TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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DAVID L. LAKEY, M.D.
COMMISSIONER

September 2, 2011

Mr. Mark S. Delligatti
Acting Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Delligatti:

Enclosed are the following final revisions to the Texas Regulations for Control of Radiation, 25 Texas Administrative that will become effective October 1, 2011. The final changes to the regulations are shown as shaded text and correspond to the following table that identifies the equivalent amendments to NRC's regulations.

§289.202 relating to Standards for Protection Against Radiation from Radioactive Materials

§289.203 relating to Notices, Instructions, and Reports to Workers; Inspections

§289.252 relating to Licensing of Radioactive Material

§289.256 relating to Medical and Veterinary Use of Radioactive Material

§289.257 relating to Packaging and Transportation of Radioactive Material

Rats ID	Title	State Section
1995-3	Low-Level Waste Shipment Manifest Information and Reporting	§289.257
2002-2	Medical Use of Byproduct Material	§289.202 §289.256
2003-1	Financial Assurance for Materials Licensees	§289.252

Rats ID	Title	State Section
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments	§289.257
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards	§289.256
2006-1	Minor Amendments	§289.256
2007-3	Requirements for Expanded Definition of Byproduct Material	§289.256
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent	§289.203
2009-	Medical Use of Byproduct Material – Authorized User Clarification	§289.256

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

The following table also specifies a few items that are not compatible and provides Texas' rationale for promulgating a regulation that is not compatible with NRC's regulations.

If you have any questions, please feel free to contact me at 512-834-6770, ext. 2010, or BarbaraJ.Taylor@dshs.state.tx.us.

Sincerely,

Barbara J. Taylor, Manager
Radiation Group
Policy, Standards, and Quality Assurance Unit
Department of State Health Services

Enclosures

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
§289.202(bbb)	35.3067	2002-2	C	**NRC comment per letters dated November 19, 2010 and October 29, 2009** **Report of a leaking source** Texas omits that the written report must include "the model number and serial number if assigned of the leaking source, and the radionuclide and its estimated activity" making their regulation less restrictive. Texas needs to add the above to 289.202(bbb) in order to meet the Compatibility Category C designation assigned to 10 CFR 35.3067.	Meets compatibility
§289.203(d)(2)	19.13	2008-1	C	**NRC comment per letter dated January 21, 2010** **Notification and reports to individuals.** Texas omits equivalent regulations to 19.13(b) from 289.203(d). Texas needs to add an equivalent section to 19.13(b) to 289.203(d) in order to meet the Compatibility Category C designation assigned to 10 CFR 19.13.	Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
§289.251(f)(4)(K)(i)	31.12	2007-3	C	**NRC comment per letters dated November 19, 2010 and April 25, 2011** **General license for certain items and self-luminous products containing radium-226** Texas omits the following wording: "….manufactured prior to November 30, 2007." Texas omits equivalent requirements to 10 CFR 31.12(c)(3). Texas needs to make the above changes to meet the Compatibility Category C designation assigned to 10 CFR 31.12.	TX will address this item in a future rule revision
§289.252(gg)(1)(D) & (3)(D)	30.35 40.36	2003-1	H&S	**NRC comment per letters dated November 19, 2010 and January 21, 2010** **Financial assurance and recordkeeping for decommissioning** Texas omits equivalent sections to 10 CFR 40.36(a) & the intro paragraph of 40.36(b) in 289.252(gg). Texas needs to apply financial assurance and decommissioning requirements to "possession and use of more than 100mCi of source material in a readily dispersible form" and "possession and use of quantities	Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
				of source material greater than 10mCi but less than or equal to 100mCi in a readily dispersible form." Texas needs to make the above change to 289.252(gg) in order to meet the Compatibility Category H&S designation assigned to 10 CFR 40.36.	
§289.256(a)(3)	35.11(b)	2002-2 2007-3	[C]		Meets compatibility
§289.256(c)(3)(C)	35.2	2002-2 2006-1	B	**NRC comment per letters dated November 19, 2010, October 29, 2009, October 5, 2009, and April 25, 2011** **Definition: Authorized Medical Physicist** Texas adds an additional section (289.256(c)(3)(C)) to their definition of Authorized Medical Physicist. This section makes this definition more restrictive than NRC's definition. Texas needs to remove section (C) from 289.256(c)(3) Authorized Medical Physicist to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized Medical Physicist.	§289.256(c)(3)(C) is required per the Texas Medical Physics Practice Act, Texas Occupations Code, Chapter 602. Subparagraph (C) of this definition will remain in rule. To remove this language would put the program in conflict with state law.

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
§289.256(c)(4)(E)	35.2	2002-2 2006-1	B	**NRC comment per letters dated November 19, 2010, October 29, 2009, October 5, 2009, and April 25, 2011** **Definition: Authorized nuclear pharmacist** Texas adds an additional section (289.256(c)(4)(E)) to their definition of Authorized Nuclear Pharmacist. This section makes this definition more restrictive than NRC's definition. Texas omitted an "or" at the end of 289.256(c)(4)(B)(iv). Texas needs to make the above changes to their definition of Authorized Nuclear Pharmacist to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized Nuclear Pharmacist.	§289.256(c)(4)(E) is required per the Texas Pharmacy Act, Texas Occupations Code, Title 3, Subtitle J, Chapters 551-566, 568 and 569. Subparagraph (E) of this definition will remain in rule. To remove this language would put the program in conflict with state law.
§289.256(c)(5)	35.2	2002-2	B	**NRC comment per letters dated November 19, 2010, October 29, 2009, October 5, 2009, and April 25, 2011** **Definition: Authorized user** Texas adds additional text to this definition making it more restrictive that NRC's definition.	§289.256(c)(5) is required per the Texas Medical Board, Texas Occupations Code, Title 3, Subtitle B, Chapters 151-165, and 167; Texas State Board of Dental Examiners

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
				Texas requires the physician, dentist, and podiatrist be licensed by the Texas Medical Board, the Texas State Board of Dental Examiners, and the Texas State Board of Podiatric Medicine respectfully. Texas needs to remove this language from the definition. Texas needs to make the above change to 289.256(c)(5) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition Authorized User.	Texas Occupations Code, Title 3, Subtitle D, Chapters 251-267; and the Texas State Board of Podiatric Medicine Texas Occupations Code, Title 3, Subtitle C, Chapter 202. Subparagraph (A) of this definition will remain in rule. To remove this language would put the program in conflict with state law.
§289.256(c)(22)	35.2	2002-2	C	**NRC comment per letters dated November 19, 2010 and October 29, 2009** **Definition: Prescribed dosage** Texas uses the term "radiopharmaceutical" instead of unsealed byproduct material in their definition of Prescribed dosage. This makes their definition less restrictive than NRC's definition. Texas needs to remove the word radiopharmaceutical and replace it	Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
				with unsealed byproduct material (or unsealed radioactive material) in order to meet the Compatibility Category C designation assigned to 10 CFR 35.2 Definition Prescribed Dosage.	
§289.256(h)(1)	35.50	2002-2 2005-2 2006-1	B	**NRC comment per letters dated November 19, 2010 and October 29, 2009** **Training for the Radiation Safety Officer** Texas lists the wrong citation in the introductory paragraph of 289.256(h)(1). Texas states "… and who meets the requirements of sections (4) and (5) of this subsection." The correct statement is "…and who meets the requirements of sections (5) and (6) of this section." Texas needs to make the above change to 289.256(h) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.50.	Meets compatibility
§289.256(h)(1)(B)(ii)(II)	35.50	2009-1	B		Meets compatibility
§289.256(j)(1)(B)(ii)	35.51(a)(2)(ii)	2009-1	B		Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
§289.256(j)(2)(C)	35.51(b)(2)	2009-1	B		Meets compatibility
§289.256(l)(3)	35.57	2009-1	B		Meets compatibility
§289.256(x)	35.63	2007-3	H&S		Meets compatibility
§289.256(ee)	35.92		H&S		Meets compatibility
§289.256(ff)	35.100(a) and (b)	2007-3	H&S	**NRC comment per letters dated November 19, 2010 and September 29, 2009** **Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required** Texas omitted the requirements for PET radionuclide production when discussing methods with which to obtain medical isotopes for uptake, dilution, and excretion studies for which a written directive is not required. Texas needs to add the PET production requirements to 289.256(ff) to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.100 (a) and (b).	Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
See comment section	35.190 35.290 35.390 35.392 35.394 35.396 35.490 35.491 35.690	2006-1 2009-1	B	**NRC comment per letter dated November 19, 2010** **Multiple** Texas omits the phrase: "...or equivalent Nuclear Regulatory Commission or Agreement State requirements..." in: 289.256(gg)(2), 289.256(gg)(3)(B), 289.256(gg)(4), 289.256(jj)(1)(B), 289.256(jj)(1)(C)(ii), 289.256(jj)(1)(D), 289.256(nn)(2)(B), 289.256(nn)(2)(C), 289.256(oo)(3)(B), 289.256(oo)(3)(C), 289.256(pp)(2), 289.256(pp)(3)(B), 289.256(pp)(3)(C), 289.256(qq)(1), 289.256(qq)(4)(B), 289.256(qq)(4)(C), 289.256(qq)(5), 289.256(zz)(2)(B), 289.256(zz)(2)(C), 289.256(zz)(2)(D), 289.256(aaa)(1), 289.256(aaa)(2)(C), 289.256(ttt)(2)(B), 289.256(ttt)(2)(C). Texas needs to add the wording mentioned above to Texas' applicable sections to meet the Compatibility Category B	Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
				designation assigned to 10 CFR 35.	
§289.256(hh)	35.200(a) and (b)	2007-3	H&S	**NRC comment per letters dated November 19, 2010 and September 29, 2009** **Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.** Texas omitted the requirements for PET radionuclide production when discussing methods with which to obtain medical isotopes for imaging and localization studies for which a written directive is not required. Texas needs to add the PET production requirements to 289.256(hh) to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.200 (a) and (b).	Meets compatibility
§289.256(ii)	35.204(a)	2007-3	H&S		Meets compatibility
§289.256(jj)(2)	35.290	2002-2 2005-2	B	**NRC comment per letters dated November 19, 2010, October 29, 2009, and April 25, 2011** **Training for imaging and**	TX will leave the additional authorized user training requirements for the use of PET

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
				localization studies Texas regulation 289.256(jj)(2) contains additional requirements for the use of PET radionuclides. This paragraph is more restrictive than Section 35.290 and should be removed. Texas needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.290.	radionuclides specified in paragraph (2) of this subsection because the higher energy and greater dose potential from these radionuclides warrants some level of training and indoctrination into the additional exposure to both patient and user personnel associated with these radionuclides.
§289.256(kk)	35.300(a) and (b)	2007-3	H&S	**NRC comment per letters dated November 19, 2010 and September 29, 2009** **Use of unsealed byproduct material for which a written directive is required** Texas omitted the requirements for PET radionuclide production when discussing methods with which to obtain medical isotopes for which a written directive is required. Texas needs to add the PET production requirements to 289.256(kk) to meet the	Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
				Compatibility Category H&S designation assigned to Section 10 CFR 35.300 (a) and (b).	
§289.256(aaa)(2)(C)	35.491	2009-1	B	**NRC comment per letter dated April 25, 2011** **Training for ophthalmic use of strontium-90.** In 289.256(aaa)(2)(C) references, Texas has an incorrect reference. The phrase "…of paragraphs (1) and (2) of this subsection …" should be revised to "…of **paragraph (2)** of this subsection …" Texas needs to correct the above references in order to meet the Compatibility Category B designation assigned to 10 CFR 35.491.	Meets compatibility
§289.256(ttt)(2)(D)	35.690	2006-1	B	**NRC comment per letter dated November 19, 2010** **Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.** In 289.2569(ttt)(2)(D) Texas omits the following phrase: "...or	Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
				equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status" Texas needs to add the above phrase into 289.256(ttt)(2)(D) to meet the Compatibility Category B designation assigned to 10 CFR 35.690(b)(3).	
§289.257(d)(38)(A)(ii) and (iii)	71.4	2004-1	B	**NRC comment per letter dated January 21, 2010** **Definition: Surface contaminated object** Texas has numerical errors in its definition of Surface contaminated object in 289.257(d)(38). 289.257(d)(38)(A)(ii) and (iii) should both read "…(10^{-2}uCi/cm^2) for all other alpha emitters;" instead of "… (10^{-1} uCi/cm^2) for all other alpha emitters;". Texas needs to make the above change to their definition of Surface contaminated object in order to meet the Compatibility Category B designation assigned to 10 CFR 71.4 Definition: Surface Contaminated Object.	Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
§289.257(e)(1)	71.5	2004-1	B	**NRC comment per letter dated January 21, 2010** **Transportation of licensed material.** Texas references DOT regulations 49 CFR "Part 107, Parts 171 through 189 and 390-397" in 289.257(e)(1). The references should be "49 CFR Part 107, Parts 171-180 and 390-397". Texas needs to make the above change to 289.257(e) in order to meet the Compatibility Category B designation assigned to 10 CFR 71.5.	Meets compatibility
§289.257(k)(2)	71.85	2004-1	B	**NRC comment per letter dated January 21, 2010** **Preliminary determinations.** Texas omits the unit "f" in the maximum normal operating pressure 35kPa (5 lb"**f**"/in²) requirement for structural integrity testing. Texas needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 71.85.	Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
§289.257(t)	71.103	2004-1	C	**NRC comment per letter dated January 21, 2010** **Quality assurance requirements.** Texas omits the footnote from its requirement. Texas needs to add the footnote to its regulation in order to meet the Compatibility Category C designation assigned to 10 CFR 71.101 (g).	Meets compatibility
§289.257(u)(1)(A)	71.105	2004-1	C	**NRC comment per letter dated January 21, 2010** **Quality assurance program.** In paragraph (v) (1) (A) of its regulation, Texas references 10 CFR "71.**01**" through 71.137. Texas needs to correct the regulation reference to "71.**101**" in order to meet the Compatibility Category C designation assigned to 10 CFR 71.105 (a).	Meets compatibility
§289.257(ff)(6)(E)	10 CFR 20 Appendix G.I.B5	1995-3	B	**NRC comment per letter dated January 21, 2010** **Transfer for disposal and manifests** Texas' regulation 289.257(gg)(6)(E) includes	Meets compatibility

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	TX RESPONSE
				radium-226. 10 CFR 20 Appendix G (I)(B(5) does not list this isotope therefore it needs to be removed. Texas needs to make the above change to 289.257(gg)(6)(E) in order to meet the Compatibility Category B designation assigned to 10 CFR 20 Appendix G.	

RC Form 202-2
(October 2011)

Texas Department of State Health Services/Radiation Control

CUMULATIVE OCCUPATIONAL EXPOSURE HISTORY

1. NAME (LAST, FIRST, MIDDLE INITIAL)	2. IDENTIFICATION NUMBER	3. ID TYPE	4. SEX: MALE ☐ FEMALE ☐	5. DATE OF BIRTH

6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

19. SIGNATURE OF MONITORED INDIVIDUAL	20. DATE SIGNED	21. CERTIFYING ORGANIZATION	22. SIGNATURE OF DESIGNEE	23. DATE SIGNED

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF RC FORM 202-2

(All doses should be stated in rems)

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).

2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.

3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other

4. Check the box that denotes the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.

7. Enter the name of the licensee, registrant, or facility not licensed by the Agency that provided monitoring.

8. Enter the Agency license or registration number or numbers.

9. Place an "X" in Record, Estimate, or No Record. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee or registrant intends to assign the record dose on the basis of TLD results that are not yet available.

10. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee should sum them and report the total of all PSEs.

11. Enter the deep dose equivalent (DDE) to the whole body.

12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE,WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE,ME).

15. Enter the committed effective dose equivalent (CEDE).

16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ.

17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. Signature of the monitored individual. The signature of the monitored individual on this form indicates that the information contained on the form is complete and correct to the best of his or her knowledge.

20. Enter the date this form was signed by the monitored individual.

21. [OPTIONAL] Enter the name of the licensee, registrant or facility not licensed by the Agency, providing monitoring for exposure to radiation (such as a DOE facility) or the employer if the individual is not employed by the licensee or registrant and the employer chooses to maintain exposure records for its employees.

22. [OPTIONAL] Signature of the person designated to represent the licensee, registrant or employer entered in item 21. The licensee, registrant or employer who chooses to countersign the form should have on file documentation of all the information on the Agency Form Y being signed.

23. [OPTIONAL] Enter the date this form was signed by the designated representative.

RC Form 202-3
(October 2011)

Texas Department of State Health Services/Radiation Control

OCCUPATIONAL EXPOSURE RECORD FOR A MONITORING PERIOD

1. NAME (LAST, FIRST, MIDDLE INITIAL)	2. IDENTIFICATION NUMBER	3. ID TYPE	4. SEX	5. DATE OF BIRTH
			☐ MALE ☐ FEMALE	

6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER(S)	9A.	9B.
			☐ RECORD ☐ ESTIMATE	☐ ROUTINE ☐ PSE

INTAKES

10A. RADIONUCLIDE	10B. CLASS	10C. MODE	10D. INTAKE IN μCi

DOSES (in rem)

DEEP DOSE EQUIVALENT (DDE)	11.
EYE DOSE EQUIVALENT TO THE LENS OF THE EYE (LDE)	12.
SHALLOW DOSE EQUIVALENT, WHOLE BODY (SDE,WB)	13.
SHALLOW DOSE EQUIVALENT, MAX EXTREMITY (SDE,ME)	14.
COMMITTED EFFECTIVE DOSE EQUIVALENT (CEDE)	15.
COMMITTED DOSE EQUIVALENT, MAXIMALLY EXPOSED ORGAN (CDE)	16.
TOTAL EFFECTIVE DOSE EQUIVALENT ***(BLOCKS 11+15) (TEDE)***	17.
TOTAL ORGAN DOSE EQUIVALENT, MAX ORGAN ***(BLOCKS 11+16) (TODE)***	18.

19. COMMENTS

20. SIGNATURE -- LICENSEE OR REGISTRANT	21. DATE PREPARED

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF RC FORM 202-3

(All doses should be stated in rems)

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).

2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.

3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other

4. Check the box that denotes the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.

7. Enter the name of the licensee or registrant.

8. Enter the Agency license or registration number or numbers.

9A. Place an "X" in Record or Estimate. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of TLD results that are not yet available.

9B. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee or registrant should sum them and report the total of all PSEs.

10A. Enter the symbol for each radionuclide that resulted in an internal exposure recorded for the individual, using the format "Xx-###x," for instance, Cs-137 or Tc-99m.

10B. Enter the lung clearance class as listed in subsection (ggg)(2)(F) of this section for all intakes by inhalation.

10C. Enter the mode of intake. For inhalation, enter "H." For absorption through the skin, enter "B." For oral ingestion, enter "G." For injection, enter "J."

10D. Enter the intake of each radionuclide in μCi.

11. Enter the deep dose equivalent (DDE) to the whole body.

12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE,WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE,ME).

15. Enter the committed effective dose equivalent (CEDE) or "NR" for "Not Required" or "NC" for "Not Calculated".

16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ or "NR" for "Not Required" or "NC" for "Not Calculated".

17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. COMMENTS.
In the space provided, enter additional information that might be needed to determine compliance with limits. An example might be to enter the note that the SDE,ME was the result of exposure from a discrete hot particle. Another possibility would be to indicate that an overexposed report has been sent to the Agency in reference to the exposure report.

20. Signature of the person designated to represent the licensee or registrant.

21. Enter the date this form was prepared.

25 TEXAS ADMINISTRATIVE CODE (TAC)

§289.202

Standards for Protection Against Radiation from Radioactive Materials

Texas Regulations for Control of Radiation

(revisions effective October 1, 2011 are shown as shaded text)

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§289.202. Standards for Protection Against Radiation from Radioactive Materials.

(a) Purpose.

(1) This section establishes standards for protection against ionizing radiation resulting from activities conducted in accordance with licenses issued by the agency.

(2) The requirements in this section are designed to control the receipt, possession, use, and transfer of sources of radiation by any licensee so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this section. However, nothing in this section shall be construed as limiting actions that may be necessary to protect health and safety in an emergency.

(b) Scope.

(1) Except as specifically provided in other sections of this chapter, this section applies to persons who receive, possess, use, or transfer sources of radiation, unless otherwise exempted. No person may use, manufacture, produce, transport, transfer, receive, acquire, own, possess, process, or dispose of sources of radiation unless that person has a license or exemption from the agency. The dose limits in this section do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with this chapter, or to voluntary participation in medical research programs. However, no radiation may be deliberately applied to human beings except by or under the supervision of an individual authorized by and licensed in accordance with Texas' statutes to engage in the healing arts.

(2) Licensees who are also registered by the agency to receive, possess, use, and transfer radiation machines must also comply with the requirements of §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

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

(1) Air-purifying respirator--A respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(2) Annual limit on intake (ALI)--The derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by Reference Man that would result in a committed effective dose equivalent of 5 rems (0.05 sievert (Sv)) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Columns 1 and 2 of Table I of subsection (ggg)(2) of this section.

(3) Assigned protection factor (APF)--The expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(4) Atmosphere-supplying respirator--A respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

(5) Class--A classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which apply to a range of clearance half-times: for Class D, Days, of less than 10 days; for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of this section, lung class and inhalation class are equivalent terms.

(6) Debris--the remains of something destroyed, disintegrated, or decayed. Debris does not include soils, sludges, liquids, gases, naturally occurring radioactive material regulated in accordance with §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material (NORM)), or low-level radioactive waste received from other persons.

(7) Declared pregnant woman--A woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman voluntarily withdraws the declaration in writing or is no longer pregnant.

(8) Demand respirator--An atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(9) Derived air concentration (DAC)--The concentration of a given radionuclide in air that, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of 1 ALI. For purposes of this section, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Column 3 of Table I of subsection (ggg)(2) of this section.

(10) Derived air concentration-hour (DAC-hour)--The product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

(11) Disposable respirator--A respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus.

(12) Dosimetry processor--A person that processes and evaluates personnel monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

(13) Filtering facepiece (dust mask)--A negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(14) Fit factor--A quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(15) Fit test--The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(16) Helmet--A rigid respiratory inlet covering that also provides head protection against impact and penetration.

(17) Hood--A respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(18) Inhalation class (see definition for Class).

(19) Loose-fitting facepiece--A respiratory inlet covering that is designed to form a partial seal with the face.

(20) Lung class (see definition for Class).

(21) Nationally tracked source--A sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in subsection (hhh)(2) of this section. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

(22) Negative pressure respirator (tight fitting)--A respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(23) Nonstochastic effect--A health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of this section, deterministic effect is an equivalent term.

(24) Planned special exposure--An infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

(25) Positive pressure respirator--A respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(26) Powered air-purifying respirator--An air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

(27) Pressure demand respirator--A positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(28) Qualitative fit test--A pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(29) Quantitative fit test--An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(30) 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.

(31) Reference man--A hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of Reference Man is contained in the International Commission on Radiological Protection Report, ICRP Publication 23, "Report of the Task Group on Reference Man."

(32) Respiratory protective equipment--An apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

(33) Sanitary sewerage--A system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

(34) Self-contained breathing apparatus--An atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(35) Stochastic effect--A health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of this section probabilistic effect is an equivalent term.

(36) Supplied-air respirator or airline respirator--An atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

(37) Tight-fitting facepiece--A respiratory inlet covering that forms a complete seal with the face.

(38) User seal check (fit check)--An action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

(39) Weighting factor w_T for an organ or tissue (T)--The proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

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ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30*
Whole Body	1.00**

* 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

** For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

(d) Implementation.

(1) Any existing license condition that is more restrictive than this section remains in force until there is an amendment or renewal of the license that modifies or removes this condition.

(2) If a license condition exempts a licensee from a provision of this section in effect on or before January 1, 1994, it also exempts the licensee from the corresponding provision of this section.

(3) If a license condition cites provisions of this section in effect prior to January 1, 1994, that do not correspond to any provisions of this section, the license condition remains in force until there is an amendment or renewal of the license that modifies or removes this condition.

(e) Radiation protection programs.

(1) Each licensee shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this section. See subsection (mm) of this section for recordkeeping requirements relating to these programs. Documentation of the radiation protection program may be incorporated in the licensee's operating, safety, and emergency procedures.

(2) The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

(3) The licensee shall, at intervals not to exceed 12 months, ensure the radiation protection program content and implementation is reviewed. The review shall include a reevaluation of the assessments made to determine monitoring is not required in accordance with subsection (q)(1) and (3) of this section in conjunction with the licensee's current operating conditions.

(4) To implement the ALARA requirement in paragraph (2) of this subsection and notwithstanding the requirements in subsection (n) of this section, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 millirems (mrem) (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as required in subsection (yy) of this section and promptly take appropriate corrective action.

(5) If monitoring is not required in accordance with subsection (q)(1) and (3) of this section, the licensee shall document assessments made to determine the requirements of subsection (q)(1) and (3) of this section are not applicable. The licensee shall maintain the documentation in accordance with subsection (rr)(5) of this section.

(f) Occupational dose limits for adults.

(1) The licensee shall control the occupational dose to individuals, except for planned special exposures in accordance with subsection (k) of this section, to the following dose limits.

(A) An annual limit shall be the more limiting of:

(i) the total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(B) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities shall be:

(i) a lens dose equivalent of 15 rems (0.15 Sv); and

(ii) a shallow dose equivalent of 50 rems (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See subsection (k)(6)(A) and (B) of this section.

(3) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the agency. The assigned deep dose equivalent shall be for the portion of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous 10 square centimeters (cm^2) of skin receiving the highest exposure.

(4) The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys, or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(5) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in Table I of subsection (ggg)(2) of this section and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See subsection (rr) of this section.

(6) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams (mg) in a week in consideration of chemical toxicity. See footnote 3 of subsection (ggg)(2) of this section.

(7) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See subsection (j)(4) of this section.

(g) Compliance with requirements for summation of external and internal doses.

(1) If the licensee is required to monitor in accordance with both subsection (q)(1) and (3) of this section, the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only in accordance with subsection (q)(1) of this section or only in accordance with subsection (q)(3) of this section, then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses in accordance with paragraphs (2)-(4) of this subsection. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(2) If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(A) the sum of the fractions of the inhalation ALI for each radionuclide; or

(B) the total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

(C) the sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10% of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

(3) If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than 10% of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(4) The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for in accordance with this paragraph.

(h) Determination of external dose from airborne radioactive material.

(1) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See footnotes 1 and 2 of subsection (ggg)(2) of this section.

(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

(i) Determination of internal exposure.

(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required in accordance with subsection (q) of this section, take suitable and timely measurements of:

(A) concentrations of radioactive materials in air in work areas;

(B) quantities of radionuclides in the body;

(C) quantities of radionuclides excreted from the body; or

(D) combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in subsection (x) of this section, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

(A) use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record;

(B) upon prior approval of the agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(C) separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See subsection (ggg)(2) of this section.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in paragraph (1)(A) or (B) of this subsection, the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by subsections (xx) or (yy) of this section. This delay permits the licensee to make additional measurements basic to the assessments.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(A) the sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from subsection (ggg)(2) of this section for each radionuclide in the mixture; or

(B) the ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

(A) the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in subsection (f) of this section and in complying with the monitoring requirements in subsection (q)(3) of this section;

(B) the concentration of any radionuclide disregarded is less than 10% of its DAC; and

(C) the sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30%.

(8) When determining the committed effective dose equivalent, the following information may be considered.

(A) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of 1 ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rems (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(B) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 50 rems (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rems (0.05 Sv), that is, the stochastic ALI, is listed in parentheses in Table I of subsection (ggg)(2) of this section. The licensee may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALI, the licensee shall also demonstrate that the limit in subsection (f)(1)(A)(ii) of this section is met.

(j) Determination of occupational dose for the current year.

(1) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring in accordance with subsection (q) of this section, the licensee shall determine the occupational radiation dose received during the current year.

(2) In complying with the requirements of paragraph (1) of this subsection, a licensee may:

(A) accept, as a record of the occupational dose that the individual received during the current year, RC Form 202-2 from prior or other current employers, or other clear and legible record, of all information required on that form and indicating any periods of time for which data are not available; or

(B) accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's prior or other current employer(s) for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; or

(C) obtain reports of the individual's dose equivalent from prior or other current employer(s) for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee, by telephone, telegram, facsimile, or letter. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(3) The licensee shall record the exposure data for the current year, as required by paragraph (1) of this subsection, on RC Form 202-3, or other clear and legible record, of all the information required on that form.

(4) If the licensee is unable to obtain a complete record of an individual's current occupational dose while employed by any other licensee, the licensee shall assume in establishing administrative controls in accordance with subsection (f)(7) of this section for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 millisieverts (mSv)) for each quarter; or 416 mrem (4.16 mSv) for each month for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

(5) If an individual has incomplete (e.g., a lost or damaged personnel monitoring device) current occupational dose data for the current year and that individual is employed solely by the licensee during the current year, the licensee shall:

(A) assume that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter;

(B) assume that the allowable dose limit for the individual is reduced by 416 mrem (4.16 mSv) for each month; or

(C) assess an occupational dose for the individual during the period of missing data using surveys, radiation measurements, or other comparable data for the purpose of demonstrating compliance with the occupational dose limits.

(6) Administrative controls established in accordance with paragraph (4) of this subsection shall be documented and maintained for inspection by the agency. Occupational dose assessments made in accordance with paragraph (5) of this subsection and records of data used to make the assessment shall be maintained for inspection by the agency. The licensee shall retain the records in accordance with subsection (rr) of this section.

(k) Planned special exposures. A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in subsection (f) of this section provided that each of the following conditions is satisfied.

(1) The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the doses estimated to result from the planned special exposure are unavailable or impractical.

(2) The licensee and employer, if the employer is not the licensee, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(3) Before a planned special exposure, the licensee ensures that each individual involved is:

(A) informed of the purpose of the planned operation;

(B) informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(C) instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(4) Prior to permitting an individual to participate in a planned special exposure, the licensee shall determine:

(A) the internal and external doses from all previous planned special exposures;

(B) all doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

(C) all lifetime cumulative occupational radiation doses.

(5) In complying with the requirements of paragraph (4)(C) of this subsection, a licensee may:

(A) accept, as the record of lifetime cumulative radiation dose, an up-to-date RC Form 202-2 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee; and

(B) obtain reports of the individual's dose equivalent from prior employer(s) for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee, by telephone, telegram, facsimile, or letter. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(6) Subject to subsection (f)(2) of this section, the licensee shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(A) the numerical values of any of the dose limits in subsection (f)(1) of this section in any year; and

(B) five times the annual dose limits in subsection (f)(1) of this section during the individual's lifetime.

(7) The licensee maintains records of the conduct of a planned special exposure in accordance with subsection (qq) of this section and submits a written report to the agency in accordance with subsection (zz) of this section.

(8) The licensee records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual in accordance with subsection (f)(1) of this section but shall be included in evaluations required by paragraphs (4) and (6) of this subsection.

(9) The licensee shall record the exposure history, as required by paragraph (4) of this subsection, on RC Form 202-2, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing RC Form 202-2 or equivalent.

(l) Occupational dose limits for minors. The annual occupational dose limits for minors are 10% of the annual occupational dose limits specified for adult workers in subsection (f) of this section.

(m) Dose equivalent to an embryo/fetus.

(1) If a woman declares her pregnancy, the licensee shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). If a woman chooses not to declare pregnancy, the occupational dose limits specified in subsection (f)(1) of this section are applicable to the woman. See subsection (rr) of this section for recordkeeping requirements.

(2) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (1) of this subsection. The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

(3) The dose equivalent to an embryo/fetus shall be taken as:

(A) the dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman; and

(B) the dose equivalent that is most representative of the dose equivalent to the embryo/fetus from external radiation, that is, in the mother's lower torso region.

(i) If multiple measurements have not been made, assignment of the highest deep dose equivalent for the declared pregnant woman shall be the dose equivalent to the embryo/fetus.

(ii) If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device that is most representative of the dose equivalent to the embryo/fetus shall be the dose equivalent to the embryo/fetus. Assignment of the highest deep dose equivalent for the declared pregnant woman to the embryo/fetus is not required unless that dose equivalent is also the most representative deep dose equivalent for the region of the embryo/fetus.

(4) If by the time the woman declares pregnancy to the licensee, the dose equivalent to the embryo/fetus has exceeded 0.45 rem (4.5 mSv), the licensee shall be deemed to be in compliance with paragraph (1) of this subsection, if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

(n) Dose limits for individual members of the public.

(1) Each licensee shall conduct operations so that:

(A) The total effective dose equivalent to individual members of the public from the licensed and/or registered operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material), from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with subsection (gg) of this section; and

(B) the dose in any unrestricted area from licensed and/or registered external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with §289.256 of this title, does not exceed 0.002 rem (0.02 mSv) in any one hour.

(2) If the licensee permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

(3) A licensee or an applicant for a license may apply for prior agency authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

(A) demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (1) of this subsection;

(B) the licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(C) the procedures to be followed to maintain the dose ALARA.

(4) In addition to the requirements of this section, a licensee subject to the provisions of the United States Environmental Protection Agency's (EPA) generally applicable environmental radiation standards in 40 Code of Federal Regulations (CFR), §190 shall comply with those requirements.

(5) The agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

(6) Notwithstanding paragraph (1)(A) of this subsection, a licensee may permit visitors to an individual who cannot be released, in accordance with §289.256 of this title, to receive a radiation dose greater than 0.1 rem (1 mSv) if:

(A) the radiation dose received does not exceed 0.5 rem (5 mSv); and

(B) the authorized user, as defined in §289.256 of this title, has determined before the visit that it is appropriate.

(o) Compliance with dose limits for individual members of the public.

(1) The licensee shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public as required in subsection (n) of this section.

(2) A licensee shall show compliance with the annual dose limit in subsection (n) of this section by:

(A) demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(B) demonstrating that:

(i) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of subsection (ggg)(2) of this section; and

(ii) if an individual were continuously present in an unrestricted area, the dose from external sources of radiation would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

(3) Upon approval from the agency, the licensee may adjust the effluent concentration values in Table II, of subsection (ggg)(2) of this section, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

(p) General surveys and monitoring.

(1) Each licensee shall make, or cause to be made, surveys that:

(A) are necessary for the licensee to comply with this chapter; and

(B) are necessary under the circumstances to evaluate:

(i) the magnitude and extent of radiation levels;

(ii) concentrations or quantities of radioactive material; and

(iii) the potential radiological hazards.

(2) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are operable and calibrated:

(A) by a person licensed or registered by the agency, another agreement state, a licensing state, or the United States Nuclear Regulatory Commission (NRC) to perform such service;

(B) at intervals not to exceed 12 months unless a different time interval is specified in another section of this chapter;

(C) after each instrument or equipment repair;

(D) for the types of radiation used and at energies appropriate for use; and

(E) at an accuracy within 20% of the true radiation level.

(3) All individual monitoring devices, except for direct and indirect reading pocket dosimeters, electronic personal dosimeters, and those individual monitoring devices used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees to comply with subsection (f) of this section, with other applicable provisions of this chapter, or with conditions specified in a license, shall be processed and evaluated by a dosimetry processor:

(A) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology;

(B) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(4) All individual monitoring devices shall be appropriate for the environment in which they are used.

(q) Conditions requiring individual monitoring of external and internal occupational dose. Each licensee shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this section. As a minimum:

(1) each licensee shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

(A) adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in subsection (f)(1) of this section;

(B) minors likely to receive, in one year from sources of radiation external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(C) declared pregnant women likely to receive during the entire pregnancy, from sources of radiation external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and

(D) individuals entering a high or very high radiation area;

(2) notwithstanding paragraph (1)(C) of this subsection, a licensee is exempt from supplying individual monitoring devices to healthcare personnel who may enter a high radiation area while providing patient care if:

(A) the personnel are not likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in subsection (f)(1) of this section; and

(B) the licensee complies with the requirements of subsection (e)(2) of this section; and

(3) each licensee shall monitor, to determine compliance with subsection (i) of this section, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(A) adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in Columns 1 and 2 of Table I of subsection (ggg)(2) of this section;

(B) minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

(C) declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

(r) Location and use of individual monitoring devices.

(1) Each licensee shall ensure that individuals who are required to monitor occupational doses in accordance with subsection (q)(l) of this section wear and use individual monitoring devices as follows.

(A) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar).

(B) If an additional individual monitoring device is used for monitoring the dose to an embryo/fetus of a declared pregnant woman, in accordance with subsection (m)(1) of this section, it shall be located at the waist under any protective apron being worn by the woman.

