Each source of radiation, except accelerators, shall be provided with a storage and/or transport container. Each container shall have a lock (or tamper seal for calibration sources) to prevent unauthorized removal of, or exposure to, the source of radiation.

(2) Each area or room in which sources of radiation are stored shall be posted in accordance with §289.202(aa)(5) or §289.231(x) of this title, as applicable.

(3) Sources of radiation shall be stored downhole or in a bunker in order to minimize the danger from explosion and/or fire.

(4) Sources of radiation may not be stored in residential locations. This section does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with subsection (aa)(2) of this section.

(5) Sources of radiation in storage shall be secured to prevent tampering, or removal by unauthorized individuals.

(g) Transport precautions. Transport containers shall be locked and physically secured to the transporting vehicle to prevent shifting during transport, accidental loss, tampering, or unauthorized removal.

(h) Radiation survey instruments.

(1) The licensee or registrant shall maintain a sufficient number of calibrated and operable radiation survey instruments at each location where sources of radiation are stored or used to make physical radiation surveys as required by this section and by §289.202(p) or §289.231(s), of this title, as applicable. Instrumentation shall be capable of measuring 0.1 milliroentgen per hour (mR/hr) (1 microsievert per hour (μSv/hr)) through at least 50 mR/hr (500 μSv/hr). (Instrumentation capable of measuring 0.1 mR/hr (1 μSv/hr) through 50 mR/hr (500 μSv/hr) may not be sufficient to determine compliance with DOT requirements.)

(2) A licensee using tracer material shall have available at each additional authorized use/storage location and temporary job site additional calibrated and operable radiation survey instruments sensitive enough to detect the radioactive surface contamination limits specified in §289.202(eee) of this title.

(3) Each radiation survey instrument shall be calibrated:

(A) by a person specifically licensed or registered by the agency, another agreement state or licensing state or the United States Nuclear Regulatory Commission (NRC) to perform such service;

(B) at intervals not to exceed six months and after each survey instrument repair;

(C) for the types of radiation used and at energies appropriate for use; and

(D) at an accuracy within ±20% of the true radiation level at each calibration point.

(4) The licensee or registrant shall maintain calibration records in accordance with subsection (dd)(5) of this section.

(i) Leak testing of sealed sources.

(1) Testing and record keeping. Sealed sources shall be tested for leakage and contamination in accordance with this section and §289.201(g) of this title. The licensee shall maintain records of leak tests in accordance with subsection (dd)(5) of this section.

(2) Each energy compensation source that is not exempt from testing in accordance with §289.201(g)(2) of this title must be tested at intervals not to exceed three years. In the absence of a certificate from a transferor that a test has been made within the three years before the transfer, the energy compensation source may not be used until tested in accordance with §289.201(g) of this title.

(3) If a sealed source is found to be leaking in accordance with §289.201(g) of this title, the licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by persons specifically authorized by the agency, the NRC, an agreement state or a licensing state, to perform such services.

(j) Quarterly inventory. Each licensee or registrant shall conduct a physical inventory to account for all sources of radiation received or possessed at intervals not to exceed three months. The licensee or registrant shall make and maintain records of inventories in accordance with subsection (dd)(5) of this section and shall include the following:

(1) the quantities and kinds of sources of radiation;

(2) the location where sources of radiation are assigned;

(3) a unique identification of each source of radiation;

(4) the date of the inventory; and

(5) the name of the individual conducting the inventory.

(k) Utilization records. Utilization records shall be maintained by each licensee or registrant in accordance with subsection (dd)(5) of this section and shall include the following information for each source of radiation:

(1) identification of each source of radiation to include:

(A) the make and model number and/or serial number (or if absent, a description) of each sealed source used; or

(B) the radionuclide and activity of tracer materials and radioactive markers used at a particular well site and the disposition of any unused tracer materials.

(2) the identity of the logging supervisor or individual who is responsible for receiving sources of radiation, to whom assigned; and

(3) the locations where used and dates of use.

(l) Design and performance criteria for sealed sources used in well logging operations.

(1) Each sealed source used in well logging applications shall meet the following minimum criteria.

(A) The sealed source is of doubly encapsulated construction.

(B) The sealed source contains radioactive material with a chemical/physical form as insoluble and nondispersible as practicable.