(C) An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with subsection (f)(1)(B)(*i*) of this section, shall be located at the neck (collar) or at a location closer to the eye, outside any protective apron being worn by the monitored individual.

(D) An individual monitoring device used for monitoring the dose to the skin of the extremities, to demonstrate compliance with subsection (f)(1)(B)(ii) of this section, shall be worn on the skin of the extremity likely to receive the highest exposure. Each individual monitoring device, to the extent practicable, shall be oriented to measure the highest dose to the skin of the extremity being monitored.

(E) An individual monitoring device shall be assigned to and worn by only one individual.

(F) An individual monitoring device shall be worn for the period of time authorized by the dosimetry processor's certificate of registration or for no longer than three months, whichever is more restrictive.

(2) Each licensee shall ensure that individual monitoring devices are returned to the dosimetry processor for proper processing.

(3) Each licensee shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

(s) Control of access to high radiation areas.

(1) The licensee shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(A) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in one hour at 30 centimeters (cm) from the source of radiation from any surface that the radiation penetrates;

(B) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(C) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by paragraph (1) of this subsection for a high radiation area, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The licensee may apply to the agency for approval of alternative methods for controlling access to high radiation areas.

(4) The licensee shall establish the controls required by paragraphs (1) and (3) of this subsection in a way that does not prevent individuals from leaving a high radiation area.

(5) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the United States Department of Transportation (DOT) provided that:

(A) the packages do not remain in the area longer than three days; and

(B) the dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 millisievert) per hour.

(6) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to sources of radiation in excess of the established limits in this section and to operate within the ALARA provisions of the licensee's radiation protection program.

(t) Control of access to very high radiation areas. In addition to the requirements in subsection (s) of this section, the licensee shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in one hour at 1 m from a source of radiation or any surface through which the radiation penetrates at this level.

(u) Control of access to very high radiation areas for irradiators.

(1) This subsection applies to licensees with sources of radiation in non-self-shielded irradiators. This subsection does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

(2) Each area in which there may exist radiation levels in excess of 500 rads (5 grays) in one hour at 1 m from a source of radiation that is used to irradiate materials shall meet the following requirements.

(A) Each entrance or access point shall be equipped with entry control devices that:

(i) function automatically to prevent any individual from inadvertently entering a very high radiation area;

(ii) permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and

(iii) prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 0.1 rem (1 mSv) in one hour.

(B) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subparagraph (A) of this paragraph:

(i) the radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and

(ii) conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(C) The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(i) the radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and

(ii) conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(D) When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(E) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances, need not meet the requirements of subparagraphs (C) and (D) of this paragraph.

(F) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

(G) Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

(H) Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour.

(I) The entry control devices required in subparagraph (A) of this paragraph shall be tested for proper functioning. See subsection (uu) of this section for recordkeeping requirements.

(i) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day.

(ii) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption.

(iii) The licensee shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(J) The licensee shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(K) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

(3) Licensees or applicants for licenses for sources of radiation within the purview of paragraph (2) of this subsection that will be used in a variety of positions or in locations, such as open fields or forests, which make it impracticable to comply with certain requirements of paragraph (2) of this subsection, such as those for the automatic control of radiation levels, may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in paragraph (2) of this subsection. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

(4) The entry control devices required by paragraphs (2) and (3) of this subsection shall be established in such a way that no individual will be prevented from leaving the area.

(v) Use of process or other engineering controls. The licensee shall use, to the extent practicable, process or other engineering controls, such as containment, decontamination, or ventilation, to control the concentrations of radioactive material in air.

(w) Use of other controls.

(1) When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

(A) control of access;

(B) limitation of exposure times;

(C) use of respiratory protection equipment; or

(D) other controls

(2) If the licensee performs an ALARA analysis to determine whether respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee shall also consider the impact of respirator use on workers' industrial health and safety.

(x) Use of individual respiratory protection equipment.

(1) If the licensee uses respiratory protection equipment to limit intakes of radioactive material in accordance with subsection (w) of this section, the licensee shall do the following.

(A) Except as provided in subparagraph (B) of this paragraph, the licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH).

(B) If the licensee wishes to use equipment that has not been tested or certified by the NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application to the agency for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(C) The licensee shall implement and maintain a respiratory protection program that includes:

(i) air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(ii) surveys and bioassays, as appropriate, to evaluate actual intakes;

(iii) testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(iv) written procedures regarding the following:

(I) monitoring, including air sampling and bioassays;

(II) supervision and training of respirator users;

(III) fit testing;

(IV) respirator selection;

(V) breathing air quality;

(VI) inventory and control;

(VII) storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(VIII) recordkeeping; and

(IX) limitations on periods of respirator use and relief from respirator use;

(v) determination by a physician prior to initial fitting of a face sealing respirator and the first field use of non-face sealing respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment; and

(vi) fit testing, with fit factor > 10 times the APF for negative pressure devices, and a fit factor > 500 for any positive pressure, continuous flow, and presure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing shall be performed with the facepiece operating in the negative pressure mode.

(D) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(E) The licensee shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide for vision correction, adequate communication, low-temperature work environment, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(F) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual may have difficulty extricating himself or herself. The standby persons shall be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(G) Atmosphere-supplying respirators shall be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (Title 29, CFR, §1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include:

(i) oxygen content (volume/volume) of 19.5-23.5%;

(ii) hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(iii) carbon monoxide (CO) content of 10 parts per million (ppm) or less;

(iv) carbon dioxide content of 1,000 ppm or less; and

(v) lack of noticeable odor.

(H) the licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face-facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(I) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

(2) The agency may impose restrictions in addition to those in paragraph (1) of this subsection, subsection (w) of this section, and subsection (ggg)(1) of this section, in order to:

(A) ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(B) limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

(3) The licensee shall obtain authorization from the agency before assigning respiratory protection factors in excess of those specified in subsection (ggg)(1) of this section. The agency may authorize a licensee to use higher protection factors on receipt of an application that:

(A) describes the situation for which a need exists for higher protection factors; and

(B) demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

(y) Security and control of licensed sources of radiation.

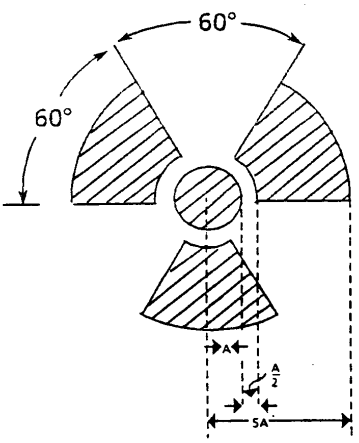
(1) The licensee shall secure radioactive material from unauthorized removal or access.

(2) The licensee shall maintain constant surveillance, using devices and/or administrative procedures to prevent unauthorized access to use of radioactive material that is in an unrestricted area and that is not in storage.

(3) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(z) Caution signs.

(1) Unless otherwise authorized by the agency, the standard radiation symbol prescribed shall use the colors magenta, or purple, or black on yellow background. The standard radiation symbol prescribed is the three-bladed design as follows:



(A) the cross-hatched area of the symbol is to be magenta, or purple, or black; and

(B) the background of the symbol is to be yellow

(2) Notwithstanding the requirements of paragraph (1) of this subsection, licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(aa) Posting requirements.

(1) The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(2) The licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(3) The licensee shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA." If the very high radiation area involves medical treatment of patients, the licensee may omit the word "GRAVE" from the sign or signs.

(4) The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(5) The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in subsection (ggg)(3) of this section with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

(bb) Exceptions to posting requirements.

(1) A licensee is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:

(A) the sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this section; and

(B) the area or room is subject to the licensee's control.

(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs in accordance with subsection (aa) of this section provided that the patient could be released from licensee control in accordance with this chapter.

(3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source(s) provided the radiation level at 30 centimeters from the surface of the sealed source container(s) or housing(s) does not exceed 0.005 rem (0.05 mSv) per hour.

(4) Rooms in medical facilities that are used for teletherapy are exempt from the requirement to post caution signs in accordance with subsection (aa) of this section provided the following conditions are met.

(A) Access to the room is controlled in accordance with this chapter; and

(B) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this section.

(cc) Labeling containers.

(1) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(dd) Exemptions to labeling requirements. A licensee is not required to label:

(1) containers holding licensed material in quantities less than the quantities listed in subsection (ggg)(3) of this section;

(2) containers holding licensed material in concentrations less than those specified in Table III of subsection (ggg)(2) of this section;

(3) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this section;

(4) containers when they are in transport and packaged and labeled in accordance with the rules of the DOT (labeling of packages containing radioactive materials is required by the DOT if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations 49 CFR §§173.403(m) and (w) and 173.424);

(5) containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(6) installed manufacturing or process equipment, such as piping and tanks.

(ee) Procedures for receiving and opening packages.

(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in §289.201(b) of this title and specified in §289.257(ee)(6) of this title (relating to Packaging and Transportation of Radioactive Material), shall make arrangements to receive:

(A) the package when the carrier offers it for delivery; or

(B) the notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(2) Each licensee shall:

(A) monitor the external surfaces of a labeled package, labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations Title 49, CFR, §§172.403 and 172.436-440, for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in §289.201(b) of this title;

(B) monitor the external surfaces of a labeled package, labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations 49 CFR §§172.403 and 172.436-440, for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in §289.201(b) of this title and specified in §289.257(ee)(6) of this title; and

(C) monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(3) The licensee shall perform the monitoring required by paragraph (2) of this subsection as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours. If a package is received after working hours, the package shall be monitored no later than three hours from the beginning of the next working day. If the licensee discovers there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged, the package shall be surveyed immediately.

(4) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the agency when removable radioactive surface contamination or external radiation levels exceed the limits established in subparagraphs (A) and (B) of this paragraph.

(A) Limits for removable radioactive surface contamination levels.

(i) The level of removable radioactive contamination on the external surfaces of each package offered for shipment shall be ALARA. The level of removable radioactive contamination may be determined by wiping an area of 300 square centimeters (cm^2) of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in clause (iii) of this subparagraph, the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in clause (ii) of this subparagraph at any time during transport. If other methods are used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in clause (ii) of this subparagraph.

(ii) Removable external radioactive contamination wipe limits are as follows.

Contaminant	Maximum Permissible Limits pCi/cm^2 *	 dpm/cm^2
Beta-gamma emitting radionuclides; all radionuclides with half-lives less than 10 days; natural uranium; natural thorium, uranium-235; uranium-238; thorium-232; thorium-228; and thorium-230 when contained in ores or physical concentrates….	100	220
All other alpha emitting radionuclides….	10	22

(iii) In the case of packages transported as exclusive use shipments by rail or highway only, the removable radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in clause (ii) of this subparagraph. The levels at the beginning of transport must not exceed the levels in clause (ii) of this subparagraph.

* To convert picocuries (pCi) to SI units of millibecquerels, multiply the values by 37.

(B) Limits for external radiation levels.

(i) External radiation levels around the package and around the vehicle, if applicable, will not exceed 200 millirems per hour (mrem/hr) (2 millisieverts per hour (mSv/hr)) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10.

(ii) For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in clause (i) of this subparagraph but shall not exceed any of the following:

(I) 200 mrem/hr (2 mSv/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1,000 mrem/hr (10 mSv/hr):

(-a-) the shipment is made in a closed transport vehicle;

(-b-) provisions are made to secure the package so that its position within the vehicle remains fixed during transportation; and

(-c-) there are no loading or unloading operations between the beginning and end of the transportation;

(II) 200 mrem/hr (2 mSv/hr) at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flat-bed style vehicle, with a personnel barrier, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used), and on the lower external surface of the vehicle (a flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 200 mrem/hr (2 mSv/hr) at the surface.);

(III) 10 mrem/hr (0.1 mSv/hr) at any point 2 m from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point 2 m from the vertical planes projected from the outer edges of the vehicle; and

(IV) 2 mrem/hr (0.02 mSv/hr) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with §289.203(c) of this title (relating to Notices, Instructions, and Reports to Workers; Inspections).

(5) Each licensee shall:

(A) establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(B) ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(6) Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of paragraph (2) of this subsection, but are not exempt from the monitoring requirement in paragraph (2) of this subsection for measuring radiation levels that ensures that the source is still properly lodged in its shield.

(ff) General requirements for waste management.

(1) Unless otherwise exempted, a licensee shall discharge, treat, or decay licensed material or transfer waste for disposal only:

(A) by transfer to an authorized recipient as provided in subsection (jj) of this section, §289.252 of this title (relating to Licensing of Radioactive Material), §289.257 of this title, §289.259 of this title, or to the United States Department of Energy (DOE);

(B) by decay in storage with prior approval from the agency, except as authorized in §289.256(ee) of this title (relating to Medical and Veterinary Use of Radioactive Material);

(C) by release in effluents within the limits in subsection (n) of this section; or

(D) as authorized in accordance with paragraph (2) of this subsection, and subsections (gg), (hh), and (fff) of this section.

(2) Upon agency approval, emission control dust and other material from electric arc furnaces or foundries contaminated as a result of inadvertent melting of cesium-137 or americium-241 sources may be transferred for disposal to a hazardous waste disposal facility authorized by the Texas Commission on Environmental Quality (Commission) or its successor, another state's regulatory agency with jurisdiction to regulate hazardous waste as classified under Subtitle C of the Resource Conservation and Recovery Act (RCRA), or the EPA. The material may be transferred for disposal without regard to its radioactivity if the following conditions are met.

(A) Contaminated material described in paragraph (2) of this subsection, whether packaged or unpackaged (i.e., bulk), must be treated through stabilization to comply with all waste treatment requirements of the appropriate state or federal regulatory agency as listed in this paragraph. The treatment operations must be undertaken by either of the following:

(i) the owner/operator of the electric arc furnace or foundry licensed to possess, treat or transfer cesium-137 or americium-241 contaminated incident-related material; or

(ii) a service contractor licensed by the agency, NRC, or an agreement state to possess, treat, or transfer cesium-137 or americium-241 contaminated incident-related material.

(B) The emission control dust and other incident-related materials have been stored (if applicable) and transferred in accordance with operating and emergency procedures approved by the agency.

(C) The total cesium-137 or americium-241 activity contained in emission control dust and other incident-related materials to be transferred to a hazardous waste disposal facility has been specifically approved by NRC or the appropriate agreement state(s) and does not exceed the total activity associated with the inadvertent melting incident.

(D) The hazardous waste disposal facility operator has been notified in writing of the impending transfer of the incident-related materials and has agreed in writing to receive and dispose of the packaged or unpackaged materials. Copies of the notification and agreement shall be submitted to the agency.

(E) The licensee, as listed in subparagraph (A)(i) or (ii) of this paragraph, notifies the NRC or agreement state(s) in which the transferor and transferee are located, in writing, of the impending transfer, at least 30 days before the transfer.

(F) The packaged stabilized material has been packaged for transportation and disposal in non-bulk steel packaging as defined in DOT regulations at 49 CFR 173.213.

(G) The emission control dust and other incident-related materials that have been stabilized and packaged as described in subparagraph (F) of this paragraph shall contain pretreatment average concentrations of cesium-137 that do not exceed 130 pCi/g of material, above background, or pretreatment average concentrations of americium-241 that do not exceed 3 pCi/g of material, above background.

(H) The dose rate at 3.28 feet (1 m) from the surface of any package containing stabilized waste shall not exceed 20 microrem per hour or 0.20 microSv per hour, above background.

(I) The unpackaged stabilized material shall contain pretreatment average concentrations of cesium-137 that do not exceed 100 pCi/g of material, above background, or pretreatment average concentrations of americium-241 that do not exceed 3 pCi/g of material, above background.

(J) The licensee transferring the cesium-137 or americium-241 contaminated incident-related material must consult with the agency, the Commission or its successor, another state's regulatory agency with jurisdiction to regulate hazardous waste as classified under RCRA, or the EPA and other authorized parties, including state and local governments, and obtain all necessary approvals, in addition to those of NRC and/or appropriate agreement states, for the transfers described in paragraph (2) of this subsection.

(K) Nothing in this subsection shall be or is intended to be construed as a waiver of any RCRA permit condition or term, of any state or local statute or regulation, or of any federal RCRA regulation.

(L) The total incident-related cesium-137 activity described in paragraph (2) of this subsection received by a facility over its operating life shall not exceed 1 Ci (37 GBq). The total incident-related americium-241 activity described in paragraph (2) of this subsection received by a facility over its operating life shall not exceed 30 mCi (1.11MBq). The agency will maintain a record of the total incident-related cesium-137 or americium-241 activity shipped by a person licensed by the agency. Upon consultation with the Commission, the agency will determine if the total incident-related activity received by a hazardous waste disposal facility over its operating life has reached 1 Ci (37 GBq) of cesium-137 or 30 mCi (1.11MBq) of americium-241. The agency will not approve shipments of cesium-137 or americium-241 contaminated incident-related material that will cause this limit to be exceeded.

(3) A person shall be specifically licensed to receive waste containing licensed material from other persons for:

(A) treatment prior to disposal;

(B) treatment by incineration;

(C) decay in storage;

(D) disposal at an authorized land disposal facility; or

(E) storage until transferred to a storage or disposal facility authorized to receive the waste.

(4) Byproduct material as defined in §289.201(b)(15)(C) - (E) of this title may be disposed of in accordance with Title 10, CFR, Part 61, even though it is not defined as low level radioactive waste. Therefore, any byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under Title 10, CFR, Part 61, shall meet the requirements of this chapter.

(5) A licensee may dispose of byproduct material, as defined in §289.201(b)(15)(C) - (E) of this title, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law.

(6) Any licensee shipping byproduct material as defined in §289.201(b)(15)(C) - (E) of this title intended for ultimate disposal at a land disposal facility licensed under Title 10, CFR, Part 61, shall document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with §289.257(gg) of this title.

(gg) Discharge by release into sanitary sewerage.

(1) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(A) the material is readily soluble, or is readily dispersible biological material, in water;

(B) the quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of subsection (ggg)(2) of this section; and

(C) if more than one radionuclide is released, the following additional conditions must also be satisfied:

(i) the fraction of the limit in Table III of subsection (ggg)(2) of this section represented by discharges into sanitary sewerage determined by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of subsection (ggg)(2) of this section; and

(ii) the sum of the fractions for each radionuclide required by clause (i) of this subparagraph does not exceed unity; and

(D) the total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 5 curies (Ci) (185 gigabecquerels (GBq)) of hydrogen-3, 1 Ci (37 GBq) of carbon-14, and 1 Ci (37 GBq) of all other radioactive materials combined.

(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in paragraph (1) of this subsection.

(hh) Treatment by incineration. A licensee may treat licensed material by incineration only in the form and concentration specified in subsection (fff)(1) of this section or as authorized by the agency.

(ii) Discharge by release into septic tanks. No licensee shall discharge radioactive material into a septic tank system except as specifically approved by the agency.

(jj) Transfer for disposal and manifests.

(1) The control of transfers of LLRW intended for disposal at a licensed low-level radioactive waste disposal facility, the establishment of a manifest tracking system, and additional requirements concerning transfers and recordkeeping for those wastes are found in §289.257(s)(5) of this title.

(2) Each person involved in the transfer of waste for disposal including the waste generator, waste collector, and waste processor, shall comply with the requirements specified in §289.257(s)(5) of this title.

(kk) Compliance with environmental and health protection regulations. Nothing in subsections (ff), (gg), (hh), or (jj) of this section relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of in accordance with subsections (ff), (gg), (hh), or (jj) of this section.

(ll) General provisions for records.

(1) Each licensee shall use the International System of Units (SI) units becquerel, gray, sievert, and coulomb per kilogram, or the special units curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this section. Disintegrations per minute may be indicated on records of surveys performed to determine compliance with subsections (ee)(4) and (ggg)(6) of this section. To ensure compatibility with international transportation standards, all limits in this section are given in terms of dual units: The SI units followed or preceded by United States (U.S.) standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this section, either unit may be used.

(2) Notwithstanding the requirements of paragraph (1) of this subsection, when recording information on shipment manifests, as required in §289.257 of this title, information must be recorded in SI units or in SI and units as specified in paragraph (1) of this subsection.

(3) The licensee shall make a clear distinction among the quantities entered on the records required by this section, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(4) Records required in accordance with §289.201(d) of this title, and subsections (mm)-(oo), and (ss) - (uu) of this section shall include the date and the identification of individual(s) making the record, and, as applicable, a unique identification of survey instrument(s) used, and an exact description of the location of the survey. Records of receipt, transfer, and disposal of sources of radiation shall uniquely identify the source of radiation.

(5) Copies of records required in accordance with §289.201(d) of this title, and subsections (mm)-(uu) of this section, and by license condition that are relevant to operations at an additional authorized use/storage site shall be maintained at that site in addition to the main site specified on a license.

(mm) Records of radiation protection programs.

(1) Each licensee shall maintain records of the radiation protection program, including:

(A) the provisions of the program; and

(B) audits and other reviews of program content and implementation.

(2) The licensee shall retain the records required by paragraph (1)(A) of this subsection until the agency terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph (1)(B) of this subsection for three years after the record is made.

(nn) Records of surveys.

(1) Each licensee shall maintain records showing the results of surveys and calibrations required by subsections (p) and (ee)(2) of this section and include a unique identification of survey instrument(s). The licensee shall retain these records for three years after the record is made.

(2) The licensee shall retain each of the following records until the agency terminates each pertinent license requiring the record:

(A) the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

(B) results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(C) results of air sampling, surveys, and bioassays required in accordance with subsection (x)(1)(C)(i) and (ii) of this section; and

(D) results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

(oo) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by §289.201(g) of this title shall be kept in units of becquerel or microcurie and retained for inspection by the agency for five years after the records are made.

(pp) Records of lifetime cumulative occupational radiation dose. The licensee shall retain the records of lifetime cumulative occupational radiation dose as specified in subsection (k) of this section on RC Form 202-2 or equivalent until the agency terminates each pertinent license requiring this record. The licensee shall retain records used in preparing RC Form 202-2 or equivalent for three years after the record is made.

(qq) Records of planned special exposures.

(1) For each use of the provisions of subsection (k) of this section for planned special exposures, the licensee shall maintain records that describe:

(A) the exceptional circumstances requiring the use of a planned special exposure;

(B) the name of the management official who authorized the planned special exposure and a copy of the signed authorization;

(C) what actions were necessary;

(D) why the actions were necessary;

(E) what precautions were taken to assure that doses were maintained ALARA;

(F) what individual and collective doses were expected to result; and

(G) the doses actually received in the planned special exposure.

(2) The licensee shall retain the records until the agency terminates each pertinent license requiring these records.

(rr) Records of individual monitoring results.

(1) Each licensee shall maintain records of doses received by all individuals for whom monitoring was required in accordance with subsection (q) of this section, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed. These records shall include, when applicable:

(A) the deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

(B) the estimated intake of radionuclides, see subsection (g) of this section;

(C) the committed effective dose equivalent assigned to the intake of radionuclides;

(D) the specific information used to calculate the committed effective dose equivalent in accordance with subsection (i)(1) and (3) of this section and when required by subsection (q)(1) of this section;

(E) the total effective dose equivalent when required by subsection (g) of this section;

(F) the total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose; and

(G) the data used to make occupational dose assessments in accordance with subsection (j)(5) of this section.

(2) The licensee shall make entries of the records specified in paragraph (1) of this subsection at intervals not to exceed 1 year and by April 30 of the following year.

(3) The licensee shall maintain the records specified in paragraph (1) of this subsection on RC Form 202-3, in accordance with the instructions for RC Form 202-3, or in clear and legible records containing all the information required by RC Form 202-3.

(4) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(5) The licensee shall retain each required form or record until the agency terminates each pertinent license requiring the record. The licensee shall retain records used in preparing RC Form 202-3 or equivalent for three years after the record is made.

(ss) Records of dose to individual members of the public.

(1) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See subsection (n) of this section.

(2) The licensee shall retain the records required by paragraph (1) of this subsection until the agency terminates each pertinent license requiring the record.

(tt) Records of discharge, treatment, or transfer for disposal.

(1) Each licensee shall maintain records of the discharge or treatment of licensed materials made in accordance with subsection (gg) and (hh) of this section and of transfers for disposal made in accordance with subsection (jj) of this section and §289.257 of this title.

(2) The licensee shall retain the records required by paragraph (1) of this subsection until the agency terminates each pertinent license requiring the record.

(uu) Records of testing entry control devices for very high radiation areas.

(1) Each licensee shall maintain records of tests made in accordance with subsection (u)(2)(I) of this section on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(2) The licensee shall retain the records required by paragraph (1) of this subsection for three years after the record is made.

(vv) Form of records. Each record required by this chapter shall be legible throughout the specified retention period. The record shall 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 or 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, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(ww) Reports of stolen, lost, or missing licensed sources of radiation.

(1) Each licensee shall report to the agency by telephone as follows:

(A) immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in subsection (ggg)(3) of this section, under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or

(B) within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in subsection (ggg)(3) of this section that is still missing.

(2) Each licensee required to make a report in accordance with paragraph (1) of this subsection shall, within 30 days after making the telephone report, make a written report to the agency setting forth the following information:

(A) a description of the licensed source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form;

(B) a description of the circumstances under which the loss or theft occurred;

(C) a statement of disposition, or probable disposition, of the licensed source of radiation involved;

(D) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(E) actions that have been taken, or will be taken, to recover the source of radiation; and

(F) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed sources of radiation.

(3) Subsequent to filing the written report, the licensee shall also report additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(4) The licensee shall prepare any report filed with the agency in accordance with this subsection so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(xx) Notification of incidents.

(1) Notwithstanding other requirements for notification, each licensee shall immediately report each event involving a source of radiation possessed by the licensee that may have caused or threatens to cause:

(A) an individual, except a patient administered radiation for purposes of medical diagnosis or therapy, to receive:

(i) a total effective dose equivalent of 25 rems (0.25 Sv) or more;

(ii) a lens dose equivalent of 75 rems (0.75 Sv) or more; or

(iii) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rads (2.5 grays) or more; or

(B) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(2) Each licensee shall, within 24 hours of discovery of the event, report to the agency each event involving loss of control of a licensed source of radiation possessed by the licensee that may have caused, or threatens to cause:

(A) an individual to receive, in a period of 24 hours:

(i) a total effective dose equivalent exceeding 5 rems (0.05 Sv);

(ii) a lens dose equivalent exceeding 15 rems (0.15 Sv); or

(iii) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rems (0.5 Sv); or

(B) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) Licensees shall make the initial notification reports required by paragraphs (1) and (2) of this subsection by telephone to the agency and shall confirm the initial notification report within 24 hours by telegram, mailgram, or facsimile to the agency.

(4) The licensee shall prepare each report filed with the agency in accordance with this section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(5) The provisions of this section do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported in accordance with subsection (zz) of this section.

(6) Each licensee shall notify the agency as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radioactive materials that could exceed regulatory limits or releases of radioactive materials that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(7) Each licensee shall notify the agency within 24 hours after the discovery of any of the following events involving radioactive material:

(A) an unplanned contamination event that:

(i) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) involves a quantity of material greater than five times the lowest annual limit on intake specified in subsection (ggg)(2) of this section for the material; and

(iii) has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(B) an event in which equipment is disabled or fails to function as designed when:

(i) the equipment is required by rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) the equipment is required to be available and operable when it is disabled or fails to function; and

(iii) no redundant equipment is available and operable to perform the required safety function;

(C) an event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body; or

(D) an unplanned fire or explosion damaging any radioactive material or any device, container, or equipment containing radioactive material when:

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified in subsection (ggg)(2) of this section for the material; and

(ii) the damage affects the integrity of the radioactive material or its container.

(8) Preparation and submission of reports. Reports made by licensees in response to the requirements of paragraphs (6) and (7) of this subsection shall be made as follows.

(A) Licensees shall make reports required by paragraphs (6) and (7) of this subsection by telephone to the agency. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

(i) the caller's name and call back telephone number;

(ii) a description of the event, including date and time;

(iii) the exact location of the event;

(iv) the isotopes, quantities, and chemical and physical form of the radioactive material involved; and

(v) any personnel radiation exposure data available.

(B) Each licensee who makes a report required by paragraphs (6) and (7) of this subsection shall submit to the agency a written follow-up report within 30 days of the initial report. Written reports prepared in accordance with other requirements of this chapter may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. The reports must include the following:

(i) a description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) the exact location of the event;

(iii) the isotopes, quantities, and chemical and physical form of the radioactive material involved;

(iv) date and time of the event;

(v) corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) the extent of exposure of individuals to radioactive materials without identification of individuals by name.

(yy) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits.

(1) In addition to the notification required by subsection (xx) of this section, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

(A) incidents for which notification is required by subsection (xx) of this section;

(B) doses in excess of any of the following:

(i) the occupational dose limits for adults in subsection (f) of this section;

(ii) the occupational dose limits for a minor in subsection (l) of this section;

(iii) the limits for an embryo/fetus of a declared pregnant woman in subsection (m) of this section;

(iv) the limits for an individual member of the public in subsection (n) of this section;

(v) any applicable limit in the license; or

(vi) the ALARA constraints for air emissions as required by subsection (e)(4) of this section;

(C) levels of radiation or concentrations of radioactive material in:

(i) a restricted area in excess of applicable limits in the license; or

(ii) an unrestricted area in excess of 10 times the applicable limit set forth in this section or in the license, whether or not involving exposure of any individual in excess of the limits in subsection (n) of this section; or

(D) for licensees subject to the provisions of the EPA's generally applicable environmental radiation standards in 40 CFR §190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those requirements.

(2) Each report required by paragraph (1) of this subsection shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(A) estimates of each individual's dose;

(B) the levels of radiation and concentrations of radioactive material involved;

(C) the cause of the elevated exposures, dose rates, or concentrations; and

(D) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

(3) Each report filed in accordance with paragraph (1) of this subsection shall include for each individual exposed: the name, identification number, and date of birth. With respect to the limit for the embryo/fetus in subsection (m) of this section, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(4) All licensees who make reports in accordance with paragraph (1) of this subsection shall submit the report in writing to the agency.

(zz) Reports of planned special exposures. The licensee shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with subsection (k) of this section, informing the agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by subsection (qq) of this section.

(aaa) Notifications and reports to individuals.

(1) Requirements for notification and reports to individuals of exposure to sources of radiation are specified in §289.203 of this title.

(2) When a licensee is required in accordance with subsection (yy) or (zz) of this section to report to the agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to sources of radiation, the licensee shall also notify the individual and provide a copy of the report submitted to the agency, to the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency, and shall comply with the provisions of §289.203(d)(1) of this title.

(bbb) Reports of leaking or contaminated sealed sources. The licensee shall immediately notify the agency if the test for leakage or contamination required in accordance with §289.201(g) of this title indicates a sealed source is leaking or contaminated. A written report of a leaking or contaminated source shall be submitted to the agency within five days. The report shall include the equipment involved, the test results, the date of the test, model and serial number, if assigned, of the leaking source, the radionuclide and its estimated activity, and the corrective action taken.

(ccc) Vacating premises.

(1) Each licensee or person possessing non-exempt sources of radiation shall, no less than 30 days before vacating and relinquishing possession or control of premises, notify the agency, in writing, of the intent to vacate.

(2) The licensee or person possessing non-exempt radioactive material shall decommission the premises to a degree consistent with subsequent use as an unrestricted area and in accordance with the requirements of subsection (ddd) of this section.

(ddd) Radiological requirements for license termination.

(1) General provisions and scope.

(A) The requirements in this section apply to the decommissioning of facilities licensed in accordance with §289.252 of this title, §289.255 of this title, and §289.258 of this title (relating to Licensing and Radiation Safety Requirements for Irradiators).

(B) The requirements in this section do not apply to the following:

(i) sites that have been decommissioned prior to October 1, 2000, in accordance with requirements identified in this section and in §289.252 of this title; or

(ii) sites that have previously submitted and received approval on a decommissioning plan by October 1, 2000.

(C) After a site has been decommissioned and the license terminated in accordance with the requirements in the subsection, the agency will require additional cleanup if it determines that the requirements of the subsection were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(D) When calculating TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE dose expected within the first 1,000 years after decommissioning.

(2) Radiological requirements for unrestricted use. A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA. Determination of the levels that are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

(3) Alternate requirements for license termination.

(A) The agency may terminate a license using alternate requirements greater than the dose requirements specified in paragraph (2) of this subsection if the licensee does the following:

(i) provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv per year (100 mrem per year) limit specified in subsection (o) of this section, by submitting an analysis of possible sources of exposure;

(ii) reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal; and

(iii) has submitted a decommissioning plan to the agency indicating the licensee's intent to decommission in accordance with the requirements in §289.252(l)(7) of this title, and specifying that the licensee proposes to decommission by use of alternate requirements. The licensee shall document in the decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for the following:

(I) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(II) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(III) a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(B) The use of alternate requirements to terminate a license requires the approval of the agency after consideration of the agency's recommendations that will address any comments provided by the EPA and any public comments submitted in accordance with paragraph (4) of this subsection.

(4) Public notification and public participation. Upon receipt of a decommissioning plan from the licensee, or a proposal from the licensee for release of a site in accordance with paragraph (3) of this subsection, or whenever the agency deems such notice to be in the public interest, the agency will do the following:

(A) notify and solicit comments from the following:

(i) local and state governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(ii) the EPA for cases where the licensee proposes to release a site in accordance with paragraph (3) of this subsection; and

(B) publish a notice in the Texas Register and a forum, such as local newspapers, letters to state of local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

(5) Minimization of contamination. Applicants for licenses, other than renewals, after October 1, 2000, shall describe in the application how facility design and procedures for operation will minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practical, the generation of LLRW.

(eee) Limits for contamination of soil, surfaces of facilities and equipment, and vegetation.

(1) No licensee shall possess, receive, use, or transfer radioactive material in such a manner as to cause contamination of surfaces of facilities or equipment in unrestricted areas to the extent that the contamination exceeds the limits specified in subsection (ggg)(6) of this section.

(2) No licensee shall possess, receive, use, or transfer radioactive material in such a manner as to cause contamination of soil in unrestricted areas, to the extent that the contamination exceeds, on a dry weight basis, the concentration limits specified in:

(A) subsection (ddd) of this section; or

(B) the effluent concentrations in Table II, Column 2 of subsection (ggg)(2)(F) of this section, with the units changed from microcuries per milliliter to microcuries per gram, for radionuclides not specified in paragraph (4) of this subsection.

(3) Where combinations of radionuclides are involved, the sum of the ratios between the concentrations present and the limits specified in paragraph (2) of this subsection shall not exceed one.

(4) Notwithstanding the limits specified in paragraph (2) of this subsection, no licensee shall cause the concentration of radium-226 or radium-228 in soil in unrestricted areas, averaged over any 100 square meters (m^2), to exceed the background level by more than:

(A) 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

(B) 15 pCi/g (0.555 Bq/g), averaged over 15 cm thick layers of soil more than 15 cm below the surface.

(5) No licensee shall possess, receive, use, or transfer radioactive material in such a manner as to cause contamination of vegetation in unrestricted areas to exceed 5 pCi/g (0.185 Bq/g), based on dry weight, for radium-226 or radium-228.

(6) Notwithstanding the limits specified in paragraph (2) of this subsection, no licensee shall cause the concentration of natural uranium with no daughters present, based on dry weight and averaged over any 100 m^2 of area, to exceed the following limits:

(A) 30 pCi/g (1.11 Bq/g), averaged over the top 15 cm of soil below the surface; and

(B) 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.

(fff) Exemption of specific wastes.

(1) A licensee may discard the following licensed material without regard to its radioactivity:

(A) 0.05 microcurie (µCi) (1.85 kilobecquerels (kBq)), or less, of hydrogen-3, carbon-14, or iodine-125 per gram of medium used for liquid scintillation counting or in vitro clinical or in vitro laboratory testing; and

(B) 0.05 µCi (1.85 kBq), or less, of hydrogen-3, carbon-14, or iodine-125, per gram of animal tissue, averaged over the weight of the entire animal.

(2) A licensee shall not discard tissue in accordance with paragraph (1)(B) of this subsection in a manner that would permit its use either as food for humans or as animal feed.

(3) The licensee shall maintain records in accordance with subsection (tt) of this section.

(4) Any licensee may, upon agency approval of procedures required in paragraph (6) of this subsection, discard licensed material included in subsection (ggg)(7) of this section, provided that it does not exceed the concentration and total curie limits contained therein, in a Type I municipal solid waste site as defined in the Municipal Solid Waste Regulations of the authorized regulatory agency (31 Texas Administrative Code Chapter 330), unless such licensed material also contains hazardous waste, as defined in §3(15) of the Solid Waste Disposal Act, Health and Safety Code, Chapter 361. Any licensed material included in subsection (ggg)(7) of this section and which is a hazardous waste as defined in the Solid Waste Disposal Act may be discarded at a facility authorized to manage hazardous waste by the authorized regulatory agency.

(5) Each licensee who discards material described in paragraphs (1) or (4) of this subsection shall:

(A) make surveys adequate to assure that the limits of paragraphs (1) or (4) of this subsection are not exceeded; and

(B) remove or otherwise obliterate or obscure all labels, tags, or other markings that would indicate that the material or its contents is radioactive.

(6) Prior to authorizations in accordance with paragraph (4) of this subsection, a licensee shall submit procedures to the agency for:

(A) the physical delivery of the material to the disposal site;

(B) surveys to be performed for compliance with paragraph (5)(A) of this subsection;

(C) maintaining secure packaging during transportation to the site; and

(D) maintaining records of any discards made under paragraph (4) of this subsection.

(7) Nothing in this section relieves the licensee of maintaining records showing the receipt, transfer, and discard of such radioactive material as specified in §289.201(d) of this title.

(8) Nothing in this section relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials.

(9) Licensed material discarded under this section is exempt from the requirements of §289.252(ff) of this title.

(ggg) Appendices.

(1) Assigned protection factors for respirators. The following table contains assigned protection factors for respirators[a]:

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	Operating Mode	Assigned Protection Factors
I. Air Purifying Respirators (Particulate[b] only)[c]:		
Filtering faceplate disposable[d]	Negative Pressure	([d])
Facepiece, half[e]	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere Supplying Respirators (particulate, gases and vapors[f]):		
1. Air-line respirator		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	([g])
2. Self-contained breathing apparatus (SCBA):		
Facepiece, full	Demand	100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full	Demand, Recirculating	[h]100
Facepiece, full	Positive Pressure Recirculating	[i]10,000
III. Combination Respirators		
Any combination of air-purifying atmosphere-supplying respirators	Assigned protection factor for type and mode of operation as listed above	

[a]These assigned protection factors apply only in a respiratory protection program that meets the requirements of this section. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances shall also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of subsection (ggg)(2)(F) of this section are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

[b]Air purifying respirators with APF < 100 must be equipped with particulate filters that are at least 95% efficient. Air purifying respirators with APF = 100 shall be equipped with particulate filters that are at least 99% efficient. Air purifying respirators with APFs > 100 shall be equipped with particulate filters that are at least 99.97% efficient.

[c]The licensee may apply to the agency for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

[d]Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use seal check on this type of device. All other respiratory protection program requirements listed in subsection (x) of this section apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

[e]Under-chin type only. No distinction is made in this paragraph between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95% efficient and all other requirements of this section are met.

[f]The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

[g]No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met, for example, subsection (x) of this section.

[h]The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

[i]This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

(2) Annual limits on intake (ALI) and derived air concentrations (DAC) of radionuclides for occupational exposure; effluent concentrations; concentrations for release to sanitary sewerage.

(A) Introduction.

(i) For each radionuclide, Table I of subparagraph (F) of this paragraph indicates the chemical form that is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 micron, and for three classes (D, W, Y) of radioactive material, which refer to their retention (approximately days, weeks, or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II of subparagraph (F) of this paragraph provides concentration limits for airborne and liquid effluents released to the general environment. Table III of subparagraph (F) of this paragraph provides concentration limits for discharges to sanitary sewerage.

(ii) The values in Tables I, II, and III of subparagraph (F) of this paragraph are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^{2} or 600, and 6E+0 represents 6×10^{0} or 6.

(B) Occupational values.

(i) Note that the columns in Table I of subparagraph (F) of this paragraph captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

(ii) The ALIs in subparagraph (F) of this paragraph are the annual intakes of given radionuclide by "Reference Man" that would result in either a committed effective dose equivalent of 5 rems (0.05 Sv), stochastic ALI, or a committed dose equivalent of 50 rems (0.5 Sv) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 5 rems (0.05 Sv). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of "weighting factor" in subsection (c) of this section. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

(iii) A value of $w_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract; stomach, small intestine, upper large intestine, and lower large intestine, are to be treated as four separate organs.

(iv) The dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

(v) When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used as follows:

(I) LLI wall = lower large intestine wall;

(II) St. wall = stomach wall;

(III) Blad wall = bladder wall; and

(IV) Bone surf = bone surface.

(vi) The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 50 rems (0.5 sievert) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, $\sum$ (intake (in μCi) of each radionuclide/ALI_{ns}) $\leq$ 1.0. If there is an external deep dose equivalent contribution of H_d, then this sum must be less than 1 - (H_d/50), instead of $\leq$ 1.0.

(vii) The dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

(viii) The DAC values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

DAC = ALI(in μCi)/(2000 hours per working year x 60 minutes/hour x 2×10^4 ml per minute) = [ALI/2.4×10^9] μCi/ml,

where 2×10^4 milliliter is the volume of air breathed per minute at work by Reference Man under working conditions of light work.

(ix) The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

(x) The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

(xi) The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See subsection (g) of this section. When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

(xii) It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

(C) Effluent concentrations.

(i) The columns in Table II of subparagraph (F) of this paragraph captioned "Effluents," "Air," and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of subsection (o) of this section. The concentration values given in Columns 1 and 2 of Table II of subparagraph (F) of this paragraph are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.05 rem (0.5 mSv).

(ii) Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II of subparagraph (F) of this paragraph. For this reason, the DAC and airborne effluent limits are not always proportional as they were in the previous radiation protection standards.

(iii) The air concentration values listed in Column I of Table II of subparagraph (F) of this paragraph were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9, relating the inhalation ALI to the DAC, as explained in subparagraph (B)(viii) of this paragraph, and then divided by a factor of 300. The factor of 300 includes the following components:

(I) a factor of 50 to relate the 5 rems (0.05 Sv) annual occupational dose limit to the 0.1 rem limit for members of the public;

(II) a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and

(III) a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

(iv) For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Column 3 of Table I of subparagraph (F) of this paragraph was divided by 219. The factor of 219 is composed of a factor of 50, as described in clause (iii) of this subparagraph, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

(v) The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7. The factor of 7.3×10^7 milliliters (ml) includes the following components:

(I) the factors of 50 and 2 described in clause (iii) of this subparagraph; and

(II) a factor of 7.3×10^5 (ml) which is the annual water intake of "Reference Man."

(vi) Note 2 of subparagraph (F) of this paragraph provides groupings of radionuclides that are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations, and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

(D) Releases to sewers. The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in subsection (gg) of this section. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (ml), the annual water intake by "Reference Man," and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a "Reference Man" during a year, would result in a committed effective dose equivalent of 0.5 rem.

(E) List of elements.

Name	Symbol	Atomic Number	Name	Symbol	Atomic Number
Actinium	Ac	89	Iodine	I	53
Aluminum	Al	13	Iridium	Ir	77
Americium	Am	95	Iron	Fe	26
Antimony	Sb	51	Krypton	Kr	36
Argon	Ar	18	Lanthanum	La	57
Arsenic	As	33	Lead	Pb	82
Astatine	At	85	Lutetium	Lu	71
Barium	Ba	56	Magnesium	Mg	12
Berkelium	Bk	97	Manganese	Mn	25
Beryllium	Be	4	Mendelevium	Md	101
Bismuth	Bi	83	Mercury	Hg	80
Bromine	Br	35	Molybdenum	Mo	42
Cadmium	Cd	48	Neodynium	Nd	60
Calcium	Ca	20	Neptunium	Np	93
Californium	Cf	98	Nickel	Ni	28
Carbon	C	6	Niobium	Nb	41
Cerium	Ce	58	Nitrogen	N	7
Cesium	Cs	55	Osmium	Os	76
Chlorine	Cl	17	Oxygen	O	8
Chromium	Cr	24	Palladium	Pd	46
Cobalt	Co	27	Phosphorus	P	15
Copper	Cu	29	Platinum	Pt	78
Curium	Cm	96	Plutonium	Pu	94
Dysprosium	Dy	66	Polonium	Po	84
Einsteinium	Es	99	Potassium	K	19
Erbium	Er	68	Praseodymium	Pr	59
Europium	Eu	63	Promethium	Pm	61
Fermium	Fm	100	Protactinium	Pa	91
Fluorine	F	9	Radium	Ra	88
Francium	Fr	87	Radon	Rn	86
Gadolinium	Gd	64	Rhodium	Rh	45
Gallium	Ga	31	Rubidium	Rb	37
Germanium	Ge	32	Ruthenium	Ru	44
Gold	Au	79	Samarium	Sm	62
Hafnium	Hf	72	Scandium	Sc	21
Holmium	Ho	67	Selenium	Se	34
Hydrogen	H	1	Silicon	Si	14
Indium	In	49	Silver	Ag	47

Name	Symbol	Atomic Number	Name	Symbol	Atomic Number
Sodium	Na	11			
Strontium	Sr	38			
Sulful	S	16			
Tantalum	Ta	73			
Technetium	Tc	43			
Tellurium	Te	52			
Terbium	Tb	65			
Thallium	Tl	81			
Thorium	Th	90			
Thulium	Tm	69			
Tin	Sn	50			
Titanium	Ti	22			
Tungsten	W	74			
Uranium	U	92			
Vanadium	V	23			
Xenon	Xe	54			
Ytterbium	Yb	70			
Yttrium	Y	39			
Zinc	Zn	30			
Zirconium	Zr	40			

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(F) Tables - Values for annual limits. The following tables contain values for annual limits on intake (ALI) and derived air concentrations (DAC) of radionuclides for occupational exposure; effluent concentrations; concentrations for release to sanitary sewerage:

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(3) Quantities of licensed material requiring labeling. The following tables contain quantities† of licensed material requiring labeling:

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Hydrogen-3	1,000	Vanadium 47	1,000
Beryllium-7	1,000	Vanadium-48	100
Beryllium-10	1	Vanadium-49	1,000
Carbon-11	1,000	Chromium-48	1,000
Carbon-14	1,000	Chromium-49	1,000
Fluorine-18	1,000	Chromium-51	1,000
Sodium-22	10	Manganese-51	1,000
Sodium-24	100	Manganese-52m	1,000
Magnesium-28	100	Manganese-52	100
Aluminum-26	10	Manganese-53	1,000
Silicon-31	1,000	Manganese-54	100
Silicon-32	1	Manganese-56	1,000
Phosphorus-32	10	Iron-52	100
Phosphorus-33	100	Iron-55	100
Sulfur-35	100	Iron-59	10
Chlorine-36	10	Iron-60	1
Chlorine-38	1,000	Cobalt-55	100
Chlorine-39	1,000	Cobalt-56	10
Argon-39	1,000	Cobalt-57	100
Argon-41	1,000	Cobalt-58m	1,000
Potassium-40	100	Cobalt-58	100
Potassium-42	1,000	Cobalt-60m	1,000
Potassium-43	1,000	Cobalt-60	1
Potassium-44	1,000	Cobalt-61	1,000
Potassium-45	1,000	Cobalt-62m	1,000
Calcium-41	100	Nickel-56	100
Calcium-45	100	Nickel-57	100
Calcium-47	100	Nickel-59	100
Scandium-43	1,000	Nickel-63	100
Scandium-44m	100	Nickel-65	1,000
Scandium-44	100	Nickel-66	10
Scandium-46	10	Copper-60	1,000
Scandium-47	100	Copper-61	1,000
Scandium-48	100	Copper-64	1,000
Scandium-49	1,000	Copper-67	1,000
Titanium-44	1	Zinc-62	100
Titanium-45	1,000	Zinc-63	1,000

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Zinc-65	10	Bromine-74m	1,000
Zinc-69m	100	Bromine-74	1,000
Zinc-69	1,000	Bromine-75	1,000
Zinc-71m	1,000	Bromine-76	100
Zinc-72	100	Bromine-77	1,000
Gallium-65	1,000	Bromine-80m	1,000
Gallium-66	100	Bromine-80	1,000
Gallium-67	1,000	Bromine-82	100
Gallium-68	1,000	Bromine-83	1,000
Gallium-70	1,000	Bromine-84	1,000
Gallium-72	100	Krypton-74	1,000
Gallium-73	1,000	Krypton-85	1,000
Germanium-66	1,000	Krypton-87	1,000
Germanium-67	1,000	Krypton-88	1,000
Germanium-68	10	Rubidium-79	1,000
Germanium-69	1,000	Rubidium-81m	1,000
Germanium-71	1,000	Rubidium-81	1,000
Germanium-75	1,000	Rubidium-82m	1,000
Germanium-77	1,000	Rubidium-83	100
Germanium-78	1,000	Rubidium-84	100
Arsenic-69	1,000	Rubidium-86	100
Arsenic-70	1,000	Rubidium-87	100
Arsenic-71	100	Rubidium-88	1,000
Arsenic-72	100	Rubidium-89	1,000
Arsenic-73	100	Strontium-80	100
Arsenic-74	100	Strontium-81	1,000
Arsenic-76	100	Strontium-83	100
Arsenic-77	100	Strontium-85m	1,000
Arsenic-78	1,000	Strontium-85	100
Selenium-70	1,000	Strontium-87m	1,000
Selenium-73m	1,000	Strontium-89	10
Selenium-73	100	Strontium-90	0.1
Selenium-75	100	Strontium-91	100
Selenium-79	100	Strontium-92	100
Selenium-81m	1,000	Yttrium-86m	1,000
Selenium-81	1,000	Yttrium-86	100
Selenium-83	1,000	Yttrium-87	100

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Yttrium-88	10	Technitium-96m	1,000
Yttrium-90m	1,000	Technitium-96	100
Yttrium-90	10	Technitium-97m	100
Yttrium-91m	1,000	Technitium-97	1,000
Yttrium-91	10	Technitium-98	10
Yttrium-92	100	Technitium-99m	1,000
Yttrium-93	100	Technitium-99	100
Yttrium-94	1,000	Technitium-101	1,000
Yttrium-95	1,000	Technitium-104	1,000
Zirconium-86	100	Ruthenium-94	1,000
Zirconium-88	10	Ruthenium-97	1,000
Zirconium-89	100	Ruthenium-103	100
Zirconium-93	1	Ruthenium-105	1,000
Zirconium-95	10	Ruthenium-106	1
Zirconium-97	100	Rhodium-99m	1,000
Niobium-88	1,000	Rhodium-99	100
Krypton-76	1,000	Rhodium-100	100
Krypton-77	1,000	Rhodium-101m	1,000
Krypton-79	1,000	Rhodium-101	10
Krypton-81	1,000	Rhodium-102m	10
Krypton-83m	1,000	Rhodium-102	10
Krypton-85m	1,000	Niobium-89	
Niobium-94	1	(66 min)	1,000
Niobium-95m	100	Niobium-89	
Niobium-85	100	(122 min)	1,000
Niobium-96	100	Niobium-90	100
Niobium-97	1,000	Niobium-93m	10
Niobium-98	1,000	Silver-104	1,000
Molybdenum-90	100	Silver-105	100
Molybdenum-93m	100	Silver-106m	100
Molybdenum-93	10	Silver-106	1,000
Molybdenum-99	100	Silver-108m	1
Molybdenum-101	1,000	Silver-110m	10
Technitium-93m	1,000	Silver-111	100
Technitium-93	1,000	Silver-112	100
Technitium-94m	1,000	Silver-115	1,000
Technitium-94	1,000	Cadmium-104	1,000

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Cadmium-107	1,000	Silver-104m	1,000
Cadmium-109	1	Antimony-116	1,000
Cadmium-113m	0.1	Antimony-117	1,000
Cadmium-113	100	Antimony-118m	1,000
Cadmium-115m	10	Antimony-119	1,000
Cadmium-115	100	Antimony-120	
Cadmium-117m	1,000	(16m)	1,000
Cadmium-117	1,000	Antimony-120	
Indium-109	1,000	(5.76d)	100
Indium-110m		Antimony-122	100
(69.1m)	1,000	Antimony-124m	1,000
Indium-110m		Antimony-124	10
(4.9h)	1,000	Antimony-125	100
Indium-111	100	Antimony-126m	1,000
Indium-112	1,000	Antimony-126	100
Indium-113m	1,000	Antimony-127	100
Indium-114m	10	Antimony-128	
Indium-115m	1,000	(10.4m)	1,000
Indium-115	100	Antimony-128	
Indium-116m	1,000	(9.01h)	100
Indium-117m	1,000	Antimony-129	100
Indium-117	1,000	Antimony-130	1,000
Indium-119m	1,000	Antimony-131	1,000
Tin-110	100	Tellurium-116	1,000
Tin-111	1,000	Tellurium-121m	10
Tin-113	100	Tellurium-121	100
Rhodium-103m	1,000	Tellurium-123m	10
Rhodium-105	100	Tellurium-123	100
Rhodium-106m	1,000	Tellurium-125m	10
Rhodium-107	1,000	Tellurium-127m	10
Palladium-100	100	Tellurium-127	1,000
Palladium-101	1,000	Tellurium-129m	10
Palladium-103	100	Tin-117m	100
Palladium-107	10	Tin-119m	100
Palladium-109	100	Tin-121m	100
Silver-102	1,000	Tin-121	1,000
Silver-103	1,000	Tin-123m	1,000

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Tin-123	10	Cesium-137	10
Tin-125	10	Tellurium-129	1,000
Tin-126	10	Tellurium-131m	10
Tin-127	1,000	Tellurium-131	100
Tin-128	1,000	Tellurium-132	10
Antimony-115	1,000	Tellurium-133m	100
Antimony-116m	1,000	Tellurium-133	1,000
Iodine-131	1	Tellurium-134	1,000
Iodine-132m	100	Iodine-120m	1,000
Iodine-132	100	Iodine-120	100
Iodine-133	10	Iodine-121	1,000
Iodine-134	1,000	Iodine-123	100
Iodine-135	100	Iodine-124	10
Xenon-120	1,000	Iodine-125	1
Xenon-121	1,000	Iodine-126	1
Xenon-122	1,000	Iodine-128	1,000
Xenon-123	1,000	Iodine-129	1
Xenon-125	1,000	Iodine-130	10
Xenon-127	1,000	Lanthanum-140	100
Xenon-129m	1,000	Lanthanum-141	100
Xenon-131m	1,000	Lanthanum-142	1,000
Xenon-133m	1,000	Lanthanum-143	1,000
Xenon-133	1,000	Cerium-134	100
Xenon-135m	1,000	Cerium-135	100
Xenon-135	1,000	Cerium-137m	100
Xenon-138	1,000	Cerium-137	1,000
Cesium-125	1,000	Cerium-139	100
Cesium-127	1,000	Cerium-141	100
Cesium-129	1,000	Cerium-143	100
Cesium-130	1,000	Cerium-144	1
Cesium-131	1,000	Praseodymium-136	1,000
Cesium-132	100	Praseodymium-137	1,000
Cesium-134m	1,000	Praseodymium-138m	1,000
Cesium-134	10	Praseodymium-139	1,000
Cesium-135m	1,000	Praseodymium-142m	1,000
Cesium-135	100	Praseodymium-142	100
Cesium-136	10	Praseodymium-143	100

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Praseodymium-144	1,000	Europium-152	1
Praseodymium-145	100	Europium-154	1
Praseodymium-147	1,000	Europium-155	10
Neodymium-136	1,000	Europium-156	100
Neodymium-138	100	Europium-157	100
Neodymium-139m	1,000	Europium-158	1,000
Neodymium-139	1,000	Gadolinium-145	1,000
Cesium-138	1,000	Gadolinium-146	10
Barium-126	1,000	Gadolinium-147	100
Barium-128	100	Gadolinium-148	0.001
Barium-131m	1,000	Gadolinium-149	100
Barium-131	100	Gadolinium-151	10
Barium-133m	100	Gadolinium-152	100
Barium-133	100	Neodymium-141	1,000
Barium-135m	100	Neodymium-147	100
Barium-139	1,000	Neodymium-149	1,000
Barium-140	100	Neodymium-151	1,000
Barium-141	1,000	Promethium-141	1,000
Barium-142	1,000	Promethium-143	100
Lanthanum-131	1,000	Promethium-144	10
Lanthanum-132	100	Promethium-145	10
Lanthanum-135	1,000	Promethium-146	1
Lanthanum-137	10	Promethium-147	10
Lanthanum-138	100	Promethium-148m	10
Samarium-153	100	Promethium-148	10
Samarium-155	1,000	Promethium-149	100
Samarium-156	1,000	Promethium-150	1,000
Europium-145	100	Proemthium-151	100
Europium-146	100	Samarium-141m	1,000
Europium-147	100	Samarium-141	1,000
Europium-148	10	Samarium-142	1,000
Europium-149	100	Samarium-145	100
Europium-150		Samarium-146	1
(12.62h)	100	Samarium-147	100
Europium-150		Samarium-151	10
(34.2y)	1	Dysprosium-166	100
Europium-152m	100	Holmium-1155	1,000

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Holmium-157	1,000	Dysprosium-155	1,000
Holmium-159	1,000	Dysprosium-157	1,000
Holmium-161	1,000	Dysprosium-159	100
Holmium-162m	1,000	Dysprosium-165	1,000
Holmium-162	1,000	Hafnium-173	1,000
Holmium-164m	1,000	Hafnium-175	100
Holmium-164	1,000	Hafnium-177m	1,000
Holmium-166m	1	Hafnium-178m	0.1
Holmium-166	100	Hafnium-179m	10
Holmium-167	1,000	Hafnium-180m	1,000
Erbium-161	1,000	Hafnium-181	10
Erbium-165	1,000	Hafnium-182m	1,000
Erbium-169	100	Hafnium-182	0.1
Erbium-171	100	Hafnium-183	1,000
Erbium-172	100	Hafnium-184	100
Thulium-162	1,000	Tantalum-172	1,000
Thulium-166	100	Tantalum-173	1,000
Thulium-167	100	Tantalum-174	1,000
Thulium-170	10	Tantalum-175	1,000
Gadolinium-153	10	Tantalum-176	100
Gadolinium-159	100	Tantalum-177	1,000
Terbium-147	1,000	Tantalum-178	1,000
Terbium-149	100	Tantalum-179	100
Terbium-150	1,000	Tantalum-180m	1,000
Terbium-151	100	Tantalum-180	100
Terbium-153	1,000	Thulium-171	10
Terbium-154	100	Thulium-172	100
Terbium-155	1,000	Thulium-173	100
Terbium-156m (5.0h)	1,000	Thulium-175	1,000
Terbium-156m (24.4h)	1,000	Ytterbium-162	1,000
Terbium-156	100	Ytterbium-166	100
Terbium-157	10	Ytterbium-167	1,000
Terbium-158	1	Ytterbium-169	100
Terbium-160	10	Ytterbium-175	100
Terbium-161	100	Ytterbium-177	1,000
		Ytterbium-178	1,000
		Lutetium-169	100

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Lutetium-170	100	Tungsten-176	1,000
Lutetium-171	100	Tungsten-177	1,000
Lutetium-172	100	Tungsten-178	1,000
Lutetium-173	10	Tungsten-179	1,000
Lutetium-174m	10	Tungsten-181	1,000
Lutetium-174	10	Tungsten-185	100
Lutetium-176m	1,000	Tungsten-187	100
Lutetium-176	100	Tungsten-188	10
Lutetium-177m	10	Rhenium-177	1,000
Lutetium-177	100	Rhenium-178	1,000
Lutetium-178m	1,000	Rhenium-181	1,000
Lutetium-178	1,000	Rhenium-182	
Lutetium-179	1,000	(12.7h)	1,000
Hafnium-170	100	Rhenium-182	
Hafnium-172	1	(64.0h)	100
Rhenium-188	100	Rhenium-184m	10
Rhenium-189	100	Rhenium-184	100
Osmium-180	1,000	Rhenium-186m	10
Osmium-181	1,000	Rhenium-186	100
Osmium-182	100	Rhenium-187	1,000
Osmium-185	100	Rhenium-188m	1,000
Osmium-189m	1,000	Mercury-194	1
Osmium-191m	1,000	Mercury-195m	100
Osmium-191	100	Mercury-195	1,000
Osmium-193	100	Mercury-197m	100
Osmium-194	100	Mercury-197	1,000
Iridium-182	1,000	Mercury-199m	1,000
Iridium-184	1,000	Mercury-203	100
Iridium-185	1,000	Thallium-194m	1,000
Iridium-186	100	Thalllium-194	1,000
Iridium-187	1,000	Thallium-195	1,000
Tantalum-182m	1,000	Thallium-197	1,000
Tantalum-182	10	Thallium-198m	1,000
Tantalum-183	100	Thallium-198	1,000
Tantalum-184	100	Thallium-199	1,000
Tantalum-185	1,000	Thallium-200	1,000
Tantalum-186	1,000	Thallium-201	1,000

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Iridium-188	100	Francium-223	100
Iridium-189	100	Radium-223	0.1
Iridium-190m	1,000	Radium-224	0.1
Iridium-190	100	Radium-225	0.1
Iridium-192m	1	Radium-226	0.1
Iridium-192	10	Radium-227	1,000
Iridium-194m	10	Thallium-202	100
Iridium-194	100	Thallium-204	100
Iridium-195m	1,000	Lead-195m	1,000
Iridium-195	1,000	Lead-198	1,000
Platinum-186	1,000	Lead-199	1,000
Platinum-188	100	Lead-200	100
Platinum-189	1,000	Lead-201	1,000
Platinum-191	100	Lead-202m	1,000
Platinum-193m	100	Lead-202	10
Platinum-193	1,000	Lead-203	1,000
Platinum-195m	100	Lead-205	100
Platinum-197m	1,000	Lead-209	1,000
Platinum-197	100	Lead-210	0.01
Platinum-199	1,000	Lead-211	100
Platinum-200	100	Lead-212	1
Gold-193	1,000	Lead-214	100
Gold-194	100	Bismuth-200	1,000
Gold-195	10	Bismuth-201	1,000
Gold-198m	100	Bismuth-202	1,000
Gold-198	100	Bismuth-203	100
Gold-199	100	Bismuth-205	100
Gold-200m	100	Bismuth-206	100
Gold-200	1,000	Bismuth-207	10
Gold-201	1,000	Bismuth-210m	0.1
Mercury-193m	100	Bismuth-210	1
Mercury-193	1,000	Bismuth-212	10
Astatine-207	100	Bismuth-213	10
Astatine-211	10	Bismuth-214	100
Radon-220	1	Polonium-203	1,000
Radon-222	1	Polonium-205	1,000
Francium-222	100	Polonium-207	1,000

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Polonium-210	0.1	Uranium-233	0.001
Neptunium-234	100	Uranium-234	0.001
Neptunium-235	100	Uranium-235	0.001
Neptunium-236		Uranium-236	0.001
(1.15x10y)	0.001	Uranium-237	100
Neptunium-236		Uranium-238	100
(22.5h)	1	Uranium-239	1,000
Neptunium-237	0.001	Uranium-240	100
Neptunium-238	10	Uranium-natural	100
Neptunium-239	100	Neptunium-232	100
Neptunium-240	1,000	Neptunium-233	1,000
Plutonium-234	10	Berkelium-246	100
Radium-228	0.1	Berkelium-247	0.001
Actinium-224	1	Berkelium-249	0.1
Actinium-225	0.01	Berkelium-250	10
Actinium-226	0.1	Californium-244	100
Actinium-227	0.001	Californium-246	1
Actinium-228	1	Californium-248	0.01
Thorium-226	10	Plutonium-235	1,000
Thorium-227	0.01	Plutonium-236	0.001
Thorium-228	0.001	Plutonium-237	100
Thorium-229	0.001	Plutonium-238	0.001
Thorium-230	0.001	Plutonium-239	0.001
Thorium-231	100	Plutonium-240	0.001
Thorium-232	100	Plutonium-241	0.01
Thorium-234	10	Plutonium-242	0.001
Thorium-natural	100	Plutonium-243	1,000
Protactinium-227	10	Plutonium-244	0.001
Protactinium-228	1	Plutonium-245	100
Protactinium-230	0.1	Americium-237	1,000
Protactinium-231	0.001	Americium-238	100
Protactinium-232	1	Americium-239	1,000
Protactinium-233	100	Americium-240	100
Protactinium-234	100	Americium-241	0.001
Uranium-230	0.01	Americium-242m	0.001
Uranium-231	100	Americium-242	10
Uranium-232	0.001	Americium-243	0.001

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Americium-244m	100	Einsteinium-251	100
Americium-244	10	Einsteinium-253	0.1
Americium-245	1,000	Einsteinium-254m	1
Americium-246m	1,000	Einsteinium-254	0.01
Americium-246	1,000	Fermium-252	1
Curium-238	100	Fermium-253	1
Curium-240	0.1	Californium-249	0.001
Curium-241	1	Californium-250	0.001
Curium-242	0.01	Californium-251	0.001
Curium-243	0.001	Californium-252	0.001
Curium-244	0.001	Californium-253	0.1
Curium-245	0.001	Californium-254	0.001
Curium-246	0.001	Fermium-254	10
Curium-247	0.001	Fermium-255	1
Curium-248	0.001	Fermium-257	0.01
Curium-249	1,000	Mendelevium-257	10
Berkelium-245	100	Mendelevium-258	0.01
Einsteinium-250	100		
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha-emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

* To convert microcurie (μCi) to kilobecquerel, multiply the microcurie value by 37.

NOTE: For purposes of subsections (aa)(5), (dd)(1), and (ww)(1) of this subsection where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" -- that is, unity.

†The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Columns 1 and 2 of Table I of subsection (ggg)(2) of this section, rounding to the nearest factor of 10, and constraining the values listed between 0.001 and 1,000 microcuries (37 becquerels and 37 megabecquerels). Values of 100 microcuries (3.7 megabecquerels) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except rhenium, 1,000 microcuries (37 megabecquerels), to take into account their low specific activity.

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(4) Classification and characteristics of low-level radioactive waste (LLRW).

(A) Classification of radioactive waste for land disposal.

(i) Considerations. Determination of the classification of LLRW involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

(ii) Classes of waste.

(I) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in subparagraph (B)(i) of this paragraph. If Class A waste also meets the stability requirements set forth in subparagraph (B)(ii) of this paragraph, it is not necessary to segregate the waste for disposal.

(II) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in subparagraph (B) of this paragraph.

(III) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in subparagraph (B) of this paragraph.

(iii) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in subclause (V) of this clause, classification shall be determined as follows.

(I) If the concentration does not exceed 0.1 times the value in subclause (V) of this clause, the waste is Class A.

(II) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in subclause (V) of this clause, the waste is Class C.

(III) If the concentration exceeds the value in subclause (V) of this clause, the waste is not generally acceptable for land disposal.

(IV) For wastes containing mixtures of radionuclides listed in subclause (V) of this clause, the total concentration shall be determined by the sum of fractions rule described in clause (*vii*) of this subparagraph.

(V) Classification table for long-lived radionuclides.

Concentration Radionuclide	curie/cubic meter*	nanocurie/gram**
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

(iv) Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in clause (iii)(V) of this subparagraph, classification shall be determined based on the concentrations shown in subclause (VI) of this clause. However, as specified in clause (vi) of this subparagraph, if radioactive waste does not contain any nuclides listed in either clause (iii)(V) of this subparagraph or subclause (VI) of this clause, it is Class A.

(I) If the concentration does not exceed the value in Column 1 of subclause (*VI*) of this clause, the waste is Class A.

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* To convert the Ci/m^3 values to gigabecquerel (GBq) per cubic meter, multiply the Ci/m^3 value by 37.

** To convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.

(II) If the concentration exceeds the value in Column 1 of subclause (VI) of this clause but does not exceed the value in Column 2 of subclause (VI) of this clause, the waste is Class B.

(III) If the concentration exceeds the value in Column 2 of subclause (VI) of this clause but does not exceed the value in Column 3 of subclause (VI) of this clause, the waste is Class C.

(IV) If the concentration exceeds the value in Column 3 of subclause (VI) of this clause, the waste is not generally acceptable for near-surface disposal.

(V) For wastes containing mixtures of the radionuclides listed in subclause (VI) of this clause, the total concentration shall be determined by the sum of fractions rule described in clause (*vii*) of this subparagraph.

(VI) Classification table for short-lived radionucides.

Radionuclide	Concentration, curie/cubic meter*		
	Column 1	Column 2	Column 3
Total of all radio-nuclides with less than 5-year half-life	700	*	*
H-3	40	*	*
Co-60	700	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7,000
Sr-90	0.04	150	7,000
Cs-137	1	44	4,600

* To convert the Ci/m^3 value to gigabecquerel (Gbq) per cubic meter, multiply the Ci/m^3 value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in this table determine the waste to be Class C independent of these radionuclides.

(v) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in clause (iii)(V) of this subparagraph and some of which are listed in clause (iv)(VI) of this subparagraph, classification shall be determined as follows:

(I) If the concentration of a radionuclide listed in clause (iii)(V) of this subparagraph is less than 0.1 times the value listed in clause (iii)(V) of this subparagraph, the class shall be that determined by the concentration of radionuclides listed in clause (iv)(VI) of this subparagraph.

(II) If the concentration of a radionuclide listed in clause (iii)(V) of this subparagraph exceeds 0.1 times the value listed in clause (iii)(V) of this subparagraph, but does not exceed the value listed in clause (iii)(V) of this subparagraph, the waste shall be Class C, provided the concentration of radionuclides listed in clause (iv)(VI) of this subparagraph does not exceed the value shown in Column 3 of clause (iv)(VI) of this subparagraph.

(vi) Classification of wastes with radionuclides other than those listed in clauses (iii)(V) and (iv)(VI) of this subparagraph. If the waste does not contain any radionuclides listed in either clauses (iii)(V) and (iv)(VI) of this subparagraph, it is Class A.

(vii) The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 50 curies per cubic meter (Ci/m^3 (1.85 terabecquerels per cubic meter (TBq/m^3)) and Cs-137 in a concentration of 22 Ci/m^3 (814 gigabecquerels per cubic meter (GBq/m^3)). Since the concentrations both exceed the values in Column 1 of clause (iv)(VI) of this subparagraph, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33, for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

(viii) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors, which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as nanocurie (becquerel) per gram.

(B) Radioactive waste characteristics.

(i) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

(I) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of this section, the site license conditions shall govern.

(II) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

(III) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

(IV) Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1.0% of the volume.

(V) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(VI) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with subclause (VIII) of this clause.

(VII) Waste must not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.

(VIII) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20 degrees Celsius. Total activity shall not exceed 100 Ci (3.7 terabecquerels (TBq)) per container.

(IX) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.

(ii) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(I) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

(II) Notwithstanding the provisions in clause (i)(III) and (IV) of this subparagraph, liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1.0% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

(III) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

(C) Labeling. Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with subparagraph (A) of this paragraph.

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(5) Time requirements for record keeping.

Specific Section	Name of Record	Time Interval Required for Record Keeping
subsection (ll)(4) of this section	Records at Additional Authorized Use/ Storage Sites	While site is authorized on license/registration
subsection (mm)(1)(A) of this section	Radiation Protection Programs	Until termination of license/registration
subsection (mm)(1)(B) of this section	Program Audits	3 years
subsection (nn)(1) of this section	Routine Surveys, Instrument Calibrations and Package Surveys	3 years
subsection (nn)(2) of this section	Surveys, Measurements, Calculations Used for Dose Determination; Results of Air Sampling, Bioassays; Measurements, Calculations Used to Determine Release of Radioactive Effluents	Until termination of license/registration
subsection (oo) of this section	Tests for leakage/ contamination of sealed sources	5 years
subsection (pp) of this section	Lifetime Cumulative Occupational Radiation Dose, RC Form 202-2	Until termination of license
subsection (pp) of this section	Records Used to Prepare RC Form 202-2	3 years
subsection (qq)(B) of this section	Planned Special Exposures	Until termination of license

Specific Section	Name of Record	Time Interval Required for Record Keeping
subsection (rr)(1-3) of this section	Individual Monitoring Results; RC Form 202-3	Update annually; Maintain until termination of license/registration
subsection (rr)(5) of this section	Records Used to Prepare RC Form 202-3	3 years
subsection (rr)(4) of this section	Embryo/Fetus Dose	Until termination of license/registration
subsection (ss) of this section	Dose to Individual Members of the Public	Until termination of license/registration
subsection (tt) of this section	Discharge, Treatment, or Transfer for Disposal	Until termination of license/registration
subsection (uu) of this section	Entry Control Device Testing for Very High Radiation Areas	3 years

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(6) Acceptable surface contamination levels.