(C) The sealed source meets one of the following requirements:

(*i*) for a sealed source manufactured on or before July 14, 1989, the requirements from the United States of America Standards Institute (USASI) N5.10-1968, "Classification of Sealed Radioactive Sources," or the requirements in clause (*ii*) or (*iii*) of this subparagraph;

(*ii*) for a sealed source manufactured after July 14, 1989, the oil-well logging requirements from the American National Standard Institute/Health Physics Society (ANSI/HPS) N43.6-1997, "Sealed Radioactive Sources-Classification," or

(*iii*) for a sealed source manufactured after July 14, 1989, the sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

(*I*) Temperature. The test source shall be held at -40 degrees Celsius for 20 minutes, 600 degrees Celsius for one hour, and then be subjected to a thermal shock test with a temperature drop from 600 degrees Celsius to 20 degrees Celsius within 15 seconds.

(*II*) Impact. A 5 kilogram (kg) steel hammer, 2.5 centimeters (cm) in diameter, shall be dropped from a height of 1 meter (m) onto the test source.

(*III*) Vibration. The test source shall be subjected to a vibration from 25 Hertz (Hz) to 500 Hz with a peak amplitude of five times the acceleration of gravity for 30 minutes.

(*IV*) Puncture. A 1 gram (gm) hammer and pin, 0.3 cm pin diameter, shall be dropped from a height of 1 m onto the test source.

(*V*) Pressure. The test source shall be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals) without leakage.

(2) The requirements in paragraph (1) of this subsection do not apply to sealed sources that contain radioactive material in gaseous form.

(3) The requirements in this subsection do not apply to energy compensation sources.

(m) Labeling.

(1) Each source, source holder, or logging tool containing radioactive material in other than an exempt quantity, shall bear a durable, legible, and clearly visible marking or label that has, as a minimum, the standard radiation caution symbol with no color requirement, and the wording DANGER (or CAUTION), RADIOACTIVE--DO NOT HANDLE, NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY).

(2) The labeling specified in paragraph (1) of this subsection shall be on the smallest component, source, source holder, or logging tool, that is transported as a separate piece of equipment.

(3) Each transport container shall have permanently attached to it a durable, legible, and clearly visible label that has, as a minimum, the standard radiation caution symbol and the wording DANGER (or CAUTION), RADIOACTIVE, NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY).

(4) Each transport container shall have attached to it a durable, legible, and clearly visible label(s) that has, as a minimum, the licensee's name, address, and telephone number, the radionuclide, its activity, and assay date.

(n) Inspection and maintenance.

(1) Each licensee or registrant shall conduct, at intervals not to exceed six months, a program of visual inspection and maintenance of source holders (or sealed source, if there is no source holder), logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. The inspection program may be performed concurrently with routine leak testing of sealed sources. Records of inspection and maintenance shall be made and maintained by the licensee or registrant in accordance with subsection (dd)(5) of this section.

(2) If any inspection conducted in accordance with paragraph (1) of this subsection reveals damage to labeling or components critical to radiation safety, the device shall be removed from service at the time the damage is discovered and until repairs have been made.

(3) Any operation, such as drilling, cutting, or chiseling on a source holder containing a sealed source, shall be performed on the source holder only by persons specifically licensed to do so by the agency, another agreement or licensing state, or the NRC. The provisions of this paragraph do not apply to logging tool recovery (fishing) operations conducted in accordance with the provisions of subsection (cc)(3) of this section.

(4) The repair, opening, or modification of any sealed source shall be performed only by persons specifically licensed to do so by the agency, another agreement or licensing state, or the NRC.

(o) Training requirements.

(1) No licensee or registrant shall permit any individual to act as a logging supervisor until such individual has met the following requirements:

(A) successfully completed an agency-accepted course or a course recognized by another agreement or licensing state, or the NRC, including at least 24 hours of formal training in the subjects outlined in subsection (dd)(1) of this section;

(B) received copies of and instruction in the following:

(*i*) the requirements contained in this section and the applicable subsections of §§289.201, 289.202, 289.203, and 289.231 of this title or their equivalent;

(*ii*) the conditions of the appropriate license or certificate of registration; and

(*iii*) the licensee's or registrant's operating, safety, and emergency procedures;

(C) demonstrated understanding of the requirements in subparagraph (A) and (B) of this paragraph by successfully completing a written examination administered by the licensee or registrant;

(D) completed two months of on-the-job training under the supervision of a logging supervisor; and

(E) demonstrated through a field evaluation, competence in the use of sources of radiation, related handling tools, and the type of radiation survey instruments that will be used in the job assignment.