NUCLIDE[a]	AVERAGE[bcf]	MAXIMUM[bdf]	REMOVABLE[bcef]
U-nat, U-235, U-238, and associated decay products except Ra-226, Th-230, Ac-227, and Pa-231	5,000 dpm alpha/ 100 cm^2	15,000 dpm alpha/ 100 cm^2	1,000 dpm alpha/ 100 cm^2
Transuranics, Ra-223, Ra-224, Ra-226, Ra-228, Th-nat, Th-228, Th-230, Th-232, U-232, Pa-231, Ac-227, Sr-90, I-129	1,000 dpm/100 cm^2	3,000 dpm/100 cm^2	200 dpm/100 cm^2
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5,000 dpm beta, gamma/100 cm^2	15,000 dpm beta, gamma/100 cm^2	1,000 dpm beta, gamma/100 cm^2
Tritium (applicable to surface and subsurface)[g]	NA	NA	10,000 dpm/100 cm^2

[a] Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides should apply independently.

[b] As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[c] Measurements of average contamination level should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each object.

[d] The maximum contamination level applies to an area of not more than 100 cm^2.

e The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

f The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr at 1 centimeter and 1.0 mrad/hr at 1 centimeter, respectively, measured through not more than 7 mg/cm^2 of total absorber.

g Property recently exposed or decontaminated, should have measurements (smears) at regular time intervals to ensure that there is not a build-up of contamination over time. Because tritium typically penetrates material it contacts, the surface guidelines in group 4 are not applicable to tritium. The agency has reviewed the analysis conducted by the Department of Energy Tritium Surface Contamination Limits Committee ("Recommended Tritium Surface Contamination Release Guides," February 1991), and has assessed potential doses associated with the release of property containing residual tritium. The agency recommends the use of the stated guideline as an interim value for removable tritium. Measurements demonstrating compliance of the removable fraction of tritium on surfaces with this guideline are acceptable to ensure that non-removable fractions and residual tritium in mass will not cause exposures that exceed dose limits as specified in this section and agency constraints.

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(7) Concentration and activity limits of nuclides for disposal in a Type I municipal solid waste site or a hazardous waste facility (for use in subsection (fff) of this section). The following table contains concentration and activity limits of nuclides for disposal in a Type I municipal solid waste site or a hazardous waste facility.

Nuclides	Concentrations Limit (Ci/m^3)	Annual Generator Disposal Limit (Ci/yr)
F-18	3×10^{-1}	8
Si-31	$1 \times 10^{+2}$	$3 \times 10^{+3}$
Na-24	9×10^{-4}	2×10^{-2}
P-32	2	$5 \times 10^{+1}$
P-33	10	$3 \times 10^{+2}$
S-35	9	$2 \times 10^{+2}$
Ar-41	3×10^{-1}	8
K-42	2×10^{-2}	5×10^{-1}
Ca-45	4	$1 \times 10^{+2}$
Ca-47	2×10^{-2}	5×10^{-1}
Sc-46	2×10^{-3}	5×10^{-2}
Cr-51	6×10^{-1}	$2 \times 10^{+1}$
Fe-59	5×10^{-3}	1×10^{-1}
Co-57	6×10^{-2}	2
Co-58	1×10^{-2}	3×10^{-1}
Zn-65	7×10^{-3}	2×10^{-1}
Ga-67	3×10^{-1}	8
Se-75	5×10^{-2}	1
Br-82	2×10^{-3}	5×10^{-2}
Rb-86	4×10^{-2}	1
Sr-85	2×10^{-2}	5×10^{-1}
Sr-89	8	$2 \times 10^{+2}$
Y-90	4	$1 \times 10^{+2}$
Y-91	4×10^{-1}	10
Zr-95	8×10^{-3}	2×10^{-1}
Nb-95	8×10^{-3}	2×10^{-1}
Mo-99	5×10^{-2}	1
Tc-99m	1	$3 \times 10^{+1}$
Rh-106	1	$3 \times 10^{+1}$
Ag-110m	2×10^{-3}	5×10^{-2}
Cd-115m	2×10^{-1}	5
In-111	9×10^{-2}	2

Nuclides	Concentrations Limit (Ci/m^3)	Annual Generator Disposal Limit (Ci/yr)
In-113m	9	$2 \times 10^{+2}$
Sn-113	6×10^{-2}	2
Sn-119	$2 \times 10^{+1}$	$5 \times 10^{+2}$
Sb-124	2×10^{-3}	5×10^{-2}
Te-129	2×10^{-1}	5
I-123	4×10^{-1}	$1 \times 10^{+1}$
I-125	7×10^{-1}	$2 \times 10^{+1}$
I-131	4×10^{-2}	1
I-133	2×10^{-2}	5×10^{-1}
Xe-127	8×10^{-2}	2
Xe-133	1	$3 \times 10^{+1}$
Ba-140	2×10^{-3}	5×10^{-2}
La-140	2×10^{-3}	5×10^{-2}
Ce-141	4×10^{-1}	$1 \times 10^{+1}$
Ce-144	1×10^{-3}	3×10^{-2}
Pr-143	6	$2 \times 10^{+2}$
Nd-147	7×10^{-2}	2
Yb-169	6×10^{-2}	2
Ir-192	1×10^{-2}	3×10^{-1}
Au-198	3×10^{-2}	8×10^{-1}
Hg-197	8×10^{-1}	$2 \times 10^{+1}$
Tl-201	4×10^{-1}	$1 \times 10^{+1}$
Hg-203	1×10^{-1}	3

NOTE: In any case where there is a mixture in waste of more than one radionuclide, the limiting values for purposes of this paragraph shall be determined as follows:

For each radionuclide in the mixture, calculate the ratio between the quantity present in the mixture and the limit established in this paragraph for the specific radionuclide when not in a mixture. The sum of such ratios for all the radionuclides in the mixture may not exceed "1" (i.e., "unity").

Examples: If radionuclides a, b, and c are present in concentrations C_a, C_b, and C_c, and if the applicable concentrations are CL_a, CL_b, and CL_c respectively, then the concentrations shall be limited so that the following relationship exists:

$$(C_a/CL_a) + (C_b/CL_b) + (C_c/CL_c) \leq 1$$

If the total curies for radionuclides a, b, and c are represented A_a, A_b, and A_c, and the annual curie limit for each radionuclide is AL_a, AL_b, and AL_c, then the generator is limited to the following:

$$(A_a/AL_a) + (A_b/AL_b) + (A_c/AL_c) \leq 1$$

(8) Cumulative occupational exposure form. The following, RC Form 202-2, or other equivalent clear and legible record, of all the information required on that form, is to be used to document cumulative occupational exposure history: (Please find RC Form 202-2 at the end of this section.)

(9) Occupational exposure form. The following, RC Form 202-3, or other equivalent clear and legible record, of all the information required on that form, is to be used to document occupational exposure record for a monitoring period: (Please find RC Form 202-3 at the end of this section.)

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25 TEXAS ADMINISTRATIVE CODE

§289.203

Notices, Instructions, and Reports to Workers; Inspections

Texas Regulations for Control of Radiation

(revisions effective October 1, 2011 are shown as shaded text)

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§289.203. Notices, Instructions, and Reports to Workers; Inspections.

(a) Scope and purpose. This section establishes requirements for notices, instructions, and reports by licensees or registrants to individuals engaged in activities under a license or certificate of registration, and options available to such individuals in connection with agency inspections of licensees or registrants to ascertain compliance with the provisions of the Texas Radiation Control Act (Act), Health and Safety Code, Chapter 401, and rules, orders, licenses, and certificates of registration issued thereunder regarding radiological working conditions. The requirements in this section apply to all persons who receive, possess, use, or transfer sources of radiation licensed by or registered with the agency in accordance with this chapter.

(b) Posting of notices to workers.

(1) Each licensee or registrant shall post current copies of the following documents:

(A) the requirements in this section and in §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials) or §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation), as applicable;

(B) the license, certificate of registration, conditions or documents incorporated into the license or certificate of registration by reference, and amendments thereto;

(C) the operating procedures applicable to work under the license or certificate of registration; and

(D) any notice of violation involving radiological working conditions or order that has:

(i) been issued in accordance with §289.201 of this title (relating to General Provisions for Radioactive Material), §289.205 of this title (relating to Hearing and Enforcement Procedures), and §289.231 of this title; and

(ii) not been labeled "withhold from public disclosure under Government Code, §552.101," or equivalent phrase, in accordance with §289.252(ii) of this title (relating to Licensing of Radioactive Material).

(2) If posting of a document specified in paragraph (1) of this subsection is not practicable, the licensee or registrant shall post a notice that describes the document and states where it may be examined.

(3) Each licensee or registrant shall post RC Form 203-1, "Notice to Employees," as contained in subsection (i) of this section, or an equivalent document containing at least the same wording as RC Form 203-1.

(4) Documents, notices, or forms posted in accordance with this subsection shall:

(A) appear in a sufficient number of places to permit individuals engaged in work under the license or certificate of registration to observe them on the way to or from any particular work location to which the document applies;

(B) shall be conspicuous; and

(C) shall be replaced if defaced or altered.

(c) Instructions to workers.

(1) All individuals likely to receive in a year an occupational dose in excess of 100 millirem (1 millisievert) shall be:

(A) kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;

(B) instructed in the health protection problems associated with exposure to sources of radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(C) instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of agency requirements, licenses, and certificates of registration, for the protection of personnel from exposures to sources of radiation occurring in such areas;

(D) instructed of their responsibility to report promptly to the licensee or registrant any condition that may constitute, lead to, or cause a violation of agency requirements, license conditions, or certificate of registration conditions, or unnecessary exposure to sources of radiation;

(E) instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to sources of radiation; and

(F) advised as to the radiation exposure reports that workers may request in accordance with subsection (d) of this section.

(2) The extent of these instructions shall be commensurate with potential radiological health protection problems associated with the source(s) of radiation in the workplace.

(d) Notifications and reports to individuals.

(1) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be made available to the individual as specified in this section. The information reported shall include data and results obtained in accordance with agency requirements, orders, license or certificate of registration conditions, as shown in records maintained by the licensee or registrant in accordance with §289.202 or §289.231 of this title, as applicable. Each notification and report shall:

(A) be in writing;

(B) include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number;

(C) include the individual's exposure information; and

(D) contain the following statement: "This report is furnished to you under the provisions of the Texas Regulations for Control of Radiation, 25 Texas Administrative Code §289.203. You should preserve this report for further reference."

(2) Each licensee or registrant shall provide an annual written report to advise each worker of the worker's dose, received in that monitoring year, as shown in records maintained by the licensee or registrant in accordance with §289.202(q), §289.202(rr) or §289.231(dd) of this title, as applicable, if:

(A) the individual's occupational dose exceeds 100 mrem (1 mSv) total effective dose equivalent or 100 mrem (1 mSv) to any individual organ or tissue; or

(B) the individual requests his or her annual dose report in writing.

(3) At the written request of a worker formerly engaged in activities controlled by the licensee or registrant, each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation. The report shall include the dose record for each year the worker was required to be monitored in accordance with §289.202(q) or §289.231(n) of this title, as applicable. Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and the dates and locations of work under the license or certificate of registration in which the worker participated during this period.

(4) When a licensee or registrant is required in accordance with §289.202(xx), (yy), and (zz) or §289.231(hh) and (ii) of this title, as applicable, to report to the agency any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a written report of that individual's exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the agency.

(5) At the written request of a worker who is terminating employment with the licensee or registrant in work involving exposure to sources of radiation during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate. When the final individual monitoring results are available, those written results shall be provided to the worker or the worker's designee.

(e) Presence of representatives of licensees or registrants and workers during inspection.

(1) Each licensee or registrant shall afford to the agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records in accordance with this chapter.

(2) During an inspection, agency inspectors may consult privately with workers as specified in subsection (f) of this section. The licensee or registrant may accompany agency inspectors during other phases of an inspection.

(3) If, at the time of inspection, an individual has been authorized by the workers to represent them during agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(4) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in subsection (c) of this section.

(5) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(6) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany agency inspectors during the inspection of physical working conditions.

(7) Notwithstanding the other provisions of this section, agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

(f) Consultation with workers during inspections.

(1) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of agency regulations and licenses and/or certificates of registration to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which that individual has reason to believe may have contributed to or caused any violation of the Act, the requirements in this chapter, license or certificate of registration conditions, or any unnecessary exposure of an individual to radiation from any source of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of subsection (g)(1) of this section.

(3) The provisions of paragraph (2) of this subsection shall not be interpreted as authorization to disregard instructions in accordance with subsection (c) of this section.

(g) Requests by workers for inspections.

(1) Any worker or representative of workers who believes that a violation of the Act, the requirements of this chapter, or license or certificate of registration conditions exists or has occurred in work under a license or certificate of registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the agency no later than at the time of inspection except that, upon the request of the worker giving such notice, the worker's name and the name(s) of individual(s) referred to therein shall not appear in such copy or on any record published, released, or made available by the agency, except for good cause shown.

(2) If, upon receipt of such notice, the agency determines that the request meets the requirements set forth in paragraph (1) of this subsection, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections in accordance with this section need not be limited to matters referred to in the request.

(3) No licensee or registrant, contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because of the following:

(A) such worker has filed any request or instituted or caused to be instituted any proceeding under this chapter;

(B) such worker has testified or is about to testify in any such proceeding; or

(C) because of the exercise by such worker on behalf of that individual or others of any option afforded by this section.

(h) Inspections not warranted.

(1) If the agency determines, with respect to a request under subsection (g) of this section, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the agency shall notify the requestor in writing of such determination. The requestor may obtain review of such determination in accordance with the provisions of the Act and the Government Code, Chapters 2001 and 2002.

(2) If the agency determines that an inspection is not warranted because the requirements of subsection (g)(1) of this section have not been met, the agency shall notify the requestor in writing of such determination. Such determination shall be without prejudice to the filing of a new request meeting the requirements of subsection (g)(1) of this section.

(i) Notice to employees. The following form, RC Form 203-1, or an equivalent as stated in subsection (b)(3) of this section, shall be posted.

RC FORM 203-1
(October 2011)

Department of State Health Services
P.O. Box 149347
Austin, Texas 78714-9347

NOTICE TO EMPLOYEES

TEXAS REGULATIONS FOR CONTROL OF RADIATION

The Department of State Health Services has established standards for your protection against radiation hazards, in accordance with the Texas Radiation Control Act, Health and Safety Code, Chapter 401.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to-

1. Apply these rules to work involving sources of radiation.
2. Post or otherwise make available to you a copy of the Department of State Health Services rules, licenses, certificates of registration, notices of violations, and operating procedures that apply to your work, and explain their provisions to you.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the rules and the operating procedures that apply to your work. You should observe the rules for your own protection and protection of your co-workers.

WHAT IS COVERED BY THESE RULES

1. Limits on exposure to sources of radiation in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Individual monitoring devices, surveys and equipment;
4. Caution signs, labels, and safety interlock equipment;
5. Exposure records and reports;
6. Options for workers regarding agency inspections; and
7. Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The rules require that your employer give you a written report if you receive an exposure in excess of any applicable limit as stated in the rules, license, or certificate of registration. The basic limits for exposure to employees are stated in 25 Texas Administrative Code (TAC) §289.202(f), (k), (l), and (m) (relating to Standards for Protection Against Radiation from Radioactive Materials) and 25 TAC §289.231(m) (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation). These subsections specify limits on exposure to radiation and exposure to concentrations of radioactive material in air and water.

2. If you work where individual monitoring devices are provided in accordance with 25 TAC §289.202 or §289.231:

(a) your employer must furnish to you an annual written report of your exposure to radiation if:
   (1) the individual's occupational dose exceeds 100 mrem (1 mSv) total effective dose equivalent or 100 mrem (1 mSv) to any individual organ or tissue; or
   (2) the individual requests his or her annual dose report in writing.

(b) your employer must give you a written report, upon termination of your employment, of your radiation exposures if you request the information on your radiation exposure in writing.

INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Department of State Health Services. In addition, any worker or representative of the workers who believe that there is a violation of the Texas Radiation Control Act, the rules issues thereunder, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Department of State Health Services. The request must state the specific grounds for the notice, and must be signed by the worker or the representative of the workers. During inspections, agency inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition that the individual believes contributed to or caused any violation as described above.

POSTING REQUIREMENT

Copies of this notice shall be posted in a sufficient number of places in every establishment where employees are employed in activities licensed or registered, in accordance with 25 TAC §289.252 (relating to Licensing of Radioactive Material) and 25 TAC §289.226 (relating to Registration of Radiation Machine Use and Services), to permit employees to observe a copy on the way to or from their place of employment.

Applicable sections of 25 TAC Chapter 289 may be reviewed online, at www.dshs.state.tx.us/radiation/rules.shtm. Our license and/or certificate of registration and any associated documents, our operating procedures, and any "Notice of Violation" or order issued by the agency may be reviewed at the following location:

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25 TEXAS ADMINISTRATIVE CODE (TAC)

§289.252

Licensing of Radioactive Material

Texas Regulations for Control of Radiation

(revisions effective October 1, 2011 are shown as shaded text)

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

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

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

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

(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 industrial radiographic operations are subject to the requirements of §289.255 of this title.

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

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

(6) Licensees possessing or using naturally occurring radioactive material are subject to the requirements of §289.259 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 (jj)(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.

(11) Action on a specific license application will be considered abandoned if the applicant does not respond within 30 days from the date of a request for any information by the agency. Abandonment of such actions does not provide an opportunity for a hearing; however, the applicant retains the right to resubmit the application in accordance with paragraphs (1) - (7) of this subsection.

(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 satisfied 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 submitted adequate operating, safety, and emergency procedures;

(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);

(9) the owner of the property is aware that radioactive material is stored and/or used on the property, if the proposed 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 subsections (d)(10) or (x)(8) of this section; and

(11) the applicant is listed on the Secretary of State's website as authorized to conduct business in the state, unless the applicant is exempt. All applicants using an assumed name in their application shall file an assumed name certificate with the Secretary of State and/or the office of the county clerk as required under the Business and Commerce Code, Chapter 71.

(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 a physical 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);

(iv) date inventory is performed;

(v) location;

(vi) unique identifying number or serial number; and

(vii) signature of person performing the inventory.

(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;

(N) to serve as the primary contact with the agency; and

(O) to have knowledge of and ensure compliance with federal and state security measures for radioactive material.

(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;

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

(11) having knowledge of and ensuring compliance with federal and state security measures for radioactive material.

(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 (Ci) 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 §289.255, §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.

(5) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt in accordance with §289.251 of this title except as specified with a license issued by the NRC.

(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 (NRC), 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 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)(5) 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.

(1) 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 Title 10, CFR, §70.39 or their equivalent.

(2) Each person licensed in accordance with this section shall perform a dry wipe test on each source containing more than 0.1 μCi (3.7 kilobecquerels) of americium-241 or radium-226 before transferring the source to a general licensee in accordance with §289.251(f)(4)(D) of this title. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 μCi (0.185 kilobecquerel) of americium-241 or radium-226. If removable contamination from any source wipe test exceeds 0.005 μCi (0.185 kilobecquerels) of americium-241 or radium-226, the source is deemed to be leaking and it shall not be transferred to a general licensee.

(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 in accordance with §289.256 of this title for use as a calibration, transmission, or reference source or for use of sealed sources listed in §289.256(q), (rr), (bbb), and (ddd) of this title 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) a legend and methods for labeling sources and devices as to their radioactive content;

(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;

(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) documentation that the radioactive material will be prepared for distribution in prepackaged units of:

(A) iodine-125 in units not exceeding 10 microcuries (μCi) (0.37 megabecquerel) each;

(B) iodine-131 in units not exceeding 10 μCi (0.37 megabecquerel) each;

(C) carbon-14 in units not exceeding 10 μCi (0.37 megabecquerel) each;

(D) hydrogen-3 (tritium) in units not exceeding 50 μCi (1.85 megabecquerels) each;

(E) iron-59 in units not exceeding 20 μCi (0.74 megabecquerel) each;

(F) cobalt-57 in units not exceeding 10 μCi (0.37 megabecquerel) each;

(G) selenium-75 in units not exceeding 10 μCi (0.37 megabecquerel) each; or

(H) mock iodine-125 in units not exceeding 0.05 μCi (1.85 kilobecquerels) of iodine-129 and 0.005 μCi (0.185 kilobecquerel) of americium-241 each;

(2) evidence that each prepackaged unit will bear 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 (0.37 megabecquerel) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 μCi (1.85 megabecquerels) of hydrogen-3 (tritium); 20 μCi (0.74 megabecquerel) of iron-59; or mock iodine-125 in units not exceeding 0.05 μCi (1.85 kilobecquerels) of iodine-129 and 0.005 μCi (0.185 kilobecquerel) 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

(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 with the United States Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug in accordance with Title 21, CFR, §207.20(a);

(ii) registered or licensed with a state agency as a drug manufacturer;

(iii) licensed as a pharmacy by the Texas State Board of Pharmacy;

(iv) operating as a nuclear pharmacy within a federal medical institution; or

(v) a positron emission tomography (PET) drug production facility registered with a state agency.

(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"; and

(II) 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) or (iv) of this subsection shall prepare radioactive drugs for medical use as defined in §289.256 of this title with the following provisions.

(A) Radioactive drugs shall be prepared by either an authorized nuclear pharmacist, as specified in subparagraphs (B) and (D) of this paragraph, or an individual under the supervision of an authorized nuclear pharmacist as specified in §289.256(s) of this title.

(B) A pharmacist shall be allowed to work as an authorized nuclear pharmacist if:

(i) the individual qualifies as an authorized nuclear pharmacist as defined in §289.256 of this title;

(ii) the individual meets the requirements specified in §289.256(k)(2) and (m) of this title, and the licensee has received from the agency, an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) the individual is designated as an authorized nuclear pharmacist in accordance with subparagraph (D) of this paragraph.

(C) The actions authorized in subparagraphs (A) and (B) of this paragraph are permitted in spite of more restrictive language in license conditions.

(D) May designate a pharmacist, as defined in §289.256 of this title, as an authorized nuclear pharmacist if:

(i) the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

(ii) the individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe or at all other pharmacies prior to the effective date of this rule as noticed by the NRC or the agency.

(E) Provide the following to the agency:

(i) a copy of each individual's certification by a specialty board whose certification process has been recognized by the NRC, agency, or an agreement state as specified in §289.256(k)(1) of this title with the written attestation signed by a preceptor as required by §289.256(k)(2)(C) of this title ; or

(ii) the agency, NRC, or another agreement state license, or

(iii) the permit issued by a broad scope licensee or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(iv) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe or at all other locations of use prior to the effective date of this rule as noticed by the NRC or the agency; and

(v) a copy of the Texas State Board of Pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, in accordance with subparagraph (B)(i) and (iii) of this paragraph, the individual to work as an authorized nuclear pharmacist.

(F) 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.

(G) 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.

(4) Nothing in this subsection relieves the licensee from complying with applicable FDA, or 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 (jj)(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 (jj)(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. Radioactive material shall not be used or stored in residential locations unless specifically authorized by the agency.

(4) The licensee shall notify the agency, in writing within 15 calendar days, of any of the following changes:

(A) name;

(B) mailing address; or

(C) RSO.

(5) Each licensee shall notify the agency's Radiation Safety Licensing Branch, 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.

(6) The notification in paragraph (5) 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.

(7) A copy of the petition for bankruptcy shall be submitted to the agency along with the written notification.

(8) 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.

(9) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with §289.256 of this title. The licensee shall record the results of each test and retain each record for 3 years after the record is made for inspection by the agency.

(y) Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(1) Except as provided in paragraph (2) 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.

(2) Expiration of the specific license does not relieve the licensee of the requirements of this chapter.

(3) 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.

(4) 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 (7) 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.

(5) Coincident with the notification required by paragraph (4) 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 (10)(E) of this subsection.

(6) 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 (4) of this subsection. The schedule for decommissioning set forth in paragraph (4) of this subsection may not commence until the agency has made a determination on the request.

(7) 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.

(8) The agency may approve an alternate schedule for submittal of a decommissioning plan required in accordance with paragraph (4) 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.

(9) The procedures listed in paragraph (7) of this subsection may not be carried out prior to approval of the decommissioning plan.

(10) 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.

(11) 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.

(12) Except as provided in paragraph (14) 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.

(13) Except as provided in paragraph (14) 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.

(14) 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.

(15) 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.

(16) 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 (3) 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.

(17) Each licensee shall submit to the agency all records required by §289.202(nn)(2) of this title before the license is terminated.

(z) Renewal of licenses.

(1) Requests for renewal of specific licenses shall be filed in accordance with subsection (d)(1) - (3) and (5) - (7) 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, not less than 30 days prior to expiration of an existing license, has filed a request in proper form for 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 90 days after the expiration of an existing license, has filed a request in proper form for renewal or for a new license authorizing the same activities, the agency may reinstate the license and extend the expiration until the request has been finally determined by the agency. The requirements in this subsection are subject to the provisions of Government Code, §2001.054.

(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.

(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;

(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; and

(F) The out-of-state licensee shall have the following documents in their possession at all times when conducting work in Texas, and make them available for agency review upon request:

(i) a copy of the agency letter granting the licensee reciprocal recognition of their out-of-state license;

(ii) a copy of the licensee's operating and emergency procedures;

(iii) a copy of the licensee's radioactive material license;

(iv) a copy of all applicable sections of 25 TAC, Chapter 289; and

(v) a copy of the completed BRC Form 252-3 notifying the agency of the licensee's intent to work in Texas.

(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 (jj)(2) of this section;

(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 (jj)(2) of this section;

(C) when sealed sources or plated foils requested or authorized on the license, with a half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in subsection (jj)(2) of this section (or when a combination of isotopes is involved if R, as defined in this subsection, divided by 10^{12} is greater than 1), shall submit a decommissioning funding plan as described in paragraph (4) of this subsection; or

(D) when radioactive material requested or authorized on the license is in quantities more than 100 mCi of source material in a readily dispersible form.

(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) $1,125,000 for quantities of material greater than 10^4 but less than or equal to 10^5 times the applicable quantities in subsection (jj)(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) $225,000 for quantities of material greater than 10^3 but less than or equal to 10^4 times the applicable quantities in subsection (jj)(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);

(C) $113,000 for quantities of material greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities in subsection (jj)(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, but R divided by 10^{12} is less than or equal to 1; or)

(D) $225,000 for quantities of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form.

(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.

(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 (jj)(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 (jj)(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 (jj)(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 (jj)(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 (jj)(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 (jj)(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 (jj)(7) of this section;

(F) operating restrictions or procedures would prevent a release fraction as large as that in subsection (jj)(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.

(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) Increased controls (ICs). Licensees possessing sources containing radioactive material, at any given time, in quantities greater than or equal to the quantities of concern listed in subsection (jj)(9) of this section shall:

(1) control access at all times to radioactive material and devices containing such radioactive material (devices) in quantities in accordance with subsection (jj)(9) of this section; and

(2) limit access to such radioactive material and devices to only approved individuals who require access to perform their duties.

(A) The licensee shall allow only trustworthy and reliable individuals, approved in writing by the licensee, to have unescorted access to radioactive material quantities of concern (RAM QC) and devices.

(B) The licensee shall approve for unescorted access only those individuals with job duties that require access to such radioactive material and devices. Personnel who require access to such radioactive material and devices to perform a job duty, but who are not approved by the licensee for unescorted access, must be escorted by an approved individual.

(C) For individuals employed by the licensee for three years or less, and for non-licensee personnel, such as physicians, physicists, house-keeping personnel, and security personnel under contract, trustworthiness and reliability shall be determined, at a minimum, by verifying employment history, education, and personal references. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the employee (i.e., seeking references not supplied by the individual). For individuals employed by the licensee for longer than three years, trustworthiness and reliability shall be determined, at a minimum, by a review of the employees' employment history with the licensee.

(D) Service providers shall be escorted unless determined to be trustworthy and reliable by an NRC required background investigation as an employee of a manufacturing and distribution (M&D) licensee. Written verification attesting to or certifying the person's trustworthiness and reliability shall be obtained from the M&D licensee providing the service.

(E) The licensee shall document the basis for concluding that there is reasonable assurance that an individual granted unescorted access is trustworthy and reliable, and does not constitute an unreasonable risk for unauthorized use of RAM QC. The licensee shall maintain a list of persons approved for unescorted access to such radioactive material and devices by the licensee.

(3) Each licensee shall have a documented program to monitor and immediately detect, assess, and respond to unauthorized access to RAM QC and devices in use or in storage. Enhanced monitoring shall be provided during periods of source delivery or shipment, where the delivery or shipment exceeds 100 times the values listed in subsection (jj)(9) of this section.

(A) The licensee shall respond immediately to any actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices. The response shall include requesting assistance from a Local Law Enforcement Agency (LLEA).

(B) The licensee shall have a pre-arranged plan with LLEA for assistance in response to an actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices which is consistent in scope and timing with a realistic potential vulnerability of the sources containing such radioactive material. The pre-arranged plan shall be updated when changes to the facility design or operation affect the potential vulnerability of the sources. Prearranged LLEA coordination is not required for temporary job sites.

(C) The licensee shall have a dependable means to transmit information between, and among, the various components used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder.

(D) After initiating appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material or of the devices, the licensee shall, as promptly as possible, notify the NRC Operations Center at (301) 816-5100.

(E) The licensee shall maintain documentation describing each instance of unauthorized access and any necessary corrective actions to prevent future instances of unauthorized access.

(4) In order to ensure the safe handling, use, and control of licensed material in transportation for domestic highway and rail shipments by a carrier other than the licensee, for quantities that equal or exceed but are less than 100 times those listed in subsection (jj)(9) of this section, per consignment, the licensee shall:

(A) Use carriers which:

(i) use package tracking systems;

(ii) implement methods to assure trustworthiness and reliability of drivers;

(iii) maintain constant control and/or surveillance during transit; and

(iv) have the capability for immediate communication to summon appropriate response or assistance.

(B) Verify and document that the carrier employs the measures in subparagraph (A) of this paragraph;

(C) Contact the recipient to coordinate the expected arrival time of the shipment;

(D) Confirm receipt of the shipment; and

(E) Initiate an investigation to determine the location of the licensed material if the shipment does not arrive on or about the expected arrival time. When, through the course of the investigation, it is determined the shipment has become lost, stolen, or is missing, the licensee shall immediately notify the NRC Operations Center at (301) 816-5100. If, after 24 hours of investigating, the location of the material still cannot be determined, the radioactive material shall be deemed missing and the licensee shall immediately notify the NRC Operations Center at (301) 816-5100.

(5) For domestic highway and rail shipments, prior to shipping licensed radioactive material that exceeds 100 times the quantities in subsection (jj)(9) of this section per consignment, the licensee shall:

(A) Notify the NRC Director, Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission, Washington, DC 20555, in writing, at least 90 days prior to the anticipated date of shipment. The NRC will issue the Order to implement the Additional Security Measures (ASMs) for the transportation of RAM QC. The licensee shall not ship this material until the ASMs for the transportation of RAM QC are implemented or the licensee is notified otherwise, in writing, by the NRC.

(B) Once the licensee has implemented the ASMs for the transportation of RAM QC, the notification requirements in subparagraph (A) of this paragraph shall not apply to future shipments of licensed radioactive material that exceeds 100 times the quantities listed in subsection (jj)(9) of this section. The licensee shall implement the ASMs for the transportation of RAM QC.

(6) If a licensee employs an M&D licensee to take possession at the licensee's location of the licensed radioactive material and ship it under its M&D license, the requirements of paragraph (5)(A) and (B) of this subsection shall not apply.

(7) If the licensee is to receive radioactive material greater than or equal to the quantities in subsection (jj)(9) of this section, per consignment, the licensee shall coordinate with the originator to:

(A) Establish an expected time of delivery; and

(B) Confirm receipt of transferred radioactive material. If the material is not received at the expected time of delivery, notify the originator and assist in any investigation.

(8) Each licensee who possesses mobile or portable devices containing radioactive material in quantities greater than or equal to the values listed in subsection (jj)(9) of this section, shall:

(A) For portable devices, have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

(B) For mobile devices:

(i) that are only moved outside of the facility (e.g., on a trailer), have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

(ii) that are only moved inside a facility, have a physical control that forms a tangible barrier to secure the material from unauthorized movement or removal when the device is not under direct control and constant surveillance by the licensee.

(C) For devices in or on a vehicle or trailer, licensees shall also utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee.

(9) The licensee shall retain documentation required by these ICs for inspection by the agency for three years after they are no longer effective.

(A) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years after the individual's employment ends.

(B) Each time the licensee revises the list of approved persons required by paragraph (2)(E) of this subsection, or the documented program required by paragraph (3) of this subsection, the licensee shall retain the previous documentation for three years after the revision.

(C) The licensee shall retain documentation on each radioactive material carrier for three years after the licensee discontinues use of that particular carrier.

(D) The licensee shall retain documentation on shipment coordination, notifications, and investigations for three years after the shipment or investigation is completed.

(E) After the license is terminated or amended to reduce possession limits below the quantities of concern, the licensee shall retain all documentation required by these ICs for three years.

(10) Detailed information generated by the licensee that describes the physical protection of RAM QC, is sensitive information and shall be protected from unauthorized disclosure.

(A) The licensee shall control access to its physical protection information to those persons who have an established need to know the information, and are considered to be trustworthy and reliable.

(B) The licensee shall develop, maintain and implement policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, its physical protection information for radioactive material covered by these requirements. The policies and procedures shall include the following:

(i) general performance requirement that each person who produces, receives, or acquires the licensee's sensitive information, protect the information from unauthorized disclosure;

(ii) protection of sensitive information during use, storage, and transit;

(iii) preparation, identification or marking, and transmission;

(iv) access controls;

(v) destruction of documents;

(vi) use of automatic data processing systems; and

(vii) removal from the licensee's sensitive information category.

(jj) 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.

(2) Isotope quantities (for use in subsection (gg) of this section).

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(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}
Pr-141 Gd-152 Bi-209m U-232 Pu-240 Cm-245 Cf-252 Ce-142 Dy-154 Po-208 U-233 Pu-241 Cm-246 Es-254 Nd-144 Dy-156 Po-209 U-234 Pu-242 Cm-247 Nd-145 Tb-159 Po-210 U-235 Pu-244 Cm-248 Sm-146 Ho-165 Ra-226 U-236 Am-241 Bk-247 Sm-147 Hf-174 Ac-227 Np-235 Am-242m Bk-249 Sm-148 W-180 Th-228 Np-237 Am-243 Cf-248 Gd-148 Pt-190 Th-229 Pu-236 Cm-242 Cf-249 Gd-150 Pb-210 Th-230 Pu-238 Cm-243 Cf-250 Gd-151 Bi-209 Pa-231 Pu-239 Cm-244 Cf-251 and any alpha-emitting radionuclide not listed above or mixtures of unknown alpha emitters of unknown composition.	0.01 µCi	0.01 mCi	0.1 mCi	1.0 mCi	100 Ci
Be-10 Fe-60 Rh-102 Te-123 Sm-145 Lu-175 Ir-199m Al-26 Zn-70 Pd-107 Te-130 Nd-150 Lu-176 Pt-192 Si-32 Ge-68 Ag-108m I-129 Eu-150 Lu-177m Pt-198 Ar-39 Ge-76 Cd-113m La-137 Tb-157 Hf-172 Hg-194 K-40 Kr-81 Cd-116 La-138 Tb-158 Hf-182 Pb-202 Ar-42 Sr-90 Sn-121m Ce-139 Dy-159 Ta-179 Pb-205 Ca-48 Zr-96 Sn-123 Pm-143 Ho-166m Re-184m Bi-208 Ti-44 Mo-100 Sn-124 Pm-144 Lu-173 Re-187 Ra-228 V-49 Tc-98 Sn-126 Pm-145 Lu-174 Re-189 Np-236 V-50 Rh-101 Te-121m Pm-146 Lu-174m Os-194 Bk-248 and any other 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 Ru-106 Cs-134 Eu-152 Bi-210 U (natural) Co-60 Ag-110m Ce-144 Eu-154 Th (natural)	1.0 µCi	1.0 mCi	10 mCi	100 mCi	10 kCi
Cl-36 Ni-63 Rb-87 Cd-109 Ba-133 Gd-153 Tm-171 Ca-45 Zn-65 Zr-93 In-115 Ba-135 Eu-155 W-181 Mn-54 Se-75 Nb-93m Sb-125 Cs-137 Tm-170 Tl-204	10 µCi	10 mCi	100 mCi	1.0 Ci	100 kCi
C-14, Co-57 Kr-85 Tc-99 Ir-194 U-238 Fe-55 Ni-59 Tc-97 Pt-193, Th-232	100 µCi	100 mCi	1.0 Ci	10 Ci	1.0MCi
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 Poor's or Aaa, Aa, or A as issued by Moody's;

(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.