(2) No licensee or registrant shall permit any individual to act as a logging assistant until such individual has met the following requirements:

(A) received copies of and instruction in the applicable subsections of §§289.201, 289.202, 289.203, and 289.231 of this title or their equivalent, and the licensee's or registrant's operating, safety, and emergency procedures;

(B) demonstrated understanding of the requirements in subparagraph (A) of this paragraph by successfully completing a written examination administered by the licensee or registrant; and

(C) demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments that will be used in the job assignment.

(3) The licensee or registrant shall provide an annual radiation safety review for logging supervisors and logging assistants.

(4) Each licensee or registrant shall maintain records that document that the requirements of paragraphs (1)-(3) of this subsection are met. Such records shall be maintained in accordance with subsection (dd)(5) of this section.

(p) Operating, safety, and emergency procedures. The licensee or registrant shall maintain written operating, safety, and emergency procedures that include descriptions of and directions in at least the items listed in subsection (dd)(4) of this section.

(q) Personnel monitoring.

(1) In addition to the requirements of §289.202(p)(3) and (q) of this title or §289.231(n) and (s)(3) of this title, as applicable, no licensee or registrant shall permit any individual to act as a logging supervisor or logging assistant unless that individual wears an individual monitoring device that is processed and evaluated by an accredited National Laboratory Accreditation Program (NVLAP) processor, at all times during well logging service operations and/or tracer studies utilizing sources of radiation. Each individual monitoring device shall be assigned to and worn by only one individual. Film badges shall be replaced at least monthly. Other individual monitoring devices shall be replaced at least quarterly. After replacement, each individual monitoring device shall be returned to the supplier for processing within 14 calendar days or as soon as practicable. In circumstances that make it impossible to return each individual monitoring device to the supplier for processing within 14 calendar days, such circumstances shall be documented and available for review by the agency.

(2) When necessary in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the agency may require a licensee or registrant to make available to the individual appropriate bioassay services and to furnish a copy of the reports of such services to the agency.

(3) Personnel monitoring records shall be maintained by the licensee or registrant in accordance with subsection (dd)(5) of this section.

(r) Radiation safety officer.

(1) A radiation safety officer (RSO) shall be designated for every license and certificate of registration issued by the agency.

(2) The RSO's documented qualifications shall include:

(A) possession of a high school diploma or a certificate of high school equivalency based on the GED test;

(B) completion of the training and testing requirements of subsection (o)(1) of this section; and

(C) two years of experience as a logging supervisor to include knowledge of well logging service operations and tracer studies.

(3) The duties of the RSO include, but are not limited to, the following:

(A) establishing and overseeing operating, safety, and emergency, and as low as reasonably achievable (ALARA) procedures, and to review them regularly to ensure that the procedures are current and conform with this chapter;

(B) overseeing and approving all phases of the training program for well logging service operations and/or tracer studies personnel so that appropriate and effective radiation protection practices are taught;

(C) ensuring that required radiation surveys and leak tests are performed and documented in accordance with this chapter, including any corrective measures when levels of radiation exceed established limits;

(D) ensuring that personnel monitoring is used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by §289.203 of this title;

(E) investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;

(F) having a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

(G) assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

(H) maintaining records as required by this chapter (see subsection (dd)(5) of this section);

(I) ensuring the proper storing, labeling, transport, and use of sources of radiation, storage, and/or transport containers;

(J) ensuring that inventories are performed in accordance with subsection (j) of this section;

(K) ensuring that personnel are complying with this chapter, the conditions of the license or the registration, and the operating, safety, and emergency procedures of the licensee or registrant; and

(L) serving as the primary contact with the agency.

(s) Security. During each well logging or tracer application, the logging supervisor or other employee who is authorized by the specific licensee for that activity, is responsible for protecting against unauthorized and/or unnecessary entry into a restricted area, as defined in §289.201(b) of this title, or §289.231 of this title, as applicable.

(t) Handling tools. The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low activity calibration sources.

(u) Tracer studies.

(1) Appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material and to avoid contamination of field stations, temporary job sites, vehicles, associated equipment, and clothing.

(2) No licensee shall permit the injection of radioactive material into usable quality groundwater (3,000 parts per million (ppm) total dissolved solids or less) without prior written authorization from the agency.

(v) Particle accelerators. No licensee or registrant shall permit above-ground testing of particle accelerators that results in the production of radiation except in areas or facilities controlled or shielded to meet the requirements of §289.202(f) or (n) of this title, or §289.231(m) or (o) of this title, as applicable.