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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	V-48 (23)	0.01	7,000
Am-241 (95)	0.001	2	Ir-192 (77)	0.001	40,000	Xe-133 (54)	1.0	900,000
Am-242 (95)	0.001	2	Fe-55 (26)	0.01	40,000	Y-91 (39)	0.01	2,000
Am-243 (95)	0.001	2	Fe-59 (26)	0.01	7,000	Zn-65 (30)	0.01	5,000
Sb-124 (51)	0.01	4,000	Kr-85 (36)	1.0	6,000,000	Zr-93 (40)	0.01	400
Sb-126 (51)	0.01	6,000	Pb-210 (82)	0.01	8	Zr-95 (40)	0.01	5,000
Ba-133 (56)	0.01	10,000	Mn-56 (25)	0.01	60,000	Any other		
Ba-140 (56)	0.01	30,000	Hg-203 (80)	0.01	10,000	ß-γemitter	0.01	10,000
Bi-207 (83)	0.01	5,000	Mo-99 (42)	0.01	30,000	Mixed fission		
Bi-210 (83)	0.01	600	Np-237 (93)	0.001	2	products	0.01	1,000
Cd-109 (48)	0.01	1,000	Ni-63 (28)	0.01	20,000	Mixed		
Cd-113 (48)	0.01	80	Nb-94 (41)	0.01	300	corrosion		
Ca-45 (20)	0.01	20,000	P-32 (15)	0.5	100	products	0.01	10,000
Cf-252 (98)	0.001	9(20mg)	P-33 (15)	0.5	1,000	Contaminated		
C-14 (6)**	0.01	50,000	Po-210 (84)	0.01	10	equipment,		
Ce-141 (58)	0.01	10,000	K-42 (19)	0.01	9,000	ß-γ	0.001	10,000
Ce-144 (58)	0.01	300	Pm-145 (61)	0.01	4,000	Irradiated		
Cs-134 (55)	0.01	2,000	Pm-147 (61)	0.01	4,000	material,		
Cs-137 (55)	0.01	2,000	Ra-226 (88)	0.001	100	any form		
Cl-36 (17)	0.5	100	Ru-106 (44)	0.01	200	other than		
Cr-51 (24)	0.01	300,000	Sm-151 (62)	0.01	4,000	solid non-		
Co-60 (27)	0.001	5,000	Sc-46 (21)	0.01	3,000	combustible	0.01	1,000
Cu-64 (29)	0.01	200,000	Se-75 (34)	0.01	10,000	Irradiated		
Cm-242 (96)	0.001	60	Ag110m (47)	0.01	1,000	material,		
Cm-243 (96)	0.001	3	Na-22 (11)	0.01	9,000	solid non-		
Cm-244 (96)	0.001	4	Na-24 (11)	0.01	10,000	combustible	0.001	10,000
Cm-245 (96)	0.001	2	Sr-89 (38)	0.01	3,000	Mixed		
Eu-152 (63)	0.01	500	Sr-90 (38)	0.01	90	radioactive		
Eu-154 (63)	0.01	400	Sr-35 (16)	0.5	900	waste, ß-γ	0.01	1,000
Eu-155 (63)	0.01	3,000	Tc-99 (43)	0.01	10,000	Packaged		
Ge-68 (32)	0.01	2,000	Tc-99m (43)	0.01	400,000	waste,		
Gd-153 (64)	0.01	5,000	Te-127m(52)	0.01	5,000	ß-γ***	0.001	10,000
Au-198 (79)	0.01	30,000	Te-129m(52)	0.01	5,000	Any other α		
Hf-172 (72)	0.01	400	Tb-160 (65)	0.01	4,000	emitter	0.001	2
Hf-181 (72)	0.01	7,000	Tm-170 (69)	0.01	4,000	Contaminated		
Ho-166 (67)	0.01	100	Sn-113 (50)	0.01	10,000	equipment α	0.0001	20
H-3 (1)	0.5	20,000	Sn-123 (50)	0.01	3,000	Packaged		
I-125 (53)	0.5	10	Sn-126 (50)	0.01	1,000	waste***	0.0001	20
I-131 (53)	0.5	10	Ti-144 (22)	0.01	100			

* 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.

(9) Radionuclide quantities of concern. The following methods shall be used to determine which sources of radioactive material require ICs:

(A) include any single source equal to or greater than the quantity of concern;

(B) include multiple collocated sources of the same radionuclide when the combined quantity equals or exceeds the quantity of concern;

(C) for combinations of radionuclides, include multiple collocated sources of different radionuclides when the aggregate quantities satisfy the following unity rule: ((amount of radionuclide A) / (quantity of concern of radionuclide A)) + ((amount of radionuclide B) / (quantity of concern of radionuclide B)) + etc.....> 1; and

(D) quantities of radioactive materials used to determine quantities of concern. The following table contains quantities of radioactive materials to be used in determining a quantity of concern.

Radionuclide	Quantity of Concern[1] (TBq)	Quantity of Concern[2] (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Ra-226	0.4	11
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above[3]	See footnote below[4]	

[1] The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

[2] The primary values used for compliance are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

[3] Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material. When transporting or storing sources on vehicles and/or trailers, the sources are automatically considered co-located.

[4] If several radionuclides are aggregated, the sum of the ratios of the activity of each source, *i* of radionuclide, *n*, A(*i,n*), to the quantity of concern for radionuclide *n*, Q(*n*), listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... >1

(kk) Requirements for the issuance of specific licenses for a medical facility or educational institution to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium.

(1) A license application will be approved if the agency determines that an application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use in accordance with §289.256 of this title includes:

(A) a request for authorization for the production of PET radionuclides or evidence of an existing license issued in accordance with this section, the NRC, or another agreement states requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;

(B) evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in subsection (r)(1)(A) of this section;

(C) identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in subsection (r)(3)(B) of this section; and

(D) information identified in subsection (r)(1)(B) of this section on the PET drugs to be noncommercially transferred to members of its consortium.

(2) Authorization in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

(3) Each licensee authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(A) satisfy the labeling requirements in subsection (r)(1)(C) of this subsection for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

(B) possess and use instrumentation meeting the requirements of §289.202(p)(2)(D) of this title to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in subsection (r)(2) of this section.

(4) A licensee that is a pharmacy authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(A) an authorized nuclear pharmacist that meets the requirements in subsection (r)(3)(B) of this section; or

(B) an individual under the supervision of an authorized nuclear pharmacist as specified in §289.256(s) of this title.

(5) A pharmacy, authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of subsection (r)(3)(E) of this section.

(ll) Specific licenses for installation, repair, or maintenance of devices containing sealed sources of radioactive material.

(1) In addition to the requirements in subsection (e) of this section, a specific license authorizing persons to perform installation, repair, or maintenance of devices containing sealed source(s) including source exchanges will be issued if the agency approves the information submitted by the applicant.

(2) Each installation, repair, or maintenance activity shall be documented and a record maintained for inspection by the agency for 5 years from the date of that service. The record shall include the date, description of the service, initial survey results, and name(s) of the individual(s) who performed the work.

(3) Installation, repair, maintenance, or source exchange activities shall be performed by a specifically licensed person unless otherwise authorized in accordance with subsection (v) of this section.

25 TEXAS ADMINISTRATIVE CODE (TAC)

§289.256

Medical and Veterinary Use of Radioactive Material

Texas Regulations for Control of Radiation

(revisions effective October 1, 2011 are shown as shaded text)

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§289.256 Medical and Veterinary Use of Radioactive Material.

(a) Purpose.

(1) This section establishes requirements for the medical and veterinary use of radioactive material and for the issuance of specific licenses authorizing the medical and veterinary use of radioactive material. Unless otherwise exempted, no person shall receive, possess, use, transfer, own, or acquire radioactive material for medical or veterinary use except as authorized in a license issued in accordance with this section.

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

(3) A specific license is not needed for a person who:

(A) receives, possesses, uses, or transfers radioactive material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in subsection (s) of this section, unless prohibited by license condition; or

(B) prepares unsealed radioactive material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in subsection (s) of this section, unless prohibited by license condition.

(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 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).

(2) Veterinarians who receive, possess, use, transfer, own, or acquire radioactive material in the practice of veterinary medicine shall comply with the requirements of this section except for subsections (d), (dd) and (uuu) of this section.

(3) An entity that is a "covered entity" as that term is defined in HIPAA (the Health Insurance Portability and Accountability Act of 1996, 45 Code of Federal Regulations, Parts 160 and 164) may be subject to privacy standards governing how information that identifies a patient can be used and disclosed. Failure to follow HIPAA requirements may result in the department making a referral of a potential violation to the United States Department of Health and Human Services.

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

(1) Address of use--The building or buildings that are identified on the license and where radioactive material may be prepared, received, used, or stored.

(2) Area of use--A portion of an address of use that has been set aside for the purpose of preparing, receiving, using, or storing radioactive material.

(3) Authorized medical physicist--An individual who meets the following:

(A) the requirements in subsections (j) and (m) of this section; or

(B) is identified as an authorized medical physicist or teletherapy physicist on one of the following:

(i) a specific medical use license issued by the agency, the United States Nuclear Regulatory Commission (NRC), an agreement state, or licensing state;

(ii) a medical use permit issued by an NRC master material licensee;

(iii) a permit issued by an NRC, agreement state, or licensing state broad scope medical use licensee; or

(iv) a permit issued by an NRC master material license broad scope medical use permittee; and

(C) holds a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in therapeutic radiological physics for uses in subsections (rr) and (ddd) of this section.

(4) Authorized nuclear pharmacist--A pharmacist who meets the following:

(A) the requirements in subsections (k) and (m) of this section; or

(B) is identified as an authorized nuclear pharmacist on one of the following;

(i) a specific license issued by the agency, the NRC, an agreement state, or licensing state that authorizes medical use or the practice of nuclear pharmacy;

(ii) a permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) a permit issued by the agency, the NRC, an agreement state, or licensing state licensee with broad scope authorization that authorizes medical use or the practice of nuclear pharmacy; or

(iv) a permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;

(C) is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(D) is designated as an authorized nuclear pharmacist in accordance with §289.252(r) of this title; and

(E) holds a current Texas license under the Texas Pharmacy Act, Occupations Code, Chapters 551 - 566, 568, and 569, as amended, and who is certified as an authorized nuclear pharmacist by the Texas State Board of Pharmacy.

(5) Authorized user--An authorized user is defined as follows:

(A) for human use, a physician licensed by the Texas Medical Board; or a dentist licensed by the Texas State Board of Dental Examiners; or a podiatrist licensed by the Texas State Board of Podiatric Medicine who:

(i) meets the requirements in subsections (m), (gg)(1), (jj)(1), (nn)(1), (oo)(1), (pp)(1), (zz)(1), (ccc)(1) or (ttt)(1) of this section; or

(ii) is identified as an authorized user on any of the following:

(I) an agency, NRC, agreement state, or licensing state license that authorizes the medical use of radioactive material;

(II) a permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

(III) a permit issued by a specific licensee with broad scope authorization issued by the agency, the NRC, an agreement state, or licensing state authorizing the medical use of radioactive material; or

(IV) a permit issued by an NRC master material licensee with broad scope authorization that is authorized to permit the medical use of radioactive material.

(B) for veterinary use, an individual who is, a veterinarian licensed by the Texas State Board of Veterinary Medical Examiners; and

(i) is certified by the American College of Veterinary Radiology for the use of radioactive materials in veterinary medicine; or

(ii) has received training in accordance with subsections (gg), (jj), (oo), (pp) and (ttt) of this section as applicable; or

(iii) is identified as an authorized user on any of the following:

(I) an agency, NRC, agreement state, or licensing state license that authorizes the veterinary use of radioactive material;

(II) a permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

(III) a permit issued by a specific licensee with broad scope authorization issued by the agency, the NRC, an agreement state, or licensing state authorizing the medical or veterinary use of radioactive material; or

(IV) a permit issued by an NRC master material licensee with broad scope authorization that authorizes the medical use of radioactive material.

(6) Brachytherapy--A method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

(7) Brachytherapy sealed source--A sealed source or a manufacturer-assembled source train, or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(8) High dose-rate remote afterloader--A device that remotely delivers a dose rate in excess of 1200 rads (12 gray (Gy)) per hour at the point or surface where the dose is prescribed.

(9) Institutional Review Board (IRB)--Any board, committee, or other group formally designated by an institution and approved by the United States Food and Drug Administration (FDA) to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(10) Low dose-rate remote afterloader--A device that remotely delivers a dose rate of less than or equal to 200 rads (2 Gy) per hour at the point or surface where the dose is prescribed.

(11) Management--The chief executive officer or other individual delegated the authority to manage, direct, or administer the licensee's activities.

(12) Manual brachytherapy--A type of brachytherapy in which the sealed sources, for example, seeds and ribbons, are manually inserted either into the body cavities that are in close proximity to a treatment site or directly in the tissue volume.

(13) Medical event--An event that meets the criteria in subsection (uuu)(1) of this section.

(14) Medical institution--An organization in which several medical disciplines are practiced.

(15) Medical use--The intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients or human research subjects under the supervision of an authorized user.

(16) Medium dose-rate afterloader--A device that remotely delivers a dose rate greater than 200 rads (2 Gy) and less than or equal to 1200 rads (12 Gy) per hour at the point or surface where the dose is prescribed.

(17) Mobile nuclear medicine service--A licensed service authorized to transport radioactive material to, and medical use of the material at, the client's address. Services transporting calibration sources only are not considered mobile nuclear medicine licensees.

(18) Output--The exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit, a brachytherapy source, a remote afterloader unit, or a gamma stereotactic radiosurgery unit, for a specified set of exposure conditions.

(19) Patient--A human or animal under medical care and treatment.

(20) Permanent facility--A building or buildings that are identified on the license within the State of Texas and where radioactive material may be prepared, received, used, or stored. This may also include an area or areas where administrative activities related to the license are performed.

(21) Preceptor--An individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

(22) Prescribed dosage--The specified activity or range of activity of unsealed radioactive material as documented in a written directive or in accordance with the directions of the authorized user for procedures in subsections (ff) and (hh) of this section.

(23) Prescribed dose--Prescribed dose means one of the following:

(A) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(B) for teletherapy, the total dose and dose per fraction as documented in the written directive;

(C) for brachytherapy, either the total sealed source strength and exposure time, or the total dose, as documented in the written directive; or

(D) for remote afterloaders, the total dose and dose per fraction as documented in the written directive.

(24) Pulsed dose-rate remote afterloader--A special type of remote afterloading device that uses a single sealed source capable of delivering dose rates greater than 1200 rads (12 Gy) per hour, but is approximately one-tenth of the activity of typical high dose-rate remote afterloader sealed sources and is used to simulate the radiobiology of a low dose rate remote afterloader treatment by inserting the sealed source for a given fraction of each hour.

(25) Radiation safety officer (RSO)--For purposes of this section, an individual who:

(A) meets the requirements in subsections (h) and (m) of this section; or

(B) is identified as an RSO on one of the following:

(i) a specific license issued by the agency, NRC, agreement state, or licensing state license that authorizes the medical or veterinary use of radioactive material; or

(ii) a permit issued by an NRC master material licensee that authorizes the medical or veterinary use of radioactive material.

(26) Sealed source and device registry--The national registry that contains all the registration certificates, generated by both the NRC and the agreement states, that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for the product.

(27) Stereotactic radiosurgery--The use of external radiation in conjunction with a guidance device to very precisely deliver a dose to a tissue volume by the use of three-dimensional coordinates.

(28) Technologist--Technologist is defined as either of the following:

(A) in nuclear medicine, a person (nuclear medicine technologist) skilled in the performance of nuclear medicine procedures under the supervision of a physician; or

(B) in therapy, as described in subsections (rr) and (ddd) of this section, a person (radiation therapy technologist or radiation therapist) who delivers treatments of radiation therapy under the supervision of and as prescribed by an authorized user who meets the requirements of subsections (zz) or (ttt) of this section.

(29) Teletherapy--Therapeutic irradiation in which the sealed source is at a distance from the patient or human or animal research subject.

(30) Therapeutic dosage--The specified activity or range of activity of radioactive material that is intended to deliver a radiation dose to a patient or human or animal research subject for palliative or curative treatment.

(31) Therapeutic dose--A radiation dose delivered from a sealed source containing radioactive material to a patient or human or animal research subject for palliative or curative treatment.

(32) Treatment site--The anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(33) Type of use--Use of radioactive material as specified under the following subsections:

(A) uptake, and dilution and excretion studies in subsection (ff) of this section;

(B) imaging and localization studies in subsection (hh) of this section;

(C) therapy with unsealed radioactive material in subsection (kk) of this section;

(D) manual brachytherapy with sealed sources in subsection (rr) of this section;

(E) sealed sources for diagnosis in subsection (bbb) of this section; and

(F) sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit in subsection (ddd) of this section.

(34) Unit dosage--A dosage prepared for medical use for administration as a single dosage to a patient or human or animal research subject without any further modification of the dosage after it is initially prepared.

(35) Veterinary use--The intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients under the supervision of an authorized user.

(36) Written directive--An authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in subsection (t) of this section.

(d) Provisions for research involving human subjects.

(1) A licensee may conduct research involving human subjects only if it uses the radioactive materials specified on its license for the uses authorized on the license.

(2) The licensee may conduct research specified in paragraph (1) of this subsection provided that:

(A) the research is conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy for the Protection of Human Subjects as required by Title 10, Code of Federal Regulations (CFR), §35.6 (Federal Policy); or

(B) the licensee has applied for and received approval of a specific amendment to its license before conducting the research.

(3) Prior to conducting research as specified in paragraph (1) of this subsection, the licensee shall obtain the following:

(A) "informed consent," as defined and described in the Federal Policy, from the human research subjects; and

(B) review and approval of the research from an IRB as required by Title 45, CFR, Part 46, and Title 21, CFR, Part 56, and in accordance with the Federal Policy.

(4) Nothing in this subsection relieves licensees from complying with the other requirements of this chapter.

(e) Implementation.

(1) If a license condition exempted a licensee from a provision of this section or §289.252 of this title on the effective date of this rule, then the license condition continues to exempt the licensee from the requirements in the corresponding provision until there is a license amendment or license renewal that modifies or removes the license condition.

(2) When a requirement in this section differs from the requirement in an existing license condition, the requirement in this section shall govern.

(3) Licensees shall continue to comply with any license condition that requires implementation of procedures required by subsections (ggg) and (mmm) - (ooo) of this section until there is a license amendment or renewal that modifies the license condition.

(f) Specific requirements for the issuance of licenses. In addition to the requirements in §289.252(e) of this title and subsections (n) - (q) of this section, as applicable, a license will be issued if the agency determines that:

(1) the applicant satisfies any applicable special requirement in this section;

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

(3) the following information submitted by the applicant is approved:

(A) an operating, safety, and emergency procedures manual to include specific information on the following:

(i) radiation safety precautions and instructions;

(ii) methodology for measurement of dosages or doses to be administered to patients or human or animal research subjects;

(iii) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(iv) waste disposal procedures; and

(B) any additional information required by this chapter that is requested by the agency to assist in its review of the application; and

(C) qualifications of the following:

(i) RSO in accordance with subsection (h) of this section;

(ii) authorized user(s) in accordance with subsection (c)(5) of this section as applicable to the use(s) being requested;

(iii) authorized medical physicist in accordance with subsection (c)(3) of this section;

(iv) authorized nuclear pharmacist in accordance with subsection (c)(4) of this section, if applicable; and

(v) radiation safety committee (RSC), in accordance with subsection (i) of this section, if applicable; and

(4) the applicant's permanent facility is located in Texas; and

(5) the owner of the property is aware that radioactive material is stored and/or used on the property, if the proposed facility is not owned by the applicant. The applicant shall provide a written statement from the owner or the owner's agent indicating such.

(g) Radiation safety officer.

(1) Every licensee shall establish in writing the authority, duties, and responsibilities of the RSO and ensure that the RSO is provided sufficient authority, organizational freedom, time, resources, and management prerogative to perform the following duties:

(A) 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) 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;

(C) 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;

(D) 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;

(E) 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;

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

(G) identify radiation safety problems;

(H) assume control and initiate, recommend, or provide corrective actions, including shutdown of operations when necessary, in emergency situations or unsafe conditions;

(I) verify implementation of corrective actions;

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

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

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

(M) 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) serve as the primary contact with the agency.

(2) The RSO shall ensure that the duties listed in paragraph (1)(A) - (N) of this subsection are performed.

(3) The RSO shall be on site periodically commensurate with the scope of licensed activities to satisfy the requirements of paragraphs (1) and (2) of this subsection.

(4) The RSO, or staff designated by the RSO, shall be capable of physically arriving at the licensee's authorized use site(s) within a reasonable time of being notified of an emergency situation or unsafe condition.

(5) For up to 60 days each calendar year, a licensee may permit an authorized user or an individual qualified to be an RSO to function as a temporary RSO and to perform the duties of an RSO in accordance with paragraph (1) of this subsection, provided the licensee takes the actions required in paragraph (1) of this subsection, and the RSO meets the qualifications in subsection (h) of this section. Records of qualifications and dates of service shall be maintained in accordance with subsection (www) of this section for inspection by the agency.

(h) Training for radiation safety officer. Except as provided in subsection (l) of this section, the licensee shall require the individual fulfilling the responsibilities of an RSO in accordance with subsection (g) of this section for licenses for medical or veterinary use of radioactive material to be an individual who:

(1) is certified by a specialty board whose certification process has been recognized by the agency, the NRC, or an agreement state and who meets the requirements in paragraphs (5) and (6) of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation).

(A) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(i) hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(iii) pass an examination, administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology and radiation dosimetry; or

(B) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(i) hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) have two years of full-time practical training and/or supervised experience in medical physics as follows:

(I) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, the NRC, an agreement state; or a licensing state; or

(II) in clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in subsections (ll), (jj), or (nn) of this section; and

(iii) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) meets the requirements of paragraphs (5) and (6) of this subsection and has completed a structured educational program consisting of the following:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) radiation biology; and

(v) radiation dosimetry; and

(B) one year of full-time radiation safety experience under the supervision of the individual identified as the RSO on an agency, NRC, agreement state, or licensing state license or on a permit issued by an NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:

(i) shipping, receiving, and performing related radiation surveys;

(ii) using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;

(iii) securing and controlling radioactive material;

(iv) using administrative controls to avoid mistakes in the administration of radioactive material;

(v) using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(vi) using emergency procedures to control radioactive material; and

(vii) disposing of radioactive material; or

(3) is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or licensing state in accordance with subsection (j)(1) of this section and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as RSO and who meets the requirements in paragraphs (5) and (6) of this subsection; or

(4) is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities; and

(5) has obtained written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in paragraph (6) of this subsection and in paragraphs (1)(A)(i) and (ii) or (1)(B)(i) and (ii), or (2), (3), or (4) of this subsection, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee; and

(6) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

(i) Radiation safety committee (RSC). Licensees with broad scope authorization and licensees who are authorized for two or more different types of uses of radioactive material in accordance with subsections (kk), (rr), and (ddd) of this section, or two or more types of units under subsection (ddd) of this section shall establish an RSC to oversee all uses of radioactive material permitted by the license.

(1) The RSC for licenses for medical use with broad scope authorization shall be composed of the following individuals as approved by the agency:

(A) authorized users from each type of use of radioactive material authorized on the license;

(B) the RSO;

(C) a representative of nursing service;

(D) a representative of management who is neither an authorized user nor the RSO; and

(E) may include other members as the licensee deems appropriate.

(2) The RSC for licenses for medical and veterinary use authorized for two or more different types of uses of radioactive material in accordance with subsections (kk), (rr), and (ddd) of this section, or two or more types of units in accordance with subsection (ddd) of this section shall be composed of the following individuals as approved by the agency:

(A) an authorized user of each type of use permitted by the license;

(B) the RSO;

(C) a representative of nursing service, if applicable;

(D) a representative of management who is neither an authorized user nor the RSO; and

(E) may include other members as the licensee deems appropriate.

(3) Duties and responsibilities of the RSC.

(A) For licensees without broad scope authorization, the duties and responsibilities of the RSC include, but are not limited to, the following:

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

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

(I) over-exposures;

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

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

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

(iv) reviewing the audit of the radiation safety program and acting upon the findings.

(B) For licensees with broad scope authorization, the duties and responsibilities of the RSC include, but are not limited to, the items in subparagraph (A) of this paragraph and the following:

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

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

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

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

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

(4) Records documenting the RSC meetings shall be made and maintained for inspection by the agency in accordance with subsection (www) of this section. The record shall include the date, names of individuals in attendance, minutes of the meeting, and any actions taken.

(j) Training for an authorized medical physicist. Except as provided in subsection (l) of this section, the licensee shall require the authorized medical physicist to be an individual who:

(1) is certified by a specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or a licensing state and who meets the requirements in paragraphs (2)(C) and (3) of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification process recognized, a specialty board shall require all candidates for certification to meet the following:

(A) hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(B) complete two years of full-time practical training and/or supervised experience in medical physics as follows:

(i) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, agreement state, or licensing state; or

(ii) in clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in subsections (ll), (zz) or (ttt) of this section; and

(C) pass an examination administered by diplomates of the specialty board that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2) holds a post graduate degree and experience to include:

(A) a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and

(B) completion of one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and shall include:

(i) performing sealed source leak tests and inventories;

(ii) performing decay corrections;

(iii) performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(C) has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (3) of this subsection and paragraphs (1)(A) and (1)(B) or (2)(A) and (2)(B) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

(k) Training for an authorized nuclear pharmacist. Except as provided in subsection (l) of this section, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) is certified by a specialty board whose certification process has been recognized by the agency, the NRC or an agreement state and who meets the requirements of paragraph (2)(C) of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(B) hold a current, active license to practice pharmacy in the state of Texas;

(C) provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(D) pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(2) has completed a 700 hour structured educational program including both:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) chemistry of radioactive material for medical use; and

(v) radiation biology; and

(B) supervised practical experience in a nuclear pharmacy involving the following:

(i) shipping, receiving, and performing related radiation surveys;

(ii) using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(iii) calculating, assaying, and safely preparing dosages for patients or human research subjects;

(iv) using administrative controls to avoid medical events in the administration of radioactive material; and

(v) using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(C) has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (1)(A), (B) and (C) of this subsection or this paragraph and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

(l) Training for experienced RSO, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(1) An individual identified as an RSO, a teletherapy or medical physicist, or a nuclear pharmacist on one of the following before the effective date of this rule need not comply with the training requirements of subsections (h), (j), or (k) of this section, respectively:

(A) an agency, NRC, agreement state, or licensing state license;

(B) a permit issued by an agency, NRC, agreement state, or licensing state licensee with broad scope authorization;

(C) an NRC master material license permit; or

(D) an NRC master material license permit with broad scope authorization.

(2) An individual identified as a physician, dentist, podiatrist or veterinarian authorized for the medical or veterinary use of radioactive material and who performs only those medical or veterinary uses for which they were authorized on one of the following before the effective date of this rule need not comply with the training requirements of subsections (ff)-(ttt) of this section:

(A) an agency, NRC, agreement state, or licensing state license;

(B) a permit issued by an agency, NRC, agreement state, or licensing state licensee with broad scope authorization;

(C) an NRC master material license permit; or

(D) an NRC master material license permit with broad scope authorization.

(3) Individuals who need not comply with training requirements in this subsection may serve as preceptors for, and supervisors of, applicants seeking authorization on an agency license for the same uses for which these individuals are authorized.

(m) Recentness of training. The training and experience specified in subsections (h), (j), (k), (l), (ff) - (kk), (rr), (tt), (zz), (aaa), (bbb), and (ddd) of this section for medical and veterinary use shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

(n) Licenses for medical and veterinarian uses of radioactive material without broad scope authorization. In addition to the requirements of subsection (f) of this section, a license for medical and veterinarian use of radioactive material as described in the applicable subsections (ff), (hh), (kk), (rr), (bbb) and (ddd) of this section will be issued if the agency approves the following documentation submitted by the applicant:

(1) that the physician(s) or veterinarian(s) designated on the application as the authorized user(s) is qualified in accordance with subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc) and (ttt) of this section, as applicable;

(2) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(3) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses; and

(4) that an RSC has been established in accordance with subsection (i)(2) of this section, if applicable.

(o) License for medical and veterinary uses of radioactive material with broad scope authorization. In addition to the requirements of subsection (f) of this section, a license for medical use of radioactive material with broad scope authorization will be issued if the agency approves the following documentation submitted by the applicant:

(1) that the review of authorized user qualifications by the RSC is in accordance with subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc) and (ttt) of this section, as applicable;

(2) that the application is for a license authorizing unspecified forms and/or multiple types of radioactive material for medical research, diagnosis, and therapy;

(3) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(4) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;

(5) that staff has substantial experience in the use of a variety of radioactive material for a variety of human and animal uses;

(6) that the full-time RSO meets the requirements of subsection (h)(2) of this section; and

(7) that an RSC has been established in accordance with subsection (i)(1) of this section.

(p) License for the use of remote control brachytherapy units, teletherapy units, or gamma stereotactic radiosurgery units. In addition to the requirements of subsection (f) of this section, a license for the use of remote control brachytherapy (RCB) units, teletherapy units, or gamma stereotactic radiosurgery units will be issued if the agency approves the following documentation submitted by the applicant:

(1) that the physician(s) designated on the application as the authorized user(s) is qualified in accordance with subsection (ttt) of this section;

(2) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(3) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;

(4) of the radioactive isotopes to be possessed;

(5) of the sealed source manufacturer(s) name(s) and the model number(s) of the sealed source(s) to be installed;

(6) of the maximum number of sealed sources of each isotope to be possessed, including the activity of each sealed source;

(7) of the manufacturer and model name and/or number of the following units, as applicable:

(A) RCB unit;

(B) teletherapy unit; or

(C) gamma stereotactic radiosurgery unit;

(8) that the authorized medical physicist designated on the application is qualified in accordance with subsection (j) of this section;

(9) of the successful completion of unit-specific, manufacturer-provided training that includes standard clinical and emergency procedures for remote control brachytherapy and gamma stereotactic radiosurgery units for the following personnel:

(A) authorized medical physicist of this section;

(B) technologists; and

(C) authorized user;

(10) of the safety procedures and instructions as required by subsection (ggg) of this section;

(11) of the spot check procedures as required by subsections (lll) - (nnn) of this section, as applicable; and

(12) that an RSC has been established in accordance with subsection (i)(1) or (2) of this section if applicable.

(q) License for other medical or veterinary uses of radioactive material or a radiation source approved for medical or veterinary use that is not specifically addressed in this section. A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in this section if the requirements of subsection (f) of this section have been met, the applicant or licensee has received written approval from the agency in a license or license amendment and the licensee uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

(r) Amendment of licenses at request of licensee.

(1) Requests for amendment of a license or deletion of an authorized use site shall be filed in accordance with §289.252(aa) of this title.

(2) A licensee without broad-scope authorization shall apply for and shall receive a license amendment prior to the following:

(A) receiving or using radioactive material for a type of use that is authorized in accordance with under this section, but is not authorized on their current license issued in accordance with this section;

(B) permitting anyone to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist under the license;

(C) changing RSOs, except as provided in subsection (g)(5) of this section;

(D) receiving radioactive material in excess of the amount or in a different form, or receiving a different radionuclide than is authorized on the license;

(E) adding or changing the areas in which radioactive material is used or stored and are identified in the application or on the license;

(F) changing the address(es) of use identified in the application or on the license; and

(G) changing operating, safety, and emergency procedures.

(3) A licensee with broad-scope authorization shall apply for and shall receive a license amendment prior to taking actions specified in paragraph (2)(A), (C), (D), (F) and (G) of this subsection.

(s) Supervision. A licensee may permit the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, unless prohibited by license condition.

(1) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall do the following:

(A) instruct the supervised individual in the licensee's written operating, safety, and emergency procedures, written directive procedures, requirements of this chapter, and license conditions with respect to the use of radioactive material; and

(B) require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written operating, safety, and emergency procedures established by the licensee, written directive procedures, requirements of this chapter, and license conditions with respect to the medical use of radioactive material.

(2) A licensee who permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or authorized user, shall do the following:

(A) instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(B) require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written operating, safety, and emergency procedures established by the licensee, the requirements of this chapter, and license conditions.

(3) A licensee who permits supervised activities in accordance with paragraphs (1) and (2) of this subsection is responsible for the acts and omissions of the supervised individual.

(4) Only an authorized user may authorize the medical use of radioactive material.

(t) Written directives.

(1) A written directive shall be dated and signed by an authorized user prior to any administration of sodium iodide I-131 greater than 30 microcuries (µCi) (1.11 megabequerels (MBq)), administration of any therapeutic dosage of unsealed radioactive material, or administration of any therapeutic dose of radiation from radioactive material.

(A) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(B) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive or to revise a written directive would jeopardize the patient's health, an oral directive or an oral revision to an existing written directive is acceptable. The information contained in the oral directive or oral revision shall be documented in writing as soon as possible in the patient's record. A written directive or revised written directive shall be prepared and signed by the authorized user within 48 hours of the oral directive or oral revision.

(2) The written directive shall contain the patient or human research subject's name and the following information for each application.

(A) For any administration of quantities greater than 30 µCi (1.11 MBq) of sodium iodide I-131, the dosage.

(B) For an administration of a therapeutic dosage of a radiopharmaceutical other than sodium iodide I-131:

(i) the radiopharmaceutical;

(ii) the dosage; and

(iii) route of administration.

(C) For gamma stereotactic radiosurgery:

(i) the total dose;

(ii) the treatment site; and

(iii) the values for the target coordinate settings per treatment for each anatomically distinct treatment site.

(D) For teletherapy:

(i) the total dose;

(ii) dose per fraction;

(iii) number of fractions; and

(iv) treatment site.

(E) For high-dose rate remote afterloading brachytherapy:

(i) the radionuclide;

(ii) treatment site;

(iii) dose per fraction;

(iv) number of fractions; and

(v) total dose.

(F) For all other brachytherapy, including low, medium, and pulsed rate afterloaders:

(i) prior to implantation:

(I) treatment site;

(II) the radionuclide; and

(III) dose;

(ii) after implantation but prior to completion of the procedure:

(I) the radionuclide;

(II) treatment site;

(III) number of sealed sources;

(IV) total sealed source strength; and

(V) exposure time or, the total dose.

(3) The licensee shall retain the written directive in accordance with subsection (www) of this section for inspection by the agency.

(4) Procedures for administrations requiring a written directive.

(A) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to ensure that:

(i) the patient's or human research subject's identity is verified before each administration; and

(ii) each administration is in accordance with the written directive.

(B) The procedures required by subparagraph (A) of this paragraph shall, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

(i) verifying the identity of the patient or human research subject;

(ii) verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(iii) checking both manual and computer-generated dose calculations; and

(iv) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by subsection (dd) of this section.

(C) A licensee shall maintain a copy of the procedures required by subparagraph (A) of this paragraph in accordance with subsection (www) of this section.

(u) Suppliers for sealed sources or devices for medical use. A licensee may only use the following for medical use:

(1) sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued by the agency, NRC, an agreement state, or licensing state;

(2) sealed sources or devices non-commercially transferred from an NRC or agreement state medical use licensee; or

(3) teletherapy sources manufactured and distributed in accordance with a license issued by the agency, NRC, an agreement state, or licensing state.

(v) Possession, use, and calibration of dose calibrators to measure the activity of unsealed radioactive material.

(1) For direct measurements performed in accordance with subsection (x) of this section, the licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

(2) The licensee shall calibrate the instrumentation specified in paragraph (1) of this subsection in accordance with nationally recognized standards or the manufacturer's instructions.

(3) The calibration required by paragraph (2) of this subsection shall include tests for constancy, accuracy, linearity, and geometry dependence, as appropriate to demonstrate proper operation of the instrument. The tests for constancy, accuracy, linearity, and geometry dependence shall be conducted at the following intervals:

(A) constancy at least once each day prior to assay of patient dosages;

(B) linearity at installation, repair, relocation, and at least quarterly thereafter;

(C) geometry dependence at installation; and

(D) accuracy at installation and at least annually thereafter.

(4) The licensee shall maintain a record of each instrument calibration in accordance with subsection (www) of this section. The record shall include the following:

(A) model and serial number of the instrument and calibration sources;

(B) date of the calibration;

(C) results of the calibration; and

(D) name of the individual who performed the calibration.

(w) Calibration of survey instruments. A licensee shall calibrate the survey instruments used to show compliance with this subsection and with §289.202 of this title before first use, annually, and following a repair that affects the calibration. A licensee shall:

(1) calibrate all scales with readings up to 10 millisieverts (mSv) (1000 millirem (mrem)) per hour with a radiation source;

(2) calibrate two separated readings on each scale or decade that will be used to show compliance;

(3) conspicuously note on the instrument the date of calibration;

(4) not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20%; and

(5) maintain a record of each survey instrument calibration in accordance with subsection (www) of this section.

(x) Determination of dosages of unsealed radioactive material for medical use.

(1) Before medical use, the licensee shall determine and record the activity of each dosage.

(2) For a unit dosage, this determination shall be made by:

(A) direct measurement of radioactivity; or

(B) a decay correction, based on the activity or activity concentration determined by the following:

(i) a manufacturer or preparer licensed in accordance with §289.252(r) of this title, or under an equivalent NRC, agreement state, or licensing state license;

(ii) an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the U.S. Food and Drug Administration (FDA); or

(iii) a PET radioactive drug producer licensed in accordance with §289.252(kk) of this title or equivalent NRC or agreement state requirements.

(3) For other than unit dosages, this determination shall be made by:

(A) direct measurement of radioactivity;

(B) combination of measurement of radioactivity and mathematical calculations; or

(C) combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(i) a manufacturer or preparer licensed in accordance with §289.252(r) of this title, or under an equivalent NRC, agreement state, or licensing state license; or

(ii) a PET radioactive drug producer licensed in accordance with §289.252(kk) of this title or equivalent NRC or agreement state requirements.

(4) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20%.

(5) A licensee shall maintain a record of the dosage determination required by this subsection in accordance with subsection (www) of this section for inspection by the agency. The record shall contain the following:

(A) the radiopharmaceutical;

(B) patient's or human research subject's name or identification number if one has been assigned;

(C) prescribed dosage;

(D) determined dosage or a notation that the total activity is less than 30 µCi (1.1 MBq);

(E) the date and time of the dosage determination; and

(F) the name of the individual who determined the dosage.

(y) Authorization for calibration and reference sources. Any licensee authorized by subsections (n), (o), (p) or (q) of this section for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

(1) sealed sources manufactured and distributed in accordance with a license issued by the agency, NRC, or another agreement state and that do not exceed 30 millicuries (mCi) (1.11 gigabecquerel (GBq)) each;

(2) sealed sources redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed in accordance with a license issued by the agency, NRC, or another agreement state and that do not exceed 30 mCi (1.11GBq) each, provided the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0.56 GBq);

(4) any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 µCi (7.4 MBq) or 1000 times the quantities in §289.202(qqq)(3) of this title; and

(5) technetium-99m in amounts as needed.

(z) Requirements for possession of sealed sources and brachytherapy sealed sources. A licensee in possession of any sealed source or brachytherapy source shall:

(1) follow the radiation safety and handling instructions supplied by the manufacturer and the leakage test requirements in accordance with §289.201(g) of this title and reporting requirements in §289.202(bbb) of this title; and

(2) conduct a physical inventory at intervals not to exceed six months to account for all sealed sources in its possession. Records of the inventory shall be made and maintained for inspection by the agency in accordance with subsection (www) of this section and shall include the following:

(A) model number of each source and serial number if one has been assigned;

(B) identity of each source and its nominal activity;

(C) location of each source;

(D) date of the inventory; and

(E) identification of the individual who performed the inventory.

(aa) Labeling of vials and syringes. Each syringe and vial that contains a radiopharmaceutical shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

(bb) Surveys for ambient radiation exposure rate.

(1) In addition to the requirements of §289.202(p) of this title and except as provided in paragraph (2) of this subsection, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive material requiring a written directive was prepared for use or administered.

(2) A licensee does not need to perform the surveys required by paragraph (1) of this subsection in an area(s) where patients or human research subjects are confined when they cannot be released in accordance with subsection (cc) of this section or an animal that is confined. Once the patient or human or animal research subject is released from confinement, the licensee shall survey with a radiation survey instrument, the area in which the patient or human or animal research subject was confined.

(3) A record of each survey shall be retained in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the survey;

(B) results of the survey;

(C) manufacturer's name, model, and serial number of the instrument used to make the survey; and

(D) name of the individual who performed the survey.

(cc) Release of individuals containing radioactive drugs or implants containing radioactive material.

(1) The licensee may authorize the release from its control any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). Patients treated with temporary eye plaques may be released from the hospital provided that the procedures ensure that the exposure rate from the patient is less than 5 mr per hour at a distance of 1 meter from the eye plaque location.

(2) The licensee shall provide the released individual, or the individual's parent or guardian, with written instructions on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 0.1 rem (1 mSv). If the TEDE to a nursing infant or child could exceed 0.1 rem (1 mSv), assuming there was no interruption of breast-feeding, the instructions shall also include the following:

(A) guidance on the interruption or discontinuation of breast-feeding; and

(B) information on the potential consequences, if any, of failure to follow the guidance.

(3) The licensee shall maintain for inspection by the agency, a record in accordance with subsection (www) of this section of each patient released in accordance with paragraph (1) of this subsection. The record shall include the following:

(A) the basis for authorizing the release of an individual; and

(B) the instructions provided to a breast-feeding woman, if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 0.5 rem (5 mSv).

(dd) Mobile nuclear medicine service. A license for a mobile nuclear medicine service for medical or veterinary use of radioactive material will be issued if the agency approves the documentation submitted by the applicant in accordance with the requirements of subsections (f) and (n) of this section. The clients of the mobile nuclear medicine service shall be licensed if the client receives or possesses radioactive material to be used by the mobile nuclear medicine service.

(1) A licensee providing mobile nuclear medicine service shall:

(A) obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(B) check instruments used to measure the activity of unsealed radioactive material for proper function before medical or veterinary use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this subparagraph shall include a constancy check;

(C) have at least one fixed facility where records may be maintained and radioactive material may be delivered by manufacturers or distributors each day prior to the mobile nuclear medicine licensee dispatching its vans to client sites;

(D) agree to have an authorized physician user directly supervise each technologist at a reasonable frequency;

(E) check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(F) before leaving a client's address, survey all areas of use to ensure compliance with the requirements of §289.202 of this title.

(2) A mobile nuclear medicine service shall not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(3) A licensee providing mobile nuclear medicine services shall maintain records, for inspection by the agency, in accordance with subsection (www) of this section including the letter required in paragraph (1)(A) of this subsection and the record of each survey required in paragraph (1)(F) of this subsection.

(ee) Decay-in-storage.

(1) The licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage and dispose of it without regard to its radioactivity if the licensee does the following:

(A) monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(B) removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be handled as biomedical waste after it has been released from the licensee.

(2) The licensee shall retain a record of each disposal as required by paragraph (1) of this subsection in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the disposal;

(B) manufacturer's name, model number and serial number of the survey instrument used;

(C) background radiation level;

(D) radiation level measured at the surface of each waste container; and

(E) name of the individual who performed the survey.

(ff) Use of unsealed radioactive material for uptake, dilution, and excretion studies that do not require a written directive. Except for quantities that require a written directive in accordance with subsection (t) of this section, a licensee may use any unsealed radioactive material prepared for medical or veterinary use for uptake, dilution, or excretion studies that meets the following:

(1) is obtained from:

(A) a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements; or

(B) a PET radioactive drug producer licensed in accordance with §289.252(kk) of this title or equivalent NRC, agreement state, or licensing state requirements; or

(2) excluding production of PET radionuclides, prepared by:

(A) an authorized nuclear pharmacist; or

(B) a physician who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) and (jj)(1)(C)(ii)(VII) of this section; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of the authorized nuclear pharmacist or the physician who is an authorized user in subparagraphs (A) and (B) of this paragraph; or

(3) is obtained from and prepared by an NRC, agreement state, or licensing state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by the FDA; or

(4) is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by the FDA.

(gg) Training for uptake, dilution, and excretion studies. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized in subsection (ff) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC or an agreement state and who meets the requirements in paragraph (3)(C) of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification recognized, a specialty board shall require all candidates for certification to:

(A) complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraph (3)(A) and (B) of this subsection; and

(B) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) is an authorized user in accordance with subsections (jj) or (nn) of this section or equivalent NRC or agreement state requirements; or

(3) has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience shall include the following.

(A) Classroom and laboratory training in the following areas:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) chemistry of radioactive material for medical use; and

(v) radiation biology.

(B) Work experience, under the supervision of an authorized user who meets the requirements of this subsection, subsections (l), (jj), or (nn) of this section, or equivalent NRC or agreement state requirements involving the following:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) administering dosages of radioactive drugs to patients or human research subjects; and

(C) Written attestation, signed by a preceptor authorized user who meets the requirements of this subsection, subsections (l), (jj), or (nn) of this section, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of paragraph (1)(A) or (3) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (ff) of this section.

(hh) Use of unsealed radioactive material for imaging and localization studies that do not require a written directive. Except for quantities that require a written directive in accordance with subsection (t) of this section, a licensee may use any unsealed radioactive material prepared for medical or veterinary use for imaging and localization studies that meets the following:

(1) is obtained from:

(A) a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements; or

(B) A PET radioactive drug producer licensed in accordance with §289.252(kk) of this title or equivalent NRC, agreement state, or licensing state requirements; or

(2) excluding production of PET radionuclides, prepared by:

(A) an authorized nuclear pharmacist; or

(B) a physician who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) and (jj)(1)(C)(ii)(VII) of this section; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of an authorized nuclear pharmacist or an authorized user in subparagraphs (A) and (B) of this paragraph; or

(3) is obtained from and prepared by an NRC, agreement state, or licensing state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by the FDA; or

(4) is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by the FDA.

(ii) Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(1) The licensee may not administer to humans a radiopharmaceutical that contains:

(A) more than 0.15 μCi of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); or

(B) more than 0.02 μCi of strontium-82 per mCi of rubidium-82 chloride (0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride) injection; or

(C) more than 0.2 μCi of strontium-85 per mCi of rubidium-82 (0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride) injection.

(2) The licensee who uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (1) of this subsection.

(3) The licensee who uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (1) of this subsection.

(4) If the licensee is required to measure the molybdenum-99 or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) for each measured elution of technetium-99m:

(i) the ratio of the measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m (kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m);

(ii) time and date of the measurement; and

(iii) name of the individual who made the measurement.

(B) for each measured elution of rubidium-82:

(i) the ratio of the measures expressed as µCi of strontium-82 per mCi of rubidium (kilobecquerel of strontium-82 per megabecquerel of rubidium-82);

(ii) the ratio of the measures expressed as µCi of strontium-85 per mCi of rubidium (kilobecquerel of strontium-85 per megabecquerel of rubidium-82);

(iii) time and date of the measurement; and

(iv) name of the individual who made the measurement.

(jj) Training for imaging and localization studies.

(1) Except as provided in subsection (l) of this section, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized in subsection (hh) of this section to be a physician who:

(A) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC or an agreement state and who meets the requirements of subparagraph (C)(iii) of this paragraph. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(i) complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in subparagraph (C) of this paragraph; and

(ii) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(B) is an authorized user in accordance with subsection (nn) of this section and meets the requirements of subparagraph (C)(ii)(VII) of this paragraph or equivalent NRC or agreement state requirements; or

(C) has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include the following.

(i) Classroom and laboratory training in the following areas:

(I) radiation physics and instrumentation;

(II) radiation protection;

(III) mathematics pertaining to the use and measurement of radioactivity;

(IV) chemistry of radioactive material for medical use; and

(V) radiation biology.

(ii) Work experience under the supervision of an authorized user who meets the requirements in subsection (l) of this section, this subsection, or subclause (VII) of this clause, and subsection (nn) of this section, or equivalent NRC or agreement state requirements involving the following:

(I) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(VI) administering dosages of radioactive drugs to patients or human research subjects; and

(VII) eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(iii) Written attestation, signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection or subparagraph (C)(ii)(VII) of this paragraph and subsection (nn) of this section or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of subparagraph (A)(i) or (C)(i) and (ii) of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsections (ff) and (hh) of this section.

(2) In addition to the training and experience requirements of paragraph (1) of this subsection, for the use of positron emission tomography (PET) radionuclides, the licensee shall require that the authorized user has:

(A) completed 24 hours of work experience specific to the use of PET radionuclides consistent with paragraph (1)(C)(ii)(I) - (VI) of this subsection; and

(B) a written attestation statement specific to the use of PET radionuclides for diagnostic imaging.

(kk) Use of unsealed radioactive material that requires a written directive. A licensee may use any unsealed radioactive material prepared for medical use that requires a written directive that meets the following:

(1) is obtained from:

(A) a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements;

(B) A PET radioactive drug producer licensed in accordance with §289.252(kk) of this title or equivalent NRC or agreement state requirements; or

(2) excluding production of PET radionuclides, prepared by:

(A) an authorized nuclear pharmacist; or

(B) a physician who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) of this section; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of the authorized nuclear pharmacist or the physician who is an authorized user in subparagraphs (A) and (B) of this paragraph; or

(3) is obtained from and prepared by an NRC, agreement state, or licensing state licensee for use in research in accordance with an IND protocol accepted by the FDA; or

(4) is prepared by the licensee for use in research in accordance with an IND protocol accepted by the FDA.

(ll) Safety instruction to personnel.

(1) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects who cannot be released in accordance with subsection (cc) of this section. The instruction shall be appropriate to the personnel's assigned duties and include the following:

(A) patient or human or animal research subject control; and

(B) visitor control to include the following:

(i) routine visitation to hospitalized individuals or animals in accordance with §289.202(n) of this title;

(ii) contamination control;

(iii) waste control; and

(iv) notification of the RSO, or his or her designee, and an authorized user if the patient or the human or animal research subject has a medical emergency or dies.

(2) The licensee shall maintain a record for inspection by the agency, in accordance with subsection (www) of this section, of individuals receiving instruction. The record shall include the following:

(A) list of the topics covered;

(B) date of the instruction or training;

(C) name(s) of the attendee(s); and

(D) name(s) of the individual(s) who provided the instruction.

(mm) Safety precautions. For each human patient or human research subject who cannot be released in accordance with subsection (cc) of this section, the licensee shall do the following:

(1) provide a private room with a private sanitary facility; or

(2) provide a room with a private sanitary facility with another individual who also has received therapy with an unsealed radioactive material and who also cannot be released in accordance with subsection (cc) of this section;

(3) post the patient's or the research subject's room with a "Radioactive Materials" sign and note on the door and in the patient's or research subject's chart where and how long visitors may stay in the patient's or the research subject's room; and

(4) either monitor material and items removed from the patient's or the research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste; and

(5) notify the RSO, or his or her designee, and the authorized user immediately if the patient or research subject has a medical emergency or dies.

(nn) Training for use of unsealed radioactive material that requires a written directive. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized in subsection (kk) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or licensing state and who meets the requirements in paragraph (2)(B)(vi) and (C) this subsection. (Specialty boards whose certification processes have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's webpage, www.dshs.state.tx.us/radiation). To be recognized, a specialty board shall require all candidates for certification to:

(A) successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs shall include 700 hours of training and experience as described in paragraph (2)(A) - (B)(v) of this subsection. Eligible training programs shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(B) pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(2) has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience shall include the following.

(A) Classroom and laboratory training in the following areas:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) chemistry of radioactive material for medical use; and

(v) radiation biology.

(B) Work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, this subsection or equivalent NRC or agreement state requirements. A supervising authorized user, who meets the requirements of this paragraph shall also have experience in administering dosages in the same dosage category or categories (for example, in accordance with clause (vi) of this subparagraph) as the individual requesting authorized user status. The work experience shall involve the following:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(I) oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131, for which a written directive is required;

(II) oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131 (experience with at least three cases in this subclause also satisfies the requirement of subclause (I) of this clause;

(III) parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 kiloelecton volts (keV) for which a written directive is required; and/or

(IV) parenteral administration of any other radionuclide for which a written directive is required; and

(C) Written attestation that the individual has satisfactorily completed the requirements of paragraphs (1)(A) and (2)(B)(vi) or (2) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (kk) of this section. The written attestation shall be signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection or equivalent NRC or agreement state requirements. The preceptor authorized user who meets the requirements in paragraph (2) of this subsection shall have experience in administering dosages in the same dosage category or categories (for example, in accordance with paragraph (2)(B)(vi) of this subsection) as the individual requesting authorized user status.

(oo) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq). Except as provided in subsection (l) of this section, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq) to be a physician who:

(1) is certified by a medical specialty board whose certification process includes all of the requirements of paragraph (3)(A) and (B) of this subsection and whose certification has been recognized by the agency, the NRC, an agreement state, or licensing state and who meets the requirements in paragraph (3)(C) of this subsection. (The names of board certifications which have been recognized by the agency, the NRC, agreement state or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation); or

(2) is an authorized user in accordance with subsection (nn) of this section for uses listed in subsection (nn)(2)(B)(vi)(I) or (II) of this section, or subsection (pp) of this section, or equivalent NRC or agreement state requirements; or

(3) has successfully completed 80 hours of classroom and laboratory training and work experience applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training and experience shall include the following.

(A) Classroom and laboratory training shall include the following:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) chemistry of radioactive material for medical use; and

(v) radiation biology.

(B) Work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, this subsection, subsection (nn) or subsection (pp) of this section, or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in subsection (nn)(2) of this section, shall also have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(I) or (II) of this section. The work experience shall involve the following:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of less than or equal to 33mCi (1.22 GBq) of sodium iodide I-131; and

(C) Written attestation that the individual has satisfactorily completed the requirements of subparagraphs (A) and (B) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (kk) of this section. The written attestation shall be signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection, subsection (nn) or subsection (pp) of this section or equivalent NRC or agreement state requirements. A preceptor authorized user, who meets the requirements in subsection (nn)(2) of this section shall also have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(I) or (II) of this section.

(pp) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 mCi (1.22 GBq). Except as provided in subsection (l) of this section, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 mCi (1.22 GBq) to be a physician who:

(1) is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (3)(A) and (B) of this subsection and whose certification has been recognized by the agency, the NRC, an agreement state, or licensing state and who meets the requirements of paragraph (3) of this subsection. (The names of board certifications which have been recognized by the agency, the NRC, agreement state or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation);

(2) is an authorized user in accordance with subsection (nn) of this section or equivalent NRC or agreement state requirements for uses listed in subsection (nn)(2)(B)(vi)(II) of this section; or

(3) has training and experience including, successful completion of 80 hours of classroom and laboratory training applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training and experience shall include the following.

(A) Classroom and laboratory training shall include the following:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) chemistry of radioactive material for medical use;

(v) radiation biology.

(B) Work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, subsections (nn) or (pp) of this section or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements of subsection (nn)(2) of this section, shall also have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(II) of this section. The work experience shall involve the following:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of greater than 33mCi (1.22 GBq) of sodium iodide I-131; and

(C) Written attestation that the individual has satisfactorily completed the requirements of subparagraphs (A) and (B) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (kk) of this section. The written attestation shall be signed by a preceptor authorized user who meets the requirements in subsection (l) of this section, this subsection or subsection (nn) of this section or equivalent NRC or agreement state requirements. The preceptor authorized user, who meets the requirements in subsection (nn)(2) of this section, shall also have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(II) of this section.

(qq) Training for the parenteral administration of unsealed radioactive material requiring a written directive. Except as provided in subsection (l) of this section, the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

(1) is an authorized user in accordance with subsection (nn) of this section for uses listed in subsection (nn)(2)(B)(vi)(III) or (IV) of this section or equivalent NRC or agreement state requirements; or

(2) is an authorized user under subsections (zz) or (ttt) of this section or equivalent NRC or agreement state requirements and who meets the requirements of paragraph (4) of this subsection; or

(3) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or licensing state in accordance with subsection (zz) or (ttt) of this section, and who meets the requirements of paragraph (4) of this subsection. (The names of board certifications which have been recognized by the agency, the NRC, agreement state or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation); and

(4) has successfully completed training and experience including 80 hours of classroom and laboratory training applicable to parenteral administrations requiring a written directive, of any beta emitting radionuclide or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training and experience shall include the following.

(A) Classroom and laboratory training shall include the following:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) chemistry of radioactive material for medical use; and

(v) radiation biology.

(B) Work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, this subsection or subsection (nn) of this section or equivalent NRC or agreement state requirements in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements of subsection (nn) of this section, shall have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(III) and/or (IV) of this section. The work experience shall involve the following:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) administering dosages to patients or human research subjects that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(C) Written attestation that the individual has satisfactorily completed the requirements of paragraphs (2) or (3) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive materials requiring a written directive. The written attestation shall be signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection or subsection (nn) of this section or equivalent NRC or agreement state requirements. A preceptor authorized user, who meets the requirements of subsection (nn) of this section shall have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(III) and/or (IV) of this section.

(rr) Use of sealed sources for manual brachytherapy. The licensee shall use only brachytherapy sealed sources for therapeutic medical uses as follows:

(1) as approved in the Sealed Source and Device Registry; or

(2) in research in accordance with an active Investigational Device Exemption application accepted by the FDA and as approved by the agency.

(ss) Surveys after sealed source implants and removal.

(1) Immediately after implanting sealed sources in a patient or a human or animal research subject, the licensee shall perform a survey to locate and account for all sealed sources that have not been implanted.

(2) Immediately after removing the last temporary implant sealed source from a patient or a human or animal research subject, the licensee shall perform a survey of the patient or the human or animal research subject with a radiation detection survey instrument to confirm that all sealed sources have been removed.

(3) A record of each survey shall be retained, for inspection by the agency, in accordance with subsection (www) of this section. The record shall include the following:

(A) date of the survey;

(B) results of the survey;

(C) manufacturer's name and model and serial number of the instrument used to make the survey; and

(D) name of the individual who performed the survey.

(tt) Brachytherapy sealed sources accountability.

(1) The licensee shall maintain accountability at all times for all brachytherapy sealed sources in storage or use.

(2) Promptly after removing sealed sources from a patient or a human or animal research subject, the licensee shall return brachytherapy sealed sources to a secure storage area.

(3) The licensee shall maintain a record of the brachytherapy sealed source accountability in accordance with subsection (www) of this section for inspection by the agency.

(A) When removing temporary implants from storage, the licensee shall record the number and activity of sources, time and date the sources were removed, the name of the individual who removed the sources, and the location of use. When temporary implants are returned to storage, record the number and activity of sources, the time and date, and the name of the individual who returned them.

(B) When removing permanent implants from storage, the licensee shall record the number and activity of sources, date, the name of the individual who removed the sources, and the number and activity of sources permanently implanted in the patient or human research subject. Record the number and activity of sources not implanted and returned to storage, the date, and the name of the individual who returned them to storage.

(uu) Safety instruction to personnel. The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects who are receiving brachytherapy and who cannot be released in accordance with subsection (cc) of this section or animals that are confined.

(1) The instruction shall be appropriate to the personnel's assigned duties and include the following:

(A) size and appearance of brachytherapy sources;

(B) safe handling and shielding instructions;

(C) patient or human research subject control;

(D) visitor control to include visitation to hospitalized individuals in accordance with §289.202(n) of this title; and

(E) notification of the RSO, or his or her designee, and an authorized user if the patient or the human or animal research subject has a medical emergency or dies.

(2) A licensee shall maintain a record, for inspection by the agency, in accordance with subsection (www) of this section, of individuals receiving instruction. The record shall include the following:

(A) list of the topics covered;

(B) date of the instruction or training;

(C) name(s) of the attendee(s); and

(D) name(s) of the individual(s) who provided the instruction.

(vv) Safety precautions for the use of brachytherapy.

(1) For each patient or human research subject who is receiving brachytherapy and cannot be released in accordance with subsection (cc) of this section the licensee shall:

(A) provide a private room with a private sanitary facility;

(B) post the patient's or the research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or research subject's chart where and how long visitors may stay in the patient's or the research subject's room; and

(C) have available near each treatment room applicable emergency response equipment to respond to a sealed source that is inadvertently dislodged from the patient or inadvertently lodged within the patient following removal of the sealed source applicators.

(2) The RSO, or his or her designee, and the authorized user shall be notified if the patient or research subject has a medical emergency and, immediately, if the patient dies.

(ww) Calibration measurements of brachytherapy sealed sources.

(1) Prior to the first medical use of a brachytherapy sealed source on or after October 1, 2000, the licensee shall do the following:

(A) determine the sealed source output or activity using a dosimetry system that meets the requirements of subsection (iii)(1) of this section;

(B) determine sealed source positioning accuracy within applicators; and

(C) use published protocols accepted by nationally recognized bodies to meet the requirements of subparagraphs (A) and (B) of this paragraph.

(2) Instead of the licensee making its own measurements as required in paragraph (1) of this subsection, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (1) of this subsection.

(3) The licensee shall mathematically correct the outputs or activities determined in paragraph (1) of this subsection for physical decay at intervals consistent with 1.0% physical decay.

(4) The licensee shall retain a record of each calibration in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the calibration;

(B) manufacturer's name and model and serial number for the sealed source and instruments used to calibrate the sealed source;

(C) sealed source output or activity;

(D) sealed source positioning accuracy within applicators; and

(E) name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

(xx) Decay of strontium-90 sources for ophthalmic treatments.

(1) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined in accordance with subsection (ww) of this section.

(2) A licensee shall maintain a record of the strontium-90 source in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date and initial activity of the source as determined in subsection (ww) of this section; and

(B) for each decay calculation, the date and the source activity as determined in subsection (ww) of this section.

(yy) Therapy-related computer systems for manual brachytherapy. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of the following:

(1) the sealed source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays; and

(4) the accuracy of the software used to determine radioactive sealed source positions from radiographic images.

(zz) Training for use of manual brachytherapy sealed sources. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized in subsection (rr) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC or an agreement state and who meets the requirements of paragraph (2)(D) of this section. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification recognized, a specialty board shall require all candidates for certification to:

(A) successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(B) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2) has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources including the following:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology.

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements at a medical institution, involving the following:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) checking survey meters for proper operation;

(iii) preparing, implanting, and removing brachytherapy sources;

(iv) maintaining running inventories of material on hand;

(v) using administrative controls to prevent a medical event involving the use of radioactive material; and

(vi) using emergency procedures to control radioactive material; and

(C) Completion of three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph (B) of this paragraph; and

(D) Written attestation, signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of paragraph (1)(A) of this subsection or subparagraphs (A) - (C) of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy for the medical uses authorized in accordance with subsection (rr) of this section.

(aaa) Training for ophthalmic use of strontium-90. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) is an authorized user under subsection (zz) of this section or equivalent NRC or agreement state requirements; or

(2) has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include the following.

(A) Classroom training shall include the following:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology.

(B) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve:

(i) examination of each individual to be treated;

(ii) calculation of the dose to be administered;

(iii) administration of the dose; and

(iv) follow-up and review of each individual's case history; and

(C) Written attestation, signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection or subsection (zz) of this section, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of this paragraph of this subsection and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

(bbb) Use of sealed sources for diagnosis.

(1) The licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

(2) The licensee shall document that the service provider, who is performing installation and source exchange of devices containing sealed source(s) of radioactive material in medical imaging equipment, has a specific license issued by the agency in accordance with §289.252(ll) of this title. The documentation shall be maintained for inspection by the agency in accordance with subsection (www) of this section.

(ccc) Training for use of sealed sources for diagnosis. Except as provided in subsection (l) of this section, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized in accordance with subsection (bbb) of this section to be a physician, dentist, or podiatrist who:

(1) is certified by a specialty board whose certification process includes the requirements of paragraphs (2) and (3) of this subsection and whose certification has been recognized by the agency, the NRC, an agreement state, or licensing state. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation); or

(2) has completed eight hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device. The training shall include:

(A) radiation physics and instrumentation;

(B) radiation protection;

(C) mathematics pertaining to the use and measurement of radioactivity; and

(D) radiation biology; and

(3) has completed training in the use of the device for the uses requested.

(ddd) Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. The licensee shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses as follows:

(1) as approved in the Sealed Source and Device Registry; or

(2) in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of subsection (u) of this section are met.

(eee) Surveys of patients and human research subjects treated with a remote afterloader unit.

(1) Before releasing a patient or a human research subject from licensee control, the licensee shall perform a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the sealed source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(2) The licensee shall maintain a record of the surveys in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the survey;

(B) results of the survey;

(C) manufacturer's name, model, and serial number of the survey instrument used; and

(D) name of the individual who made the survey.

(fff) Installation, maintenance, adjustment, and repair.

(1) Only a person specifically licensed by the agency, the NRC, an agreement state, or licensing state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the sealed source(s) shielding, the sealed source(s) driving unit, or other electronic or mechanical component that could expose the sealed source(s), reduce the shielding around the sealed source(s), or compromise the radiation safety of the unit or the sealed source(s).

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the agency, the NRC, an agreement state, or licensing state shall install, replace, relocate, or remove a sealed source or sealed source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the agency, the NRC, an agreement state, a licensing state, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(4) The licensee shall maintain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with subsection (www) of this section for inspection by the agency. For each installation, maintenance, adjustment and repair, the record shall include the date, description of the service, and name(s) of the individual(s) who performed the work.

(ggg) Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. A licensee shall do the following:

(1) secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) permit only individuals approved by the authorized user, RSO, or authorized medical physicist to be present in the treatment room during treatment with the sealed source(s);

(3) prevent dual operation of more than one radiation producing device in a treatment room if applicable;

(4) develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the sealed source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. The procedures shall include the following and shall be physically located at the unit console:

(A) instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(B) the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(C) the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally;

(5) post instructions at the unit console to inform the operator of the following:

(A) the location of the procedures required by paragraph (4) of this subsection; and

(B) the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally;

(6) provide instruction initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, to include:

(A) procedures identified in paragraph (4) of this subsection; and

(B) operating procedures for the unit;

(7) ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually; and

(8) maintain records of individuals receiving instruction and participating in drills required by paragraphs (6) and (7) of this subsection in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) a list of the topics covered;

(B) date of the instruction or drill;

(C) name(s) of the attendee(s); and

(D) name(s) of the individual(s) who provided the instruction.

(hhh) Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. The licensee shall do the following:

(1) control access to the treatment room by a door at each entrance;

(2) equip each entrance to the treatment room with an electrical interlock system that will do the following:

(A) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(B) cause the sealed source(s) to be shielded promptly when an entrance door is opened; and

(C) prevent the sealed source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the sealed source(s) "on-off" control is reset at the console;

(3) require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels;

(4) except for low-dose remote afterloader units, construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation;

(5) for licensed activities where sealed sources are placed within the patient's or human research subject's body, only conduct treatments that allow for expeditious removal of a decoupled or jammed sealed source;

(6) in addition to the requirements specified in paragraphs (1) - (5) of this subsection, require the following:

(A) for low dose-rate**,** medium dose-rate**,** and pulsed dose-rate remote afterloader units:

(i) an authorized medical physicist, and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, be physically present during the initiation of all patient treatments involving the unit; and

(ii) an authorized medical physicist, and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the sealed source applicator(s) in the event of an emergency involving the unit, be immediately available during continuation of all patient treatments involving the unit;

(B) for high dose-rate remote afterloader units:

(i) an authorized user and an authorized medical physicist be physically present during the initiation of all patient treatments involving the unit; and

(ii) an authorized medical physicist, and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, be physically present during continuation of all patient treatments involving the unit;

(C) for gamma stereotactic radiosurgery units and teletherapy units, require that an authorized user and an authorized medical physicist be physically present throughout all patient treatments involving gamma stereotactic radiosurgery units and teletherapy units; and

(D) notify the RSO, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency or dies; and

(7) have applicable emergency response equipment available near each treatment room to respond to a sealed source that remains in the unshielded position or lodges within the patient following completion of the treatment.

(iii) Dosimetry equipment.

(1) Except for low dose-rate remote afterloader sealed sources where the sealed source output or activity is determined by the manufacturer, the licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met.

(A) The system shall have been calibrated using a system or sealed source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration.

(B) The system shall have been calibrated within the previous four years. Eighteen to 30 months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall have indicated that the calibration factor of the licensee's system had not changed by more than 2.0%. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic unit, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sealed sources of the same radionuclide as the sealed source used at the licensee's facility.

(2) The licensee shall have available for use a dosimetry system for spot check output measurements, if such measurements are required by this section. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (1) of this subsection. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot check system may be the same system used to meet the requirements of paragraph (1) of this subsection.

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison of dosimetry equipment in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the calibration;

(B) manufacturer's model and serial numbers of the instruments that were calibrated, intercompared, or compared;

(C) the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(D) the names of the individuals who performed the calibration, intercomparison, or comparison.

(jjj) Full calibration measurements on teletherapy units.

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit as follows:

(A) before the first medical use of the unit;

(B) before medical use under any of the following conditions:

(i) whenever spot check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) following replacement of the sealed source or following reinstallation of the teletherapy unit in a new location;

(iii) following any repair of the teletherapy unit that includes removal of the sealed source or major repair of the components associated with the sealed source exposure assembly; and

(C) at intervals not to exceed one year.

(2) Full calibration measurements shall include determination of the following:

(A) the output within plus or minus 3.0% for the range of field sizes and for the distance or range of distances used for medical use;

(B) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(C) uniformity of the radiation field and its dependence on the orientation of the useful beam;

(D) timer accuracy and linearity over the range of use;

(E) "on-off" error; and

(F) the accuracy of all distance measuring and localization devices in medical use.

(3) The licensee shall use the dosimetry system described in subsection (iii)(1) of this section to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (2)(A) of this subsection may be made using a dosimetry system that indicates relative dose rates.

(4) The licensee shall make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) The licensee shall mathematically correct the outputs determined in paragraph (2)(A) of this subsection for physical decay at intervals not to exceed one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1.0% decay for all other nuclides.

(6) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (5) of this subsection shall be performed by an authorized medical physicist.

(7) The licensee shall retain a record of each calibration in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the calibration;

(B) manufacturer's name, model number and serial number of the teletherapy unit's sealed source and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibrations; and

(D) signature of the authorized medical physicist who performed the full calibration.

(kkk) Full calibration measurements on remote afterloader units.

(1) A licensee authorized to use a remote afterloader for medical use shall perform full calibration measurements on each unit as follows:

(A) before the first medical use of the unit;

(B) before medical use under any of the following conditions:

(i) following replacement of the sealed source;

(ii) following reinstallation of the unit in a new location outside the facility;

(iii) following any repair of the unit that includes removal of the sealed source or major repair of the components associated with the sealed source exposure assembly;

(C) at intervals not to exceed three months for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sealed sources whose half-life exceeds 75 days; and

(D) at intervals not to exceed one year for low dose-rate afterloader units.

(2) Full calibration measurements shall include, as applicable, determination of the following:

(A) the output within plus or minus 5.0%;

(B) sealed source positioning accuracy to within plus or minus 1 millimeter (mm);

(C) sealed source retraction with backup battery upon power failure;

(D) length of the sealed source transfer tubes;

(E) timer accuracy and linearity over the typical range of use;

(F) length of the applicators; and

(G) function of the sealed source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in subsection (iii)(1) of this section to measure the output.

(4) A licensee shall make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (2) of this subsection, a licensee shall perform an autoradiograph of the sealed source(s) to verify inventory and sealed source(s) arrangement at intervals not to exceed three months.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the sealed source manufacturer that are made in accordance with paragraphs (1) - (5) of this subsection.

(7) The licensee shall mathematically correct the outputs determined in paragraph (2)(A) of this subsection for physical decay at intervals consistent with 1.0% physical decay.

(8) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (7) of this subsection shall be performed by an authorized medical physicist.

(9) The licensee shall retain a record of each calibration in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the calibration;

(B) manufacturer's name, model number and serial number of the remote afterloader unit's sealed source, and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibrations;

(D) signature of the authorized medical physicist of this section; and

(E) results of the autoradiograph required for low dose-rate remote afterloader unit.

(lll) Full calibration measurements on gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each gamma stereotactic radiosurgery unit as follows:

(A) before the first medical use of the unit;

(B) before medical use under the following conditions:

(i) whenever spot check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) following replacement of the sealed sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sealed sources or major repair of the components associated with the sealed source exposure assembly; and

(C) at intervals not to exceed one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) Full calibration measurements shall include determination of the following:

(A) the output within plus or minus 3.0%;

(B) relative helmet factors;

(C) isocenter coincidence;

(D) timer accuracy and linearity over the range of use;

(E) "on-off" error;

(F) trunnion centricity;

(G) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit "off";

(H) helmet microswitches;

(I) emergency timing circuits; and

(J) stereotactic frames and localizing devices (trunnions).

(3) The licensee shall use the dosimetry system described in subsection (iii)(1) of this section to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (2)(A) of this subsection may be made using a dosimetry system that indicates relative dose rates.