(w) Radioactive markers. The licensee may use radioactive markers in wells only if the individual markers contain quantities of radioactive material not exceeding the quantities specified in §289.251(q)(2) of this title. The use of markers is subject only to the provisions of this subsection and subsection (j) of this section.

(x) Uranium sinker bars. The licensee may use a depleted uranium sinker bar in well logging service operations only if it is legibly impressed with the wording "DANGER (or CAUTION), RADIOACTIVE-DEPLETED URANIUM, NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY) IF FOUND".

(y) Energy compensation source.

(1) The licensee may use an energy compensation source that is contained within a logging tool or other tool components.

(2) For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of subsections (i), (j), and (k) of this section.

(3) For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of subsections (d), (i), (j), (k), (bb)(4)(A), and (cc) of this section.

(z) Tritium neutron generator target source.

(1) Use of a tritium neutron generator target source containing quantities not exceeding 30 curie (Ci) (1,110 MBq) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this section, except subsections (d), (l), and (cc) of this section.

(2) Use of a tritium neutron generator target source containing quantities exceeding 30 Ci (1,110 MBq) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this section, except subsection (l) of this section.

(aa) Radiation surveys.

(1) Radiation surveys (and calculations for neutron sources) shall be made and recorded for each area where radioactive materials are stored.

(2) Radiation surveys (and calculations for neutron sources) of the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive materials shall be made and recorded. Such surveys (and calculations for neutron sources) shall include all sources of radiation transported in the vehicle.

(3) If the sealed source assembly is removed from the logging tool before departing the job site, a survey of the tool to verify that the logging tool is free of contamination shall be made and recorded.

(4) If the encapsulation of the sealed source has been damaged by an operation or is likely to have been damaged by an operation, the licensee shall immediately conduct a radiation survey and make a record of that survey, including a contamination survey, during and after the operation.

(5) Radiation surveys shall be made and recorded at the job site and/or well head for each tracer operation except for those utilizing hydrogen-3, carbon-14, sulfur-35, or krypton-85. These surveys shall include measurements of radiation levels before and after the operation.

(6) Records required in accordance with paragraphs (1)-(5) of this subsection shall also include the dates, the identification of individual(s) making the survey, the unique identification of survey instrument(s) used, radiation measurements in milliroentgen per hour (mR/hr), calculations in millirem per hour (mrem/hr) (microsievert per hour (μSv/hr)), and an exact description of the location of the survey. Each licensee or registrant shall make and maintain records of these surveys in accordance with subsection (dd)(5) of this section.

(bb) Records/documents for inspection by the agency.

(1) Each licensee or registrant shall maintain the records/documents specified in subsection (dd)(5) of this section for inspection by the agency.

(2) Each licensee or registrant maintaining additional authorized use/storage locations from which well logging service operations are conducted shall have copies of the records/documents specified in subsection (dd)(5)(B)-(E) and (G)-(O) of this section that are specific to the site available at each site for inspection by the agency.

(3) Records/documents required in accordance with paragraph (2) of this subsection shall be maintained in accordance with subsection (dd)(5) of this section.

(4) Each licensee or registrant conducting well logging service operations at a temporary job site shall have copies of the records/documents specified in subsection (dd)(5)(B), (C), (I), (K), (L), and (N) of this section available at that site for inspection by the agency.

(5) Records/documents required by paragraph (4) of this subsection shall be maintained at the temporary job site for the period of operation at that site for inspection by the agency.

(cc) Notification of incidents and lost sources; abandonment procedures for irretrievable sources.

(1) Notification of incidents and sources lost in other than downhole well logging operations shall be made in accordance with appropriate provisions of §289.202 of this title, or §289.231 of this title, as applicable.

(2) Whenever a sealed source or a device containing radioactive material has been ruptured or is likely to have been ruptured, the licensee shall notify the agency immediately by telephone and submit written notification within 30 days. The written notification shall designate the following:

(A) the well or other location;

(B) a description of the magnitude and extent of the escape of radioactive material;

(C) an assessment of the consequences of the rupture; and

(D) an explanation of the efforts planned or being taken to mitigate these consequences.

(3) Whenever a sealed source is separated from the logging tool and is lost downhole, the licensee shall notify the agency immediately by telephone prior to beginning source recovery operations.