(4) The licensee shall make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) The licensee shall mathematically correct the outputs determined in paragraph (2)(A) of this subsection at intervals not to exceed one month for cobalt-60 and at intervals consistent with 1.0% physical decay for all other radionuclides.

(6) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (5) of this subsection shall be performed by an authorized medical physicist.

(7) The licensee shall retain a record of each calibration in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the calibration;

(B) manufacturer's name, model number, and serial number for the unit and the unit's sealed source and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibration; and

(D) signature of the authorized medical physicist who performed the full calibration.

(mmm) Periodic spot checks for teletherapy units.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of the following:

(A) timer constancy and linearity over the range of use;

(B) "on-off" error;

(C) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(D) the accuracy of all distance measuring and localization devices used for medical use;

(E) the output for one typical set of operating conditions measured with the dosimetry system described in subsection (iii)(2) of this section; and

(F) the difference between the measurement made in subparagraph (E) of this paragraph and the anticipated output, expressed as a percentage of the anticipated output, the value obtained at last full calibration corrected mathematically for physical decay.

(2) The licensee shall perform measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist. That authorized medical physicist need not actually perform the spot check measurements. The licensee shall maintain a copy of the written procedures in accordance with subsection (www) of this section for inspection by the agency.

(3) The licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each sealed source installation to assure proper operation of the following:

(A) electrical interlocks at each teletherapy room entrance;

(B) electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of sealed source housing angulation or elevation, carriage or stand travel and operation of the beam "on-off" mechanism);

(C) sealed source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(D) viewing and intercom systems;

(E) treatment room doors from inside and outside the treatment room; and

(F) electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(4) The licensee shall have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(5) If the results of the checks required in paragraph (3) of this subsection indicate the malfunction of any system, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) The licensee shall retain a record of each spot check required by paragraphs (1) and (3) of this subsection, in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the spot-check;

(B) manufacturer's name and model and serial number for the teletherapy unit, and sealed source and instrument used to measure the output of the teletherapy unit;

(C) assessment of timer linearity and constancy;

(D) calculated "on-off" error;

(E) determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(F) the determined accuracy of each distance measuring and localization device;

(G) the difference between the anticipated output and the measured output;

(H) notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each sealed source exposure indicator light, and the viewing and intercom system and doors;

(I) name of the individual who performed the periodic spot-check; and

(J) the signature of the authorized medical physicist who reviewed the record of the spot check.

(nnn) Periodic spot checks for remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot checks of each remote afterloader facility and on each unit as follows:

(A) before the first use each day of use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit;

(B) before each patient treatment with a low dose-rate remote afterloader unit; and

(C) after each sealed source installation.

(2) The licensee shall perform the measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist. That individual need not actually perform the spot check measurements. The licensee shall maintain a copy of the written procedures in accordance with subsection (www) of this section for inspection by the agency.

(3) The licensee shall have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(4) To satisfy the requirements of paragraph (1) of this subsection, spot checks shall, at a minimum, assure proper operation of the following:

(A) electrical interlocks at each remote afterloader unit room entrance;

(B) sealed source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(C) viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(D) emergency response equipment;

(E) radiation monitors used to indicate the sealed source position;

(F) timer accuracy;

(G) clock (date and time) in the unit's computer; and

(H) decayed sealed source(s) activity in the unit's computer.

(5) If the results of the checks required in paragraph (4) of this subsection indicate the malfunction of any system, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) The licensee shall maintain a record, in accordance with subsection (www) of this section for inspection by the agency, of each check required by paragraph (4) of this subsection. The record shall include the following, as applicable:

(A) date of the spot-check;

(B) manufacturer's name and model and serial number for the remote afterloader unit and sealed source;

(C) an assessment of timer accuracy;

(D) notations indicating the operability of each entrance door electrical interlock, radiation monitors, sealed source exposure indicator lights, viewing and intercom systems, clock, and decayed sealed source activity in the unit's computer;

(E) name of the individual who performed the periodic spot-check; and

(F) the signature of an authorized medical physicist who reviewed the record of the spot-check.

(ooo) Periodic spot checks for gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot checks of each gamma stereotactic radiosurgery facility and on each unit as follows:

(A) monthly;

(B) before the first use of the unit on each day of use; and

(C) after each source installation.

(2) The licensee shall perform the measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist with a specialty in therapeutic radiological physics. That individual need not actually perform the spot check measurements. The licensee shall maintain a copy of the written procedures in accordance with subsection (www) of this section for inspection by the agency.

(3) The licensee shall have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(4) To satisfy the requirements of paragraph (1)(A) of this subsection, spot checks shall, at a minimum, achieve the following by:

(A) assurance of proper operation of these items:

(i) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit "off;"

(ii) helmet microswitches;

(iii) emergency timing circuits; and

(iv) stereotactic frames and localizing devices (trunnions); and

(B) determination of the following:

(i) the output for one typical set of operating conditions measured with the dosimetry system described in subsection (iii)(2) of this section;

(ii) the difference between the measurement made in clause (i) of this subparagraph and the anticipated output, expressed as a percentage of the anticipated output, (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) sealed source output against computer calculation;

(iv) timer accuracy and linearity over the range of use;

(v) "on-off" error; and

(vi) trunnion centricity.

(5) To satisfy the requirements of paragraph (1)(B) and (C) of this subsection, spot checks shall assure proper operation of the following:

(A) electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(B) sealed source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(C) viewing and intercom systems;

(D) timer termination;

(E) radiation monitors used to indicate room exposures; and

(F) emergency "off" buttons.

(6) The licensee shall arrange for prompt repair of any system identified in paragraph (4) of this subsection that is not operating properly.

(7) If the results of the checks required in paragraph (5) of this subsection indicate the malfunction of any system, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(8) The licensee shall retain a record of each check required by paragraphs (4) and (5) of this subsection in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the spot check;

(B) manufacturer's name, and model and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(C) an assessment of timer linearity and accuracy;

(D) the calculated "on-off" error;

(E) a determination of trunnion centricity;

(F) the difference between the anticipated output and the measured output;

(G) an assessment of sealed source output against computer calculations;

(H) notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency "off" buttons, electrical interlocks, sealed source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions);

(I) the name of the individual who performed the periodic spot check; and

(J) the signature of an authorized medical physicist who reviewed the record of the spot check.

(ppp) Additional technical requirements for mobile remote afterloader units.

(1) A licensee providing mobile remote afterloader service shall do the following:

(A) check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(B) account for all sealed sources before departure from a client's address of use.

(2) In addition to the periodic spot checks required by subsection (nnn) of this section, a licensee authorized to use remote afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of the following:

(A) electrical interlocks on treatment area access points;

(B) sealed source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(C) viewing and intercom systems;

(D) applicators, sealed source transfer tubes, and transfer tube-applicator interfaces;

(E) radiation monitors used to indicate room exposures;

(F) sealed source positioning (accuracy); and

(G) radiation monitors used to indicate whether the sealed source has returned to a safe shielded position.

(3) In addition to the requirements for checks in paragraph (2) of this subsection, the licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(4) If the results of the checks required in paragraph (2) of this subsection indicate the malfunction of any system, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(5) The licensee shall maintain a record for inspection by the agency, in accordance with subsection (www) of this section, of each check required by subparagraph (B) of this paragraph. The record shall include the following:

(A) date of the check;

(B) manufacturer's name, model number and serial number of the remote afterloader unit;

(C) notations accounting for all sealed sources before the licensee departs from a facility;

(D) notations indicating the operability of each entrance door electrical interlock, radiation monitors, sealed source exposure indicator lights, viewing and intercom system, applicators and sealed source transfer tubes, and sealed source positioning accuracy; and

(E) the signature of the individual who performed the check.

(qqq) Radiation surveys.

(1) In addition to the survey requirements of §289.202(p) of this title, a person licensed to use sealed sources in this section shall make surveys to ensure that the maximum radiation levels and average radiation levels, from the surface of the main sealed source safe with the sealed source(s) in the shielded position, do not exceed the levels stated in the Sealed Source and Device Registry.

(2) The licensee shall make the survey required by paragraph (1) of this subsection at installation of a new sealed source and following repairs to the sealed source(s) shielding, the sealed source(s) driving unit, or other electronic or mechanical component that could expose the sealed source, reduce the shielding around the sealed source(s), or compromise the radiation safety of the unit or the sealed source(s).

(3) The licensee shall maintain a record for inspection by the agency, in accordance with subsection (www) of this section, of the radiation surveys required by paragraph (1) of this subsection. The record shall include:

(A) date of the measurements;

(B) manufacturer's name, model number and serial number of the treatment unit, sealed source, and instrument used to measure radiation levels;

(C) each dose rate measured around the sealed source while the unit is in the "off" position and the average of all measurements; and

(D) the signature of the individual who performed the test.

(rrr) Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(1) The licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during sealed source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the sealed source exposure mechanism.

(2) This inspection and servicing may only be performed by persons specifically licensed to do so by the agency, the NRC, an agreement state, or licensing state.

(3) The licensee shall maintain a record of the inspection and servicing in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of inspection;

(B) manufacturer's name and model and serial number of both the treatment unit and the sealed source;

(C) a list of components inspected and serviced, and the type of service; and

(D) the radioactive material license number and the signature of the individual performing the inspection.

(sss) Therapy-related computer systems for photon-emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of the following:

(1) the sealed source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays;

(4) the accuracy of the software used to determine sealed source positions from radiographic images; and

(5) the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(ttt) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of a sealed source for a use authorized in subsection (ddd) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or licensing state and who meets the requirements of paragraphs (2)(D) and (3) of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification recognized, a specialty board shall require all candidates for certification to:

(A) successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(B) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2) has completed a structured educational program in basic radionuclide handling techniques applicable to the use of a sealed source in a therapeutic medical unit including the following:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology.

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section and this subsection or equivalent NRC or agreement state requirements at a medical institution involving the following:

(i) reviewing full calibration measurements and periodic spot checks;

(ii) preparing treatment plans and calculating treatment times;

(iii) using administrative controls to prevent a medical event involving the use of radioactive material;

(iv) implementing emergency procedures to be followed in the event of the abnormal operation of a medical unit or console;

(v) checking and using survey meters; and

(vi) selecting the proper dose and how it is to be administered; and

(C) Completion of three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph (B) of this paragraph; and

(D) Written attestation that the individual has satisfactorily completed the requirements of paragraphs (1)(A) or (2), and (3) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation shall be signed by a preceptor authorized user who meets the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(3) has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

(uuu) Report and notification of a medical event.

(1) The licensee shall report any event, except for events that result from intervention by a patient or human research subject, in which the administration of radioactive material, or radiation from radioactive material, results in the following:

(A) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sievert (Sv)) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin and either:

(i) the total dose delivered differs from the prescribed dose by 20% or more;

(ii) the total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or

(iii) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more;

(B) a dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

(i) an administration of a wrong radioactive drug containing radioactive material;

(ii) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) an administration of a dose or dosage to the wrong individual or human research subject;

(iv) an administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) a leaking sealed source; or

(C) a dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(2) The licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material, or radiation from radioactive material, results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify the agency by telephone no later than the next calendar day after discovery of the medical event.

(4) The licensee shall submit a written report to the agency within 15 calendar days after discovery of the medical event. The written report shall include the following, excluding the individual's name or any other information that could lead to identification of the individual:

(A) the licensee's name and radioactive material license number;

(B) the name of the prescribing physician;

(C) a brief description of the medical event;

(D) why the event occurred;

(E) the effect, if any, on the individual(s) who received the administration;

(F) actions, if any, that have been taken, or are planned, to prevent recurrence; and

(G) certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(5) The licensee shall notify the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide the written description if requested.

(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(7) The licensee shall annotate a copy of the report provided to the agency with the following information:

(A) the name of the individual who is the subject of the event; and

(B) a unique identification number of the individual who is the subject of the event.

(8) The licensee shall provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 calendar days after the discovery of the event.

(9) The licensee shall retain a copy of the annotated report of the medical event in accordance with subsection (www) of this section for inspection by the agency.

(vvv) Report and notification of a dose to an embryo/fetus or nursing child.

(1) The licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual, unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) The licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast feeding individual that:

(A) is greater than 5 rem (50 mSv) TEDE; or

(B) has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify the agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with paragraphs (1) or (2) of this subsection.

(4) The licensee shall submit a written report to the agency no later than 15 calendar days after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with paragraphs (1) or (2) of this subsection. The written report shall include the following, excluding the individual's or child's name or any other information that could lead to identification of the individual or child:

(A) the licensee's name and radioactive material license number;

(B) the name of the prescribing physician;

(C) a brief description of the event;

(D) why the event occurred;

(E) the effect, if any, on the embryo/fetus or the nursing child;

(F) actions, if any, that have been taken, or are planned, to prevent recurrence; and

(G) certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(5) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting in accordance with paragraphs (1) or (2) of this subsection, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) The licensee shall annotate a copy of the report provided to the agency with the following information:

(A) the name of the individual or the nursing child who is the subject of the event; and

(B) a unique identification number of the pregnant individual or the nursing child who is the subject of the event.

(7) The licensee shall provide a copy of the annotated report as described in paragraph (6) of this subsection to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

(8) The licensee shall retain a copy of the annotated report as described in paragraph (6) of this subsection of a dose to an embryo/fetus or a nursing child in accordance with subsection (www) of this section for inspection by the agency.

(www) Records/documents for agency inspection. Each licensee shall maintain copies of the following records/documents at each authorized use site and make them available to the agency for inspection, upon reasonable notice.

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Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
§289.201(d)(1)	Records of receipt, transfer, and disposal of radioactive material	Until disposal is authorized by the agency
§289.201(g)(7), §289.202(bbb)	Records of leak tests for specific devices and sealed sources	3 years
§289.203(b)(1)(B)	Current applicable sections of this chapter as listed in the radioactive material license	Until termination of the radioactive material license
§289.203(b)(1)(B)	Copy of the current radioactive material license	Until termination of the radioactive material license
§289.203(b)(1)(C), §289.256(f)(3)(A)	Current operating, safety, and emergency procedures	Until termination of the radioactive material license
§289.256 (f)(3)(C)(i)	Qualifications of RSO	Duration of employment
§289.256(f)(3)(C)(ii)	Qualifications of authorized users	Duration of employment
§289.256(f)(3)(C)(iii)	Qualifications of authorized medical physicist	Duration of employment
§289.256(f)(3)(C)(iv)	Qualifications of authorized nuclear pharmacist, if applicable	Duration of employment
§289.256(g)(1)	Authority of RSO	Duration of employment
§289.256(g)(5)	Qualifications and dates of service for temporary RSO	3 years
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§289.256(ee)(2)	Decay in storage/disposal	3 years
§289.256(ii)(3)	Molybdenum-99 concentrations	3 years
§289.256(ll)(2)	Safety instructions - unsealed radioactive materials	3 years

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§289.256(tt)(3)	Brachytherapy sealed sources accountability	3 years
§289.256(uu)(2)	Safety instructions - brachytherapy	3 years
§289.256(ww)(4)	Calibration measurements of brachytherapy sealed sources	3 years
§289.256(xx)(2)	Strontium 90 activity of source	Duration of life of source
§289.256(bbb)(2)	Service provider documentation	3 years
§289.256(fff)(4)	Installation, maintenance, adjustment and repair-remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	3 years
§289.256(iii)(3)	Dosimetry equipment calibration, intercomparison and comparison	Until termination of the radioactive material license
§289.256(jjj)(7)	Calibration – teletherapy units	3 years
§289.256(kkk)(9)	Calibration – remote afterleader units	3 years
§289.256(lll)(7)	Calibration – gamma stereotactic radiosurgery units	3 years
§289.256(mmm)(2)	Written procedures for spot checks- teletherapy units	Until licensee no longer possesses unit
§289.256(mmm)(6)	Spot checks- teletherapy units	Until licensee no longer possesses unit
§289.256(nnn)(2)	Written procedures for spot checks - remote afterloaders	3 years
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§289.256(ooo)(2)	Written procedures for spot checks-gamma stereotactic radiosurgery units	3 years
§289.256(ooo)(8)	Spot checks-gamma stereotactic radiosurgery units	3 years
§289.256(ppp)(5)	Technical requirements for mobile remote afterloader units	3 years
§289.256(qqq)(3)	Radiation surveys	Duration of the use of the unit
§289.256(rrr)(3)	Five-year inspection for teletherapy and gamma sterotactic radiosurgery units	Duration of the use of the unit
§289.256(uuu)(9)	Annotated report – medical event	Until termination of the radioactive material license
§289.256(vvv)(8)	Annotated report – dose to embryo/fetus or nursing child	Until termination of the radioactive material license

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§289.257

Packaging and Transportation of Radioactive Material

Texas Regulations for Control of Radiation

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§289.257. Packaging and Transportation of Radioactive Material.

(a) Purpose.

(1) This section establishes requirements for packaging, preparation for shipment, and transportation of radioactive material including radioactive waste.

(2) The packaging and transport of radioactive material are also 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 (relating to Licensing of Radioactive Material), and §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material) and to the regulations of other agencies (e.g., the United States Department of Transportation (DOT) and the United States Postal Service) having jurisdiction over means of transport. The requirements of this section are in addition to, and not in substitution for, other requirements.

(b) Scope.

(1) The requirements of this section apply to any licensee authorized by a specific or general license issued by the agency to receive, possess, use, or transfer radioactive material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the agency license, or transports that material on public highways. No provision of this section authorizes possession of radioactive material.

(2) Exemptions from the requirements for a license in subsection (c) of this section are specified in subsection (f) of this section. The general license in subsection (i) of this section requires that a United States Nuclear Regulatory Commission (NRC) certificate of compliance or other package approval be issued for the package to be used in accordance with the general license. The transport of radioactive material or delivery of radioactive material to a carrier for transport is subject to the operating controls and procedural requirements of subsections (l) - (q) of this section and to the general provisions of subsections (a) - (e) of this section, including DOT regulations referenced in subsection (e) of this section.

(c) Requirement for license. Except as authorized in a general or specific license issued by the agency, or as exempted in accordance with this section, no licensee may transport radioactive material or deliver radioactive material to a carrier for transport.

(d) Definitions. The following words and terms when used in this section shall have the following meaning, unless the context clearly indicates otherwise. To ensure compatibility with international transportation standards, all limits in this section are given in terms of dual units: The International System of Units (SI) followed or preceded by United States (U.S.) standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this section, SI units shall be used.

(1) A_1--The maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Table 257-3 of subsection (ee)(6) of this section, or may be derived in accordance with the procedure prescribed in subsection (ee) of this section.

(2) A_2--The maximum activity of radioactive material, other than special form, low specific activity (LSA) and surface contaminated object (SCO) material, permitted in a Type A package. This value is either listed in Table 257-3 of subsection (ee)(6) of this section, or may be derived in accordance with the procedure prescribed in subsection (ee) of this section.

(3) Carrier--A person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

(4) Certificate holder--A person who has been issued a certificate of compliance or other package approval by the agency.

(5) Certificate of compliance--The certificate issued by the NRC that approves the design of a package for the transportation of radioactive materials.

(6) Chelating agent--Amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and glucinic acid).

(7) Chemical description--A description of the principal chemical characteristics of a LLRW.

(8) Consignee--The designated receiver of the shipment of low-level radioactive waste.

(9) Consignment--Each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

(10) Containment system--The assembly of components of the packaging intended to retain the radioactive material during transport.

(11) Conveyance--For transport on:

(A) public highway or rail by transport vehicle or large freight container;

(B) water by vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

(C) aircraft.

(12) Criticality Safety Index (CSI)--The dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in subsection (i) of this section and Title 10, Code of Federal Regulations (CFR), §71.59.

(13) Decontamination facility--A facility operating in accordance with an NRC, agreement state, or agency license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this section, is not considered to be a consignee for LLRW shipments.

(14) Deuterium--For the purposes of this section, this means deuterium and any deuterium compound, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

(15) Disposal container--A transport container principally used to confine LLRW during disposal operations at a land disposal facility (also see definition for high integrity container). Note that for some shipments, the disposal container may be the transport package.

(16) Environmental Protection Agency (EPA) identification number--The number received by a transporter following application to the administrator of EPA as required by Title 40, CFR, Part 263.

(17) Exclusive use--The sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier shall ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor shall issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

(18) Fissile material--The radionuclides plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition. Agency jurisdiction extends only to special nuclear material in quantities not sufficient to form a "critical mass" as defined in §289.201(b) of this title. Certain exclusions from fissile material controls are provided in subsection (h) of this section.

(19) Generator--A licensee operating in accordance with an NRC, agreement state, or agency license who:

(A) is a waste generator as defined in this section; or

(B) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

(20) Graphite--For the purposes of this section, this means graphite with a boron equivalent content of less than five parts per million and density greater than 1.5 grams per cubic centimeter.

(21) High integrity container (HIC)--A container commonly designed to meet the structural stability requirements of Title 10, CFR, §61.56, and to meet DOT requirements for a Type A package.

(22) Industrial package (IP)--A packaging that, together with its low specific activity (LSA) material or surface contaminated object (SCO) contents, meets the requirements of Title 49, CFR, §173.410 and §173.411. Industrial packages are categorized in Title 49, CFR, §173.411 as either:

(A) Industrial package Type 1 (IP-1);

(B) Industrial package Type 2 (IP-2); or

(C) Industrial package Type 3 (IP-3).

(23) 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 in accordance with the Texas Radiation Control Act (Act), Health and Safety Code, §401.106;

(ii) waste, as that term is defined in Title 10, CFR, §61.2; and

(iii) subject to:

(I) concentration limits established in Title 10, CFR, §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 in Title 10, CFR, §60.2;

(ii) spent nuclear fuel as defined in Title 10, CFR, §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.

(24) Low specific activity (LSA) material--Radioactive material with limited specific activity which is nonfissile or is excepted in accordance with subsection (h) of this section, and which satisfies the following descriptions and limits set forth. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material shall be in one of the following three groups:

(A) LSA-I.

(i) Ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores which are not intended to be processed for the use of these radionuclides; or

(ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or

(iii) Radioactive material for which the A_2 value is unlimited; or

(iv) Other radioactive material (e.g.: mill tailings, contaminated earth, concrete, rubble, other debris, and activated material) in which the radioactivity is distributed throughout, and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with subsection (ee) of this section.

(B) LSA-II.

(i) Water with tritium concentration up to 0.8 terabecquerel per liter (TBq/l) (20.0 curies per liter (Ci/l)); or

(ii) Other material in which the radioactivity is distributed throughout, and the average specific activity does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids.

(C) LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of Title 10, CFR, §71.77 in which:

(i) the radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and

(ii) the radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even with a loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed 0.1 A_2; and

(iii) the average specific activity of the solid does not exceed 2 x 10^{-3} A_2/g.

(25) Low toxicity alpha emitters--Natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than ten days.

(26) Maximum normal operating pressure--The maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition specified in Title 10, CFR, §71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

(27) Natural thorium--Thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(28) Normal form radioactive material--Radioactive material that has not been demonstrated to qualify as special form radioactive material.

(29) NRC Forms 540, 540A, 541, 541A, 542, and 542A--Official NRC forms referenced in subsection (ff) of this section which includes the information required by DOT in Title 49, Code of Federal Regulations, Part 172. Licensees need not use originals of these forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media shall have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

(30) Package--The packaging together with its radioactive contents as presented for transport.

(A) Fissile material package, Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package--A fissile material packaging together with its fissile material contents.

(B) Type A package--A Type A packaging together with its radioactive contents. A Type A package is defined and shall comply with the DOT regulations in Title 49, CFR, Part 173.

(C) Type B package--A Type B packaging together with its radioactive contents. On approval by the NRC, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kilopascals (kPa) (100 pounds per square inch (lb/in^2)) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in Title 10, CFR, §71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in Title 49, CFR, Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in Title 10, CFR, §71.19.

(31) Packaging--The assembly of components necessary to ensure compliance with the packaging requirements of this section. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

(32) Physical description--The items called for on BRC Form 541 to describe a LLRW.

(33) Residual waste--LLRW resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

(34) Shipper--The licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers LLRW for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator. This definition applies only to shipments of LLRW shipped to a Texas LLRW disposal facility.

(35) Site of usage--The licensee's facility, including all buildings and structures between which radioactive material is transported and all roadways that are not within the public domain on which radioactive material can be transported.

(36) Specific activity of a radionuclide--The radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(37) Spent nuclear fuel or spent fuel--Fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

(38) Surface contaminated object (SCO)--A solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. A SCO shall be in one of the following two groups with surface activity not exceeding the following limits:

(A) SCO-I--A solid object on which:

(i) the non-fixed contamination on the accessible surface averaged over 300 square centimeters (cm^2) (or the area of the surface if less than 300 cm^2) does not exceed 4 becquerels per square centimeter (Bq/cm^2) (10^{-4} microcurie per square centimeter ($\mu Ci/cm^2$)) for beta and gamma and low toxicity alpha emitters, or 4 x 10^{-1} Bq/cm^2 (10^{-5} $\mu Ci/cm^2$) for all other alpha emitters;

(ii) the fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 x 10^4 Bq/cm^2 (1 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 4 x 10^3 Bq/cm^2 (10^{-2} $\mu Ci/cm^2$) for all other alpha emitters; and

(iii) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 x 10^4 Bq/cm^2 (1 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 4 x 10^3 Bq/cm^2 (10^{-2} $\mu Ci/cm^2$) for all other alpha emitters.

(B) SCO-II--A solid object on which the limits for SCO-I are exceeded and on which the following limits are not exceeded:

(i) the non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 400 Bq/cm^2 (10^{-2} $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm^2 (10^{-3} $\mu Ci/cm^2$) for all other alpha emitters;

(ii) the fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8 x 10^5 Bq/cm^2 (20 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 $\mu Ci/cm^2$) for all other alpha emitters; and

(iii) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8 x 10^5 Bq/cm^2 (20 µCi/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 µCi/cm^2) for all other alpha emitters.

(39) Uniform Low-Level Radioactive Waste Manifest or uniform manifest--The combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

(40) Unirradiated uranium--Uranium containing not more than 2 x 10^3 Bq of plutonium per gram of uranium-235, not more than 9 x 10^6 Bq of fission products per gram of uranium-235, and not more than 5 x 10^{-3} g of uranium-236 per gram of uranium-235.

(41) Uranium--Natural, depleted, enriched:

(A) Natural uranium--Uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(B) Depleted uranium--Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(C) Enriched uranium--Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(42) Waste collector--An entity, operating in accordance with an NRC, agreement state, or agency license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

(43) Waste description--The physical, chemical and radiological description of a LLRW as called for on NRC Form 541.

(44) Waste generator--An entity, operating in accordance with an NRC, agreement state, or agency license, who:

(A) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use; and

(B) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a waste generator if the transfer of LLRW from its facility is defined as residual waste.

(45) Waste processor--An entity, operating in accordance with an NRC or agreement state license, whose principal purpose is to process, repackage, or otherwise treat LLRW or waste generated by others prior to eventual transfer of waste to a licensed LLRW land disposal facility.

(46) Waste type--A waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically-defined media).

(e) Transportation of radioactive material.

(1) Each licensee who transports radioactive material outside the site of usage as specified in the agency license, transports on public highways, or delivers radioactive material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in Title 49, CFR, Part 107, Parts 171 - 180 and 390 - 397 appropriate to the mode of transport. The licensee shall particularly note DOT regulations in the following areas:

(A) Packaging - Title 49, CFR, Part 173: Subparts A, B, and I.

(B) Marking and labeling - Title 49, CFR, Part 172: Subpart D, and §§172.400 - 172.407 and §§172.436 - 172.441 of Subpart E.

(C) Placarding - Title 49, CFR, Part 172: Subpart F, especially §§172.500-172.519 and §172.556, and Appendices B and C.

(D) Accident reporting - Title 49, CFR, Part 171: §171.15 and §171.16.

(E) Shipping papers and emergency information - Title 49, CFR, Part 172: Subparts C and G.

(F) Hazardous material employee training - Title 49, CFR, Part 172: Subpart H.

(G) Hazardous material shipper/carrier registration - Title 49, CFR, Part 107: Subpart G.

(H) Security Plans - Title 49, CFR, Part 172: Subpart I.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(A) Rail: Title 49, CFR Part 174: Subparts A through D and K.

(B) Air: Title 49, CFR Part 175.

(C) Vessel: Title 49, CFR Part 176: Subparts A through F and M.

(D) Public Highway: Title 49, CFR Part 177 and Parts 390 through 397.

(3) If DOT regulations are not applicable to a shipment of radioactive material (i.e. DOT does not have jurisdiction), the licensee shall conform to DOT standards and requirements specified in paragraph (1) of this subsection to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements shall be filed and approved by the agency. Any notification referred to in those requirements, shall be submitted to the agency.

(4) Transporters of low-level radioactive waste to a Texas low-level radioactive waste disposal site shall submit proof of financial responsibility required by Title 49, CFR, §387.7 and §387.9, to the agency's Radiation Safety Licensing Branch and receive approval of this documentation from the agency prior to initial shipment. Proof of financial responsibility shall be submitted after each policy renewal, if the amount of liability coverage is reduced, or upon purchase of a new policy.

(5) The agency shall review and determine alternate routes for the transportation and routing of radioactive material in accordance with 49 CFR, §397.103.

(f) Exemption for low-level radioactive materials.

(1) A licensee is exempt from all requirements of this section with respect to shipment or carriage of the following low-level materials:

(A) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the values specified in Table 257-4 of subsection (ee)(7) of this section.

(B) Materials for which the activity concentration is not greater than the activity concentration values specified in Table 257-4 of subsection (ee)(7) of this section, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table 257-4 of subsection (ee)(7) of this section.

(2) Common and contract carriers, freight forwarders, and warehousemen, who are subject to the rules and regulations of the DOT or the United States Postal Service (Title 39, CFR, Parts 14 and 15), are exempt from these regulations to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto. Private carriers who are subject to the rules and regulations of the DOT are exempted from these regulations to the extent that they transport sources of radiation. Common, contract, and private carriers who are not subject to the rules and regulations of the DOT or the United States Postal Service are subject to applicable sections of these regulations.

(3) Persons who discard licensed material in accordance with §289.202(fff) of this title are exempt from all requirements of this section.

(g) Exemption of physicians. Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from Title 10, CFR, §71.5 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption shall be licensed under Title 10, CFR, Part 35 or the equivalent agreement state regulations.

(h) Exemption from classification as fissile material. Fissile materials meeting the requirements of at least one of the paragraphs (1) through (6) of this subsection are exempt from classification as fissile material and from the fissile material package standards of Title 10, CFR §71.55 and §71.59, but are subject to all other requirements of this section, except as noted.

(1) An individual package containing 2 grams or less fissile material.

(2) Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass for solid nonfissile material.

(3) Solid fissile material commingled with solid non-fissile material.

(A) Low concentrations of solid fissile material commingled with solid nonfissile material provided:

(i) that there is at least 2000 grams of solid nonfissile material for every gram of fissile material; and

(ii) there is no more than 180 grams of fissile material distributed within 360 kg of contiguous non-fissile material.

(B) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass of solid nonfissile material.

(4) Uranium enriched in uranium-235 to a maximum of 1% by weight, and with total plutonium and uranium-233 content of up to 1% of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass.

(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2 percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material shall be contained in at least a DOT Type A package.

(6) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20 percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

(i) General license.

(1) NRC-approved package.

(A) A general license is issued to any licensee of the agency to transport, or to deliver to a carrier for transport, radioactive material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC.

(B) This general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of Title 10, CFR, Part 71, Subpart H.

(C) This general license applies only to a licensee who meets the following requirements:

(i) has a copy of the CoC or other approval by the NRC of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

(ii) complies with the terms and conditions of the specific license, certificate, or other approval by the NRC, as applicable, and the applicable requirements of Title 10, CFR, Part 71, Subparts A, G, and H; and

(iii) Before the licensee's first use of the package, submits in writing to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in Title 10, CFR, Part 71, the licensee's name and license number and the package identification number specified in the package approval.

(D) This general license applies only when the package approval authorizes use of the package in accordance with this general license.

(E) For a Type B or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of paragraph (2) of this subsection.

(F) For radiography containers, a program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of §289.255(m)(2)(B) of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), is deemed to satisfy the requirements of subparagraph (B) of this paragraph.

(2) Previously approved package.

(A) A Type B package previously approved by the NRC, but not designated as B(U), B(M), B(U)F or B(M)F in the identification number of the NRC certificate of compliance, or Type AF packages approved by the NRC prior to September 6, 1983, may be used in accordance with the general license of paragraph (1) of this subsection with the following additional conditions:

(i) fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with subsection (k)(3) of this section;

(ii) a serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging ; and

(iii) subparagraph (A) of this paragraph expires October 1, 2008.

(B) A Type B(U) package, a Type B(M) package, or a fissile material package, previously approved by the NRC but without the designation "-85" in the identification number of the NRC CoC, may be used in accordance with the general license of paragraph (1) of this subsection with the following additional conditions:

(i) fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with subsection (k)(3) of this section;

(ii) a package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations Title 49, CFR §173.403; and

(iii) a serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

(C) A Type B(U) package, a Type B(M) package, or a fissile material package, previously approved by the NRC with the designation "-85" in the identification number of the NRC CoC, may be used in accordance with the general license of paragraph (1) of this subsection with the following additional conditions:

(i) Fabrication of the package shall be satisfactorily completed by December 31, 2006, as demonstrated by application of its model number in accordance with subsection (k)(3) of this section.

(ii) After December 31, 2003, a package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations Title 49, CFR, §173.403.

(3) DOT specification container.

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in Title 49, CFR, Parts 173 and 178.

(B) This general license applies only to a licensee who:

(i) has a quality assurance program required by subsections (s), (t), and (u) of this section and Title 10, CFR, Part 71, Subpart H;

(ii) has a copy of the specification; and

(iii) complies with the terms and conditions of the specification and the applicable requirements of this section.

(C) The general license in subparagraph (A) of this paragraph is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in Title 49, CFR, §173.403.

(4) Use of foreign approved package.

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate that has been revalidated by the DOT as meeting the applicable requirements of Title 49, CFR, §171.12.

(B) Except as otherwise provided by this section, the general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the applicable provisions of Title 10, CFR, Part 71.

(C) This general license applies only to international shipments.

(D) This general license applies only to a licensee who:

(i) has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment; and

(ii) complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of this section. With respect to the quality assurance provisions of Title 10, CFR, Part 71, the licensee is exempt from design, construction, and fabrication considerations.

(5) Fissile material.

(A) A general license is issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package that meets the standards of this section; however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of Title 49, CFR, §173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of Title 10, CFR, Part 71.

(C) The general license applies only when a package's contents:

(i) contain no more than a Type A quantity of radioactive material; and

(ii) contain less than 500 total grams of beryllium, graphite, or hydrogeneous material enriched in deuterium.

(D) The general license applies only to packages containing fissile material that are labeled with a CSI that:

(i) has been determined in accordance with paragraph (E) of this subsection;

(ii) has a value less than or equal to 10.0; and

(iii) for a shipment of multiple packages containing fissile material, the sum of the CSIs shall be less than or equal to 50.0 (for shipment on a nonexclusive use conveyance) and less than or equal to 100.0 (for shipment on an exclusive use conveyance).

(E) The CSI shall be as follows:

(i) the value for the CSI shall be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{grams^{235}U}{X} + \frac{grams^{233}U}{Y} + \frac{gramsPu}{Z}\right]$$

(ii) the calculated CSI shall be rounded up to the first decimal place;

(iii) the values of X, Y, and Z used in the CSI equation shall be taken from Tables 257-1 or 257-2 of this clause, as appropriate;

Table 257-1
Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per §289.257(i)(5)(E)

Fissile Material	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O. (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O [a]. (grams)
^{235}U (X).....	60	38
^{233}U (Y).....	43	27
^{239}PU or ^{241}PU (Z).....	37	24

[a]When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15% of the moderating substance has an average hydrogen density greater than H_2O.

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Table 257-2
Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per §289.257(i)(5)(E)

Uranium enrichment in weight percent of ^{235}U not exceeding	Fissile material mass of ^{235}U (X). (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

(iv) if Table 257-2 of clause (iii) of this subparagraph is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium shall be assumed to be zero; and

(v) Table 257-1 values of clause (iii) of this subparagraph for X, Y, and Z shall be used to determine the CSI if:

(I) uranium-233 is present in the package;

(II) the mass of plutonium exceeds 1% of the mass of uranium-235;

(III) the uranium is of unknown uranium-235 enrichment, or greater than 24 weight percent enrichment; or

(IV) substances having a moderating effectiveness (i.e. an average hydrogen density greater than H_20) (e.g. certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

(6) Plutonium-beryllium special form material.