(4) Whenever a sealed source or device containing radioactive material is lost downhole, the licensee shall do the following:

(A) consult with the well operator, well owner, drilling contractor, or land owner regarding methods to retrieve the source or device that may reduce the likelihood that the source or device will be damaged or ruptured during the logging tool recovery (fishing) operations;

(B) monitor with a radiation survey instrument (or logging tool adjusted to detect gamma emissions from source(s) lost downhole), at the surface for the presence of radioactive contamination during logging tool recovery (fishing) operations; and

(C) notify the agency immediately by telephone and submit written notification within 30 days if radioactive contamination is detected at the surface or if the source appears to be damaged.

(5) When efforts to recover the radioactive source are not successful, the licensee shall do the following:

(A) notify the agency by telephone of the circumstances that resulted in the inability to retrieve the source and obtain agency approval to implement abandonment procedures, or that the licensee implemented abandonment before receiving agency approval because the licensee believed there was an immediate threat to public health and safety; and

(B) advise the well operator of the Texas Railroad Commission requirements regarding abandonment and an appropriate method of abandonment, that shall include the following:

(*i*) the immobilization and sealing in place of the radioactive source with a cement plug;

(*ii*) a means to prevent inadvertent intrusion on the source, such as the setting of a whipstock or other deflection device, unless the source is not accessible to any subsequent drilling operations; and

(*iii*) the mounting of a permanent identification plaque, containing information required by paragraph (5) of this subsection, at the surface of the well;

(C) notify the agency by telephone giving the circumstances of the loss; and

(D) file a written report with the agency within 30 days of the abandonment, providing the following information:

(*i*) date of occurrence;

(*ii*) a description of the radioactive source involved, including radionuclide, activity, chemical and physical form, and serial number;

(*iii*) surface location and identification of well;

(*iv*) results of efforts to immobilize and seal the source in place;

(*v*) depth of the radioactive source;

(*vi*) depth of the top of the cement plug;

(*vii*) depth of the well; and

(*viii*) information contained on the permanent identification plaque.

(6) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque (an example of a suggested plaque is shown in subsection (dd)(3) of this section) for posting on the well or wellbore. This plaque shall meet the following requirements:

(A) be constructed of long-lasting material such as stainless steel, brass, bronze, or monel. The size of the plaque should be convenient for use on active or inactive wells; for example, a 7-inch (17 cm) square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information; for example, 1/2 inch (1.27 cm) and 1/4 inch (0.63 cm) letter size, respectively; and

(B) contain the following engraved information on its face:

(*i*) the word "CAUTION;"

(*ii*) the radiation symbol (color not required);

(*iii*) the date of abandonment;

(*iv*) the name of the well operator or well owner;

(*v*) the well name and well identification number(s) or other designation;

(*vi*) radionuclide(s) and activity(ies) of the source(s);

(*vii*) the source depth and the plug back depth (depth to the top of the plug); and

(*viii*) an appropriate warning, depending on the specific circumstances of each abandonment, such as the following:

(*I*) "Do not drill below plug back depth;"

(*II*) "Do not enlarge casing;" or

(*III*) "Do not re-enter hole before contacting Bureau of Radiation Control, Texas Department of Health."

[7] The licensee shall immediately notify the agency by telephone and confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source. Such notice shall designate well location and describe the magnitude and extent of loss of radioactive material, consequences of such loss and efforts taken or planned to mitigate these consequences.

[8] In the event of an uncontrolled release of radioactive tracer material to the environment, the licensee shall notify the agency by telephone within 24 hours and submit written notification within 30 days.

[dd] Appendices.

(1) Subjects to be included in training courses for well logging service operations and/or tracer studies are as follows:

(A) fundamentals of radiation safety that include:

(*i*) characteristics of radiation;

(*ii*) units of radiation dose (rem) and activity;

(*iii*) significance of radiation dose specifying radiation protection standards and biological effects of radiation;

(*iv*) levels of radiation from sources of radiation;

(*v*) methods of controlling radiation dose specifying time, distance, and shielding;

(*vi*) radiation safety practices, specifying prevention of contamination and methods of decontamination; and

(*vii*) discussion of ingestion, inhalation pathways.

(B) radiation detection instrumentation to be used that includes:

(*i*) use of radiation survey instruments specifying operation, calibration, and limitations;

(*ii*) survey techniques; and

(*iii*) use of individual monitoring devices;

(C) equipment to be used that specifies;

(*i*) handling equipment and remote handling tools;

(*ii*) sources of radiation;

(*iii*) storage control, disposal, and transport of equipment and sources of radiation;

(*iv*) operation and control of equipment; and

(*v*) maintenance of equipment.

(D) pertinent federal and state requirements;

(E) the licensee's or registrant's written operating, safety, and emergency procedures;

(F) the licensee's or registrant's record keeping procedures; and

(G) case histories and potential consequences of accidents in well logging service operations and tracer studies.

(2) In addition to the subjects for training courses required in paragraph (1) of this subsection, individuals performing tracer studies must also complete training in the following subjects:

(A) sources of contamination;

(B) contamination detection and control;

(C) decontamination techniques and limits;

(D) survey techniques for tracer materials; and

(E) packaging requirements for transportation of radioactive materials, especially residual materials from tracer studies.

(3) The following is an example of a plaque for identifying wells containing sealed sources of radioactive material abandoned downhole:

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

X.Y.Z. OIL COMPANY
UNIVERSITY NO. 1234

CAUTION

ONE 2 CURIE CS 137 RADIOACTIVE SOURCE ABANDONED
3-3-75 AT 8400 FT. PLUG BACK DEPTH 8200 FT.
DO NOT RE-ENTER THIS WELL BEFORE CONTACTING

BUREAU OF RADIATION CONTROL
TEXAS DEPARTMENT OF HEALTH

(4) The licensee's or registrant's operating, safety, and emergency procedures shall include descriptions of and instructions in at least the following:

(A) the handling and use of sources of radiation in wells without surface casing for protecting fresh water aquifers, if appropriate;

(B) the handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the limits established in §289.202 of this title, or §289.231 of this title, as applicable. Every reasonable effort shall be made to keep radiation exposures and releases of radioactive material in soils and effluents to unrestricted areas as low as is reasonably achievable;

(C) methods and occasions for conducting radiation surveys;

(D) methods and occasions for locking and securing sources of radiation;

(E) personnel monitoring, including bioassays, and the use of individual monitoring devices;

(F) removal of radioactive material from storage, transportation of radioactive material to field locations and temporary job sites, including packaging of sources of radiation in the vehicles, placarding of vehicles, securing sources of radiation during transportation, and return to storage;

(G) minimizing exposure of individuals during routine use and in the event of an accident;

(H) procedures for notifying proper personnel in the event of an accident or well excursion;

(I) maintenance of records;

(J) use, inspection, and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

(K) procedures to be followed in the event a sealed source is lost or lodged downhole;

(L) procedures to be used for picking up, receiving, handling, and opening packages containing radioactive material;

(M) procedures to be used for surveys of temporary job sites and equipment, and decontamination of vehicles, associated equipment, and clothing following tracer studies;

(N) storage and disposal of radioactive waste;

(O) procedures for laundering contaminated clothing, if applicable;

(P) licensee's or registrant's management structure;

(Q) posting of radiation areas and labeling radioactive material containers;

(R) procedures to be followed in the event of an uncontrolled release of radioactive tracer material to the environment; and

(S) actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material, and actions to obtain suitable radiation survey instruments as required by subsection (h) of this section.

(5) The following records/documents shall be maintained by the licensee or registrant for inspection by the agency.

THIS PORTION OF THE PAGE LEFT INTENTIONALLY BLANK

	Name of Record/Document	*Rule Cross-Reference*	*Time Interval for Keeping Record/Document*
(A)	Agreement with well operator, owner, drilling contractor, or land owner	(d)	5 years following completion of the well logging service operation or tracer study
(B)	Survey instrument calibration	(h)	3 years
(C)	Leak test	(i)	3 years
(D)	Quarterly inventory	(j)	3 years
(E)	Utilization record	(k)	3 years
(F)	Certification document	(l)	3 years
(G)	Inspection and maintenance	(n)	3 years
(H)	Training and Testing	(o)	3 years after employee terminates employment with the licensee or registrant
(I)	Current operating, safety, and emergency procedures	(p)	Until termination of license or certificate of registration
(J)	Personnel monitoring	(q)	Until disposal is authorized by the agency
(K)	Radiation surveys	(aa)	3 years after completion of the survey
(L)	Current License or Certificate of Registration	(bb)	Until termination of license or certificate of registration
(M)	Receipt, transfer, and disposal	§289.201(d)	Until disposal is authorized by the agency
(N)	Shipping papers for transportation	§289.257(e)	3 years
(O)	Current 25 TAC §289.253 of this title and other applicable sections as listed in the license or certificate of registration	(bb)	Until termination of license or certificate of registration