(A) A general license is issued to any licensee to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section This material need not be contained in a package that meets the standards of Title 10, CFR, Part 71, however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of Title 49, CFR, §173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of Title 10, CFR, Part 71.

(C) The general license applies only when a package's contents:

(i) contain no more than a Type A quantity of material; and

(ii) contain less than 1000g of plutonium, provided that plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.

(D) The general license applies only to packages labeled with a CSI that:

(i) has been determined in accordance with subparagraph (E) of this paragraph;

(ii) has a value less than or equal to 100.0; and

(iii) for a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs shall be less than or equal to 50.0 (for shipment on a nonexclusive use conveyance) and less than or equal to 100.0 (for shipment on or exclusive use conveyance).

(E) The value for the CSI shall be as follows:

(i) the CSI shall be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{grams^{239}Pu + grams^{241}Pu}{24}\right]; \text{ and}$$

(ii) the calculated CSI shall be rounded up to the first decimal place.

(j) Assumptions as to unknown properties. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

(k) Preliminary determinations. Before the first use of any packaging for the shipment of licensed material the licensee shall:

(1) ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;

(2) where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in^2) gauge, test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and

(3) conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the NRC.

(l) Routine determinations. Before each shipment of radioactive material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this section and of the license. The licensee shall determine that:

(1) the package is proper for the contents to be shipped;

(2) the package is in unimpaired physical condition except for superficial defects such as marks or dents;

(3) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;

(4) any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(5) any pressure relief device is operable and set in accordance with written procedures;

(6) the package has been loaded and closed in accordance with written procedures;

(7) for fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(8) any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of Title 10, CFR, §71.45;

(9) the level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable (ALARA), and within the limits specified in DOT regulations in Title 49, CFR, §173.443;

(10) external radiation levels around the package and around the vehicle, if applicable, will not exceed the following limits at any time during transportation:

(A) Except as provided in subparagraph (B) of this paragraph, each package of radioactive materials offered for transportation shall be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/hr (200 mrem/hr) at any point on the external surface of the package, and the transport index does not exceed 10.

(B) A package that exceeds the radiation level limits specified in subparagraph (A) of this paragraph shall be transported by exclusive use shipment only, and the radiation levels for such shipment shall not exceed the following during transportation:

(i) 2 mSv/hr (200 mrem/hr) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/hr (1,000 mrem/hr):

(I) the shipment is made in a closed transport vehicle;

(II) the package is secured within the vehicle so that its position remains fixed during transportation; and

(III) there are no loading or unloading operations between the beginning and end of the transportation;

(ii) 2 mSv/hr (200 mrem/hr) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

(iii) 0.1 mSv/hr (10 mrem/hr) at any point 2 meters (m) (6.6 feet (ft)) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 m (6.6 ft) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

(iv) 0.02 mSv/hr (2 mrem/hr) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with §289.202(q) of this title;

(C) For shipments made in accordance with the provisions of subparagraph (B) of this paragraph, the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions shall be included with the shipping paper information.

(D) The written instructions required for exclusive use shipments shall be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

(11) a package shall be designed, constructed, and prepared for transport so that in still air at 38 degrees Celsius (100 degrees Fahrenheit) and in the shade, no accessible surface of a package would have a temperature exceeding 50 degrees Celsius (122 degrees Fahrenheit) in a nonexclusive use shipment, or 85 degrees Celsius (185 degrees Fahrenheit) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

(m) Air transport of plutonium.

(1) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this section or included indirectly by citation of Title 49, CFR, Chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

(A) the plutonium is contained in a medical device designed for individual human application; or

(B) the plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Table 257-4 of subsection (ee)(7) of this section, and in which the radioactivity is essentially uniformly distributed; or

(C) the plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form, and is shipped in accordance with subsection (e) of this section; or

(D) the plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC.

(2) Nothing in paragraph (1) of this subsection is to be interpreted as removing or diminishing the requirements of Title 10, CFR, §73.24.

(3) For a shipment of plutonium by air which is subject to paragraph (1) of this subsection, the licensee shall, through special arrangement with the carrier, require compliance with Title 49, CFR, §175.704, DOT regulations applicable to the air transport of plutonium.

(n) Opening instructions. Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with §289.202(ee)(5) of this title.

(o) Records. For a period of three years after shipment, each licensee shall maintain, for inspection by the agency, a record of each shipment of radioactive material showing the following where applicable:

(1) identification of the packaging by model number and serial number;

(2) verification that there are no significant defects in the packaging, as shipped;

(3) type and quantity of radioactive material in each package, and the total quantity of each shipment;

(4) date of the shipment;

(5) for fissile packages and for Type B packages, any special controls exercised;

(6) name and address of the transferee;

(7) address to which the shipment was made; and

(8) surveys performed to determine compliance with subsection (l)(9) and (10) of this section.

(p) Reports. The shipper shall immediately report by telephone, telegram, mailgram, or facsimile, all radioactive waste transportation accidents to the agency and the local emergency planning committees in the county where the radioactive waste accident occurs. All other accidents involving radioactive material shall be reported in accordance with §289.202(xx) and (yy) of this title.

(q) Advance notification of transport of irradiated reactor fuel and certain radioactive waste.

(1) As specified in paragraphs (2)-(4) of this subsection, each licensee shall provide advance notification to the governor of a state, or the governor's designee, of the shipment of radioactive waste, through, or across the boundary of the state, before the transport, or delivery to a carrier, for transport, of radioactive waste outside the confines of the licensee's facility or other place of use or storage.

(2) Advance notification is required in accordance with this section for shipment of irradiated reactor fuel in quantities less than that subject to advance notification requirements of Title 10, CFR, §73.37. Advanced notification is also required under this subsection for shipments of radioactive material, other than irradiated fuel, meeting the following three conditions:

(A) the radioactive waste is required by this section to be in Type B packaging for transportation;

(B) the radioactive waste is being transported to or across a state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

(C) the quantity of radioactive waste in a single package exceeds the least of the following:

(i) 3000 times the A_1 value of the radionuclides as specified in subsection (ee) of this section for special form radioactive material;

(ii) 3000 times the A_2 value of the radionuclides as specified in subsection (ee) of this section for normal form radioactive material; or

(iii) 1000 terabecquerels (TBq) (27,000 curies (Ci)).

(3) The following are procedures for submitting advance notification:

(A) The notification shall be made in writing to the office of each appropriate governor or governor's designee and to the agency.

(B) A notification delivered by mail shall be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(C) A notification delivered by any other means than mail shall reach the office of the governor or of the governor's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of radioactive waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

(ii) The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

(iii) A list of the names and mailing addresses of the governors' designees is available on request from the Director, Office of State Programs, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

(D) The licensee shall retain a copy of the notification as a record for three years.

(4) Each advance notification of shipment of irradiated reactor fuel or radioactive waste shall contain the following information:

(A) the name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or radioactive waste shipment;

(B) a description of the irradiated reactor fuel or radioactive waste contained in the shipment, as specified in the regulations of DOT in Title 49, CFR, §172.202 and §172.203(d);

(C) the point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

(D) the seven-day period during which arrival of the shipment at state boundaries is estimated to occur;

(E) the destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

(F) a point of contact, with a telephone number, for current shipment information.

(5) A licensee who finds that schedule information previously furnished to a governor or governor's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the state or of the governor's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three years.

(6) The following are procedures for a cancellation notice.

(A) Each licensee who cancels an irradiated reactor fuel or radioactive waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each state or to the governor's designee previously notified, and to the agency.

(B) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three years.

(r) Emergency plan. Each shipper and transporter of radioactive waste shall adopt an emergency plan approved by the agency for responding to transportation accidents.

(s) Quality assurance requirements.

(1) Purpose. This subsection describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety.

(A) Quality Assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service.

(B) Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

(C) The licensee, certificate holder, and applicant for a CoC are responsible for the following:

(i) the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging; and

(ii) the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to this subpart.

(2) Establishment of program. Each licensee, certificate holder, and applicant for a CoC shall:

(A) Establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of this subsection, subsections (s) and (t) of this section and Title 10, CFR, §§71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging; and

(B) Execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(3) Approval of program. Before the use of any package for the shipment of licensed material subject to this subsection, each licensee shall:

(A) obtain agency approval of its quality assurance program; and

(B) file a description of its quality assurance program, including a discussion of which requirements of this subsection and subsections (t) and (u) are applicable and how they will be satisfied.

(4) Radiography containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of §289.255(m) of this title, is deemed to satisfy the requirements of subsection (i)(1)(B) of this section and paragraph (2) of this subsection.

(t) Quality assurance organization. The licensee, certificate holder, and applicant for a CoC shall (while the term "licensee" is used in these criteria, the requirements are applicable to whatever design, fabricating, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued):

(1) be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program; and

(2) clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to safety. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(3) establish quality assurance functions as follows:

(A) assuring that an appropriate quality assurance program is established and effectively executed; and

(B) verifying , by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

(4) assure that persons and organizations performing quality assurance functions have sufficient authority and organizational freedom to:

(A) identify quality problems;

(B) initiate, recommend, or provide solutions; and

(C) verify implementation of solutions.

(u) Quality assurance program. A quality assurance program shall be maintained as follows:

(1) The licensee, certificate holder, and applicant for a CoC shall:

(A) establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of this section and Title 10, CFR, §§71.101 through 71.137;

(B) document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used; and

(C) identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(2) The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall:

(A) provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material;

(B) assure that activities affecting quality are accomplished under suitable controlled conditions which include:

(i) the use of appropriate equipment;

(ii) suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and

(iii) all prerequisites for the given activity have been satisfied; and

(C) take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(3) The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components.

(A) The impact of malfunction or failure of the item to safety;

(B) The design and fabrication complexity or uniqueness of the item;

(C) The need for special controls and surveillance over processes and equipment;

(D) The degree to which functional compliance can be demonstrated by inspection or test; and

(E) The quality history and degree of standardization of the item.

(4) The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained.

(5) The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

(v) Quality control program. Each shipper shall adopt a quality control program to include verification of the following to ensure that shipping containers are suitable for shipments to a licensed disposal facility:

(1) identification of appropriate container(s);

(2) container testing documentation is adequate;

(3) appropriate container used;

(4) container packaged appropriately;

(5) container labeled appropriately;

(6) manifest filled out appropriately; and

(7) documentation maintained of each step.

(w) Handling, storage, and shipping control. The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

(x) Inspection, test, and operating status. Measures to track inspection, test and operating status shall be established as follows.

(1) The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests; and

(2) The licensee, shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

(y) Nonconforming materials, parts, or components. The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include the following, as appropriate;

(1) procedures for identification, documentation, segregation, disposition, and notification to affected organizations; and

(2) nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

(z) Corrective action. The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected.

(1) In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition.

(2) The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

(aa) Quality assurance records. The licensee, certificate holder, and applicant for a CoC shall maintain written records sufficient to describe the activities affecting quality for inspection by the agency for 3 years beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a CoC shall retain the superseded material for 3 years after it is superseded. The records must include the following;

(1) instructions, procedures, and drawings to prescribe quality assurance activities closely related specifications such as required qualifications of personnel, procedures, and equipment.

(2) instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility.

(bb) Audits. The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits, to verify compliance with all aspects of the quality assurance program, and to determine the effectiveness of the program. The audit program shall include:

(1) performance in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the area being audited;

(2) documented results that are reviewed by management having responsibility in the area audited; and

(3) follow-up action, including reaudit of deficient areas, shall be taken where indicated.

(cc) Transfer for disposal and manifests.

(1) The requirements of this section and subsection (ff) of this section are designed to:

(A) control transfers of LLRW by any waste generator, waste collector, or waste processor licensee, as defined in this section, who ships LLRW either directly, or indirectly through a waste collector or waste processor, to a licensed LLRW land disposal facility, as defined in §289.201(b) of this title;

(B) establish a manifest tracking system; and

(C) supplement existing requirements concerning transfers and recordkeeping for those wastes.

(2) Beginning March 1, 1998, all affected licensees shall use subsection (ff) of this section.

(3) Each shipment of LLRW intended for disposal at a licensed land disposal facility shall be accompanied by a shipment manifest in accordance with subsection (ff)(1) of this section.

(4) Any licensee shipping LLRW intended for ultimate disposal at a licensed land disposal facility shall document the information required on the uniform manifest and transfer this recorded manifest information to the intended consignee in accordance with subsection (ff) of this section.

(5) Each shipment manifest shall include a certification by the waste generator as specified in subsection (ff)(10) of this section, as appropriate.

(6) Each person involved in the transfer for disposal and disposal of LLRW, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in subsection (ff) of this section, as appropriate.

(7) Any licensee shipping LLRW to a licensed Texas LLRW disposal facility shall comply with the waste acceptance criteria in 30 Texas Administrative Code (TAC) Part 1, Chapter 336.

(dd) Fees.

(1) Each shipper shall be assessed a fee for shipments of LLRW originating in Texas or originating out-of-state being shipped to a licensed Texas LLRW disposal facility and these fees shall be:

(A) $10 per cubic foot of shipped LLRW;

(B) collected by the department and deposited to the credit of the radiation and perpetual care account; and

(C) used exclusively by the agency for emergency planning for and response to transportation accidents involving LLRW.

(2) Fee assessments in accordance with this section shall be suspended when the amount of fees collected reaches $500,000, except that if the balance of fees collected is reduced to $350,000 or less, the assessments shall be reinstituted to bring the balance of fees collected to $500,000.

(3) Money expended from the radiation and perpetual care account to respond to accidents involving LLRW shall be reimbursed to the radiation and perpetual care account by the responsible shipper or transporter according to rules adopted by the board.

(4) For purposes of this subsection, "shipper" means a person who generates low-level radioactive waste and ships or arranges with others to ship the waste to a disposal site.

(ee) Appendices for determination of A_1 and A_2.

(1) Values of A_1 and A_2. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these rules are given in Table 257-3 of paragraph (6) of this subsection. The curie (Ci) values specified are obtained by converting from the terabecquerel (TBq) figure. The Terabecquerel values are the regulatory standard. The curie values are for information only and are not intended to be the regulatory standard. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

(2) Values of radionuclides not listed.

(A) For individual radionuclides whose identities are known, but are not listed in Table 257-3 of paragraph (6) of this subsection, the A_1 and A_2 values contained in Table 257-5 of paragraph (8) of this subsection may be used. Otherwise, the licensee shall obtain prior NRC approval of the A_1 and A_2 values for radionuclides not listed in Table 257-3 of paragraph (6) of this subsection, before shipping the material.

(B) For individual radionuclides whose identities are known, but that are not listed in Table 257-4 of paragraph (7) of this subsection, the exempt material activity concentration and exempt consignment activity values contained in Table 257-5 of paragraph (8) of this subsection may be used. Otherwise, the licensee shall obtain prior approval of the exempt material activity concentration and exempt consignment activity values, for radionuclides not listed in Table 257-3 of paragraph (6) of this subsection, before shipping the material.

(C) The licensee shall submit requests for prior approval, described in subparagraphs (A) and (B) of this paragraph to the agency.

(3) Calculations of A_1 and A_2 for a radionuclide not in Table 257-3 of paragraph (6) of this subsection. In the calculations of A_1 and A_2 for a radionuclide not in Table 257-3 of paragraph (6) of this subsection, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter radionuclide has a half-life either longer than ten days, or longer than that of the parent radionuclide, shall be considered as a single radionuclide, and the activity to be taken into account and the A_1 or A_2 value to be applied shall be those corresponding to the parent radionuclide of that chain. In the case of radioactive decay chains in which any daughter radionuclide has a half-life either longer than ten days, or greater than that of the parent radionuclide, the parent and those daughter radionuclides shall be considered as mixtures of different radionuclides.

(4) Determination for mixtures of radionuclides whose identities and respective activities are known. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply.

(A) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide I, and $A_1(i)$ is the A_1 value for radionuclide I.

(B) For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide I and $A_2(i)$ is the A_2 value for radionuclide I.

(C) Alternatively, an A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity of nuclide I in the mixture and $A_1(i)$ is the appropriate A_1 value for nuclide I.

(D) An A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of nuclide I in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide I.

(E) The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity concentration of radionuclide I in the mixture, and [A] is the activity concentration for exempt material containing radionuclide I.

(F) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide I in the mixture, and A is the activity limit for exempt consignments for radionuclide I.

(5) Determination when activities of some of the radionuclides are not known. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph (4) of this subsection. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

(6) A_1 and A_2 values for radionuclides. The following Table 257-3 contains A_1 and A_2 values for radionuclides:

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Table 257-3

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ac-225 (a)	Actinium (89)	$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.1X10^{3}$	$5.8X10^{4}$
Ac-227 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	2.7	$7.2X10^{1}$
Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Ag-108m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.7X10^{-1}$	$2.6X10^{1}$
Ag-110m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.8X10^{2}$	$4.7X10^{3}$
Ag-111		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	2.7	$1.0X10^{-1}$	2.7	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	3.4
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		5.0	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	1.3	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.5X10^{6}$	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$
As-74		1.0	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.8X10^{4}$	$1.6X10^{6}$
As-77		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.9X10^{4}$	$1.0X10^{6}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
At-211 (a)	Astatine (85)	$2.0X10^1$	$5.4X10^2$	$5.0X10^{-1}$	$1.4X10^1$	$7.6X10^4$	$2.1X10^6$
Au-193	Gold (79)	7.0	$1.9X10^2$	2.0	$5.4X10^1$	$3.4X10^4$	$9.2X10^5$
Au-194		1.0	$2.7X10^1$	1.0	$2.7X10^1$	$1.5X10^4$	$4.1X10^5$
Au-195		$1.0X10^1$	$2.7X10^2$	6.0	$1.6X10^2$	$1.4X10^2$	$3.7X10^3$
Au-198		1.0	$2.7X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$9.0X10^3$	$2.4X10^5$
Au-199		$1.0X10^1$	$2.7X10^2$	$6.0X10^{-1}$	$1.6X10^1$	$7.7X10^3$	$2.1X10^5$
Ba-131 (a)	Barium (56)	2.0	$5.4X10^1$	2.0	$5.4X10^1$	$3.1X10^3$	$8.4X10^4$
Ba-133		3.0	$8.1X10^1$	3.0	$8.1X10^1$	9.4	$2.6X10^2$
Ba-133m		$2.0X10^1$	$5.4X10^2$	$6.0X10^{-1}$	$1.6X10^1$	$2.2X10^4$	$6.1X10^5$
Ba-140 (a)		$5.0X10^{-1}$	$1.4X10^1$	$3.0X10^{-1}$	8.1	$2.7X10^3$	$7.3X10^4$
Be-7	Beryllium (4)	$2.0X10^1$	$5.4X10^2$	$2.0X10^1$	$5.4X10^2$	$1.3X10^4$	$3.5X10^5$
Be-10		$4.0X10^1$	$1.1X10^3$	$6.0X10^{-1}$	$1.6X10^1$	$8.3X10^{-4}$	$2.2X10^{-2}$
Bi-205	Bismuth (83)	$7.0X10^{-1}$	$1.9X10^1$	$7.0X10^{-1}$	$1.9X10^1$	$1.5X10^3$	$4.2X10^4$
Bi-206		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.8X10^3$	$1.0X10^5$
Bi-207		$7.0X10^{-1}$	$1.9X10^1$	$7.0X10^{-1}$	$1.9X10^1$	1.9	$5.2X10^1$
Bi-210		1.0	$2.7X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$4.6X10^3$	$1.2X10^5$
Bi-210m (a)		$6.0X10^{-1}$	$1.6X10^1$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.1X10^{-5}$	$5.7X10^{-4}$
Bi-212 (a)		$7.0X10^{-1}$	$1.9X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$5.4X10^5$	$1.5X10^7$
Bk-247	Berkelium (97)	8.0	$2.2X10^2$	$8.0X10^{-4}$	$2.2X10^{-2}$	$3.8X10^{-2}$	1.0
Bk-249 (a)		$4.0X10^1$	$1.1X10^3$	$3.0X10^{-1}$	8.1	$6.1X10^1$	$1.6X10^3$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Br-76	Bromine (35)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$9.4X10^{4}$	$2.5X10^{6}$
Br-77		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$2.6X10^{4}$	$7.1X10^{5}$
Br-82		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{4}$	$1.1X10^{6}$
C-11	Carbon (6)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.1X10^{7}$	$8.4X10^{8}$
C-14		$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{-1}$	4.5
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	$3.1X10^{-3}$	$8.5X10^{-2}$
Ca-45		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Ca-47 (a)		3.0	$8.1X10^{1}$	$3.0X10^{-1}$	8.1	$2.3X10^{4}$	$6.1X10^{5}$
Cd-109	Cadmium (48)	$3.0X10^{1}$	$8.1X10^{2}$	2.0	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$
Cd-113m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	8.3	$2.2X10^{2}$
Cd-115 (a)		3.0	$8.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.9X10^{4}$	$5.1X10^{5}$
Cd-115m		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.4X10^{2}$	$2.5X10^{4}$
Ce-139	Cerium (58)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$2.5X10^{2}$	$6.8X10^{3}$
Ce-141		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.8X10^{4}$
Ce-143		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.6X10^{5}$
Ce-144 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.2X10^{3}$
Cf-248	Californium (98)	$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$5.8X10^{1}$	$1.6X10^{3}$
Cf-249		3.0	$8.1X10^{1}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$1.5X10^{-1}$	4.1
Cf-250		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	4.0	$1.1X10^{2}$
Cf-251		7.0	$1.9X10^{2}$	$7.0X10^{-4}$	$1.9X10^{-2}$	$5.9X10^{-2}$	1.6

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Cf-252 (h)		$5.0X10^{-2}$	1.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.4X10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	1.1	$1.1X10^{3}$	$2.9X10^{4}$
Cf-254		$1.0X10^{-3}$	$2.7X10^{-2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.1X10^{2}$	$8.5X10^{3}$
Cl-36	Chlorine (17)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{-3}$	$3.3X10^{-2}$
Cl-38		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$4.9X10^{6}$	$1.3X10^{8}$
Cm-240	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$7.5X10^{2}$	$2.0X10^{4}$
Cm-241		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$6.1X10^{2}$	$1.7X10^{4}$
Cm-242		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$1.2X10^{2}$	$3.3X10^{3}$
Cm-243		9.0	$2.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.9X10^{-3}$	$5.2X10^{1}$
Cm-244		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	3.0	$8.1X10^{1}$
Cm-245		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$6.4X10^{-3}$	$1.7X10^{-1}$
Cm-246		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$1.1X10^{-2}$	$3.1X10^{-1}$
Cm-247 (a)		3.0	$8.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.4X10^{-6}$	$9.3X10^{-5}$
Cm-248		$2.0X10^{-2}$	$5.4X10^{-1}$	$3.0X10^{-4}$	$8.1X10^{-3}$	$1.6X10^{-4}$	$4.2X10^{-3}$
Co-55	Cobalt (27)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Co-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{3}$	$3.0X10^{4}$
Co-57		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$3.1X10^{2}$	$8.4X10^{3}$
Co-58		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Co-58m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.2X10^{5}$	$5.9X10^{6}$
Co-60		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.2X10^{1}$	$1.1X10^{3}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Cr-51	Chromium (24)	$3.0X10^1$	$8.1X10^2$	$3.0X10^1$	$8.1X10^2$	$3.4X10^3$	$9.2X10^4$
Cs-129	Cesium (55)	4.0	$1.1X10^2$	4.0	$1.1X10^2$	$2.8X10^4$	$7.6X10^5$
Cs-131		$3.0X10^1$	$8.1X10^2$	$3.0X10^1$	$8.1X10^2$	$3.8X10^3$	$1.0X10^5$
Cs-132		1.0	$2.7X10^1$	1.0	$2.7X10^1$	$5.7X10^3$	$1.5X10^5$
Cs-134		$7.0X10^{-1}$	$1.9X10^1$	$7.0X10^{-1}$	$1.9X10^1$	$4.8X10^1$	$1.3X10^3$
Cs-134m		$4.0X10^1$	$1.1X10^3$	$6.0X10^{-1}$	$1.6X10^1$	$3.0X10^5$	$8.0X10^6$
Cs-135		$4.0X10^1$	$1.1X10^3$	1.0	$2.7X10^1$	$4.3X10^{-5}$	$1.2X10^{-3}$
Cs-136		$5.0X10^{-1}$	$1.4X10^1$	$5.0X10^{-1}$	$1.4X10^1$	$2.7X10^3$	$7.3X10^4$
Cs-137 (a)		2.0	$5.4X10^1$	$6.0X10^{-1}$	$1.6X10^1$	3.2	$8.7X10^1$
Cu-64	Copper (29)	6.0	$1.6X10^2$	1.0	$2.7X10^1$	$1.4X10^5$	$3.9X10^6$
Cu-67		$1.0X10^1$	$2.7X10^2$	$7.0X10^{-1}$	$1.9X10^1$	$2.8X10^4$	$7.6X10^5$
Dy-159	Dysprosium (66)	$2.0X10^1$	$5.4X10^2$	$2.0X10^1$	$5.4X10^2$	$2.1X10^2$	$5.7X10^3$
Dy-165		$9.0X10^{-1}$	$2.4X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$3.0X10^5$	$8.2X10^6$
Dy-166 (a)		$9.0X10^{-1}$	$2.4X10^1$	$3.0X10^{-1}$	8.1	$8.6X10^3$	$2.3X10^5$
Er-169	Erbium (68)	$4.0X10^1$	$1.1X10^3$	1.0	$2.7X10^1$	$3.1X10^3$	$8.3X10^4$
Er-171		$8.0X10^{-1}$	$2.2X10^1$	$5.0X10^{-1}$	$1.4X10^1$	$9.0X10^4$	$2.4X10^6$
Eu-147	Europium (63)	2.0	$5.4X10^1$	2.0	$5.4X10^1$	$1.4X10^3$	$3.7X10^4$
Eu-148		$5.0X10^{-1}$	$1.4X10^1$	$5.0X10^{-1}$	$1.4X10^1$	$6.0X10^2$	$1.6X10^4$
Eu-149		$2.0X10^1$	$5.4X10^2$	$2.0X10^1$	$5.4X10^2$	$3.5X10^2$	$9.4X10^3$
Eu-150 (short lived)		2.0	$5.4X10^1$	$7.0X10^{-1}$	$1.9X10^1$	$6.1X10^4$	$1.6X10^6$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Eu-150 (long lived)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-152		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	6.5	$1.8X10^{2}$
Eu-152m		$8.0X10^{-1}$	$2.2X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$8.2X10^{4}$	$2.2X10^{6}$
Eu-154		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	9.8	$2.6X10^{2}$
Eu-155		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$1.8X10^{1}$	$4.9X10^{2}$
Eu-156		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{3}$	$5.5X10^{4}$
F-18	Fluorine (9)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.5X10^{6}$	$9.5X10^{7}$
Fe-52 (a)	Iron (26)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.7X10^{5}$	$7.3X10^{6}$
Fe-55		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.8X10^{1}$	$2.4X10^{3}$
Fe-59		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$1.8X10^{3}$	$5.0X10^{4}$
Fe-60 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-1}$	5.4	$7.4X10^{-4}$	$2.0X10^{-2}$
Ga-67	Gallium (31)	7.0	$1.9X10^{2}$	3.0	$8.1X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Ga-68		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.5X10^{6}$	$4.1X10^{7}$
Ga-72		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Gd-146 (a)	Gadolinium (64)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Gd-148		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	1.2	$3.2X10^{1}$
Gd-153		$1.0X10^{1}$	$2.7X10^{2}$	9.0	$2.4X10^{2}$	$1.3X10^{2}$	$3.5X10^{3}$
Gd-159		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.9X10^{4}$	$1.1X10^{6}$
Ge-68 (a)	Germanium (32)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.6X10^{2}$	$7.1X10^{3}$
Ge-71		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.8X10^{3}$	$1.6X10^{5}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ge-77		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Hf-172 (a)	Hafnium (72)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Hf-175		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$3.9X10^{2}$	$1.1X10^{4}$
Hf-181		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.3X10^{2}$	$1.7X10^{4}$
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-6}$	$2.2X10^{-4}$
Hg-194 (a)	Mercury (80)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.3X10^{-1}$	3.5
Hg-195m (a)		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Hg-197		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.2X10^{3}$	$2.5X10^{5}$
Hg-197m		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.5X10^{4}$	$6.7X10^{5}$
Hg-203		5.0	$1.4X10^{2}$	1.0	$2.7X10^{1}$	$5.1X10^{2}$	$1.4X10^{4}$
Ho-166	Holmium (67)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
Ho-166m		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.6X10^{-2}$	1.8
I-123	Iodine (53)	6.0	$1.6X10^{2}$	3.0	$8.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$
I-124		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$9.3X10^{3}$	$2.5X10^{5}$
I-125		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$6.4X10^{2}$	$1.7X10^{4}$
I-126		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{3}$	$8.0X10^{4}$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5X10^{-6}$	$1.8X10^{-4}$
I-131		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
I-132		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.8X10^{5}$	$1.0X10^{7}$
I-133		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
I-134		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$9.9X10^{5}$	$2.7X10^{7}$
I-135 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.3X10^{5}$	$3.5X10^{6}$
In-111	Indium (49)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.5X10^{4}$	$4.2X10^{5}$
In-113m		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$6.2X10^{5}$	$1.7X10^{7}$
In-114m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$
In-115m		7.0	$1.9X10^{2}$	1.0	$2.7X10^{1}$	$2.2X10^{5}$	$6.1X10^{6}$
Ir-189 (a)	Iridium (77)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.9X10^{3}$	$5.2X10^{4}$
Ir-190		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.3X10^{3}$	$6.2X10^{4}$
Ir-192 (c)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.4X10^{2}$	$9.2X10^{3}$
Ir-194		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$
K-42		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.2X10^{5}$	$6.0X10^{6}$
K-43		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Kr-81	Krypton (36)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$7.8X10^{-4}$	$2.1X10^{-2}$
Kr-85		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.5X10^{1}$	$3.9X10^{2}$
Kr-85m		8.0	$2.2X10^{2}$	3.0	$8.1X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Kr-87		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.0X10^{6}$	$2.8X10^{7}$
La-137	Lanthanum (57)	$3.0X10^{1}$	$8.1X10^{2}$	6.0	$1.6X10^{2}$	$1.6X10^{-3}$	$4.4X10^{-2}$
La-140		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.1X10^{4}$	$5.6X10^{5}$
Lu-172	Lutetium (71)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{3}$	$1.1X10^{5}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Lu-173		8.0	$2.2X10^2$	8.0	$2.2X10^2$	$5.6X10^1$	$1.5X10^3$
Lu-174		9.0	$2.4X10^2$	9.0	$2.4X10^2$	$2.3X10^1$	$6.2X10^2$
Lu-174m		$2.0X10^1$	$5.4X10^2$	$1.0X10^1$	$2.7X10^2$	$2.0X10^2$	$5.3X10^3$
Lu-177		$3.0X10^1$	$8.1X10^2$	$7.0X10^{-1}$	$1.9X10^1$	$4.1X10^3$	$1.1X10^5$
Mg-28 (a)	Magnesium (12)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^5$	$5.4X10^6$
Mn-52	Manganese (25)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.6X10^4$	$4.4X10^5$
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	$6.8X10^{-5}$	$1.8X10^{-3}$
Mn-54		1.0	$2.7X10^1$	1.0	$2.7X10^1$	$2.9X10^2$	$7.7X10^3$
Mn-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.0X10^5$	$2.2X10^7$
Mo-93	Molybdenum (42)	$4.0X10^1$	$1.1X10^3$	$2.0X10^1$	$5.4X10^2$	$4.1X10^{-2}$	1.1
Mo-99 (a) (i)		1.0	$2.7X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$1.8X10^4$	$4.8X10^5$
N-13	Nitrogen (7)	$9.0X10^{-1}$	$2.4X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$5.4X10^7$	$1.5X10^9$
Na-22	Sodium (11)	$5.0X10^{-1}$	$1.4X10^1$	$5.0X10^{-1}$	$1.4X10^1$	$2.3X10^2$	$6.3X10^3$
Na-24		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.2X10^5$	$8.7X10^6$
Nb-93m	Niobium (41)	$4.0X10^1$	$1.1X10^3$	$3.0X10^1$	$8.1X10^2$	8.8	$2.4X10^2$
Nb-94		$7.0X10^{-1}$	$1.9X10^1$	$7.0X10^{-1}$	$1.9X10^1$	$6.9X10^{-3}$	$1.9X10^{-1}$
Nb-95		1.0	$2.7X10^1$	1.0	$2.7X10^1$	$1.5X10^3$	$3.9X10^4$
Nb-97		$9.0X10^{-1}$	$2.4X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$9.9X10^5$	$2.7X10^7$
Nd-147	Neodymium (60)	6.0	$1.6X10^2$	$6.0X10^{-1}$	$1.6X10^1$	$3.0X10^3$	$8.1X10^4$
Nd-149		$6.0X10^{-1}$	$1.6X10^1$	$5.0X10^{-1}$	$1.4X10^1$	$4.5X10^5$	$1.2X10^7$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	$3.0X10^{-3}$	$8.0X10^{-2}$
Ni-63		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	2.1	$5.7X10^{1}$
Ni-65		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{5}$	$1.9X10^{7}$
Np-235	Neptunium (93)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.2X10^{1}$	$1.4X10^{3}$
Np-236 (short-lived)		$2.0X10^{1}$	$5.4X10^{2}$	2.0	$5.4X10^{1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-236 (long-lived)		$9.0X10^{0}$	$2.4X10^{2}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$2.6X10^{-5}$	$7.1X10^{-4}$
Np-239		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$8.6X10^{3}$	$2.3X10^{5}$
Os-185	Osmium (76)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.8X10^{2}$	$7.5X10^{3}$
Os-191		$1.0X10^{1}$	$2.7X10^{2}$	2.0	$5.4X10^{1}$	$1.6X10^{3}$	$4.4X10^{4}$
Os-191m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.6X10^{4}$	$1.3X10^{6}$
Os-193		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$
Os-194 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{1}$	$3.1X10^{2}$
P-32	Phosphorus (15)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{4}$	$2.9X10^{5}$
P-33		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pa-230 (a)	Protactinium (91)	2.0	$5.4X10^{1}$	$7.0X10^{-2}$	1.9	$1.2X10^{3}$	$3.3X10^{4}$
Pa-231		4.0	$1.1X10^{2}$	$4.0X10^{-4}$	$1.1X10^{-2}$	$1.7X10^{-3}$	$4.7X10^{-2}$
Pa-233		5.0	$1.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.7X10^{2}$	$2.1X10^{4}$
Pb-201	Lead (82)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.2X10^{4}$	$1.7X10^{6}$
Pb-202		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.2X10^{-4}$	$3.4X10^{-3}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Pb-203		4.0	$1.1X10^2$	3.0	$8.1X10^1$	$1.1X10^4$	$3.0X10^5$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5X10^{-6}$	$1.2X10^{-4}$
Pb-210 (a)		1.0	$2.7X10^1$	$5.0X10^{-2}$	1.4	2.8	$7.6X10^1$
Pb-212 (a)		$7.0X10^{-1}$	$1.9X10^1$	$2.0X10^{-1}$	5.4	$5.1X10^4$	$1.4X10^6$
Pd-103 (a)	Palladium (46)	$4.0X10^1$	$1.1X10^3$	$4.0X10^1$	$1.1X10^3$	$2.8X10^3$	$7.5X10^4$
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9X10^{-5}$	$5.1X10^{-4}$
Pd-109		2.0	$5.4X10^1$	$5.0X10^{-1}$	$1.4X10^1$	$7.9X10^4$	$2.1X10^6$
Pm-143	Promethium (61)	3.0	$8.1X10^1$	3.0	$8.1X10^1$	$1.3X10^2$	$3.4X10^3$
Pm-144		$7.0X10^{-1}$	$1.9X10^1$	$7.0X10^{-1}$	$1.9X10^1$	$9.2X10^1$	$2.5X10^3$
Pm-145		$3.0X10^1$	$8.1X10^2$	$1.0X10^1$	$2.7X10^2$	5.2	$1.4X10^2$
Pm-147		$4.0X10^1$	$1.1X10^3$	2.0	$5.4X10^1$	$3.4X10^1$	$9.3X10^2$
Pm-148m (a)		$8.0X10^{-1}$	$2.2X10^1$	$7.0X10^{-1}$	$1.9X10^1$	$7.9X10^2$	$2.1X10^4$
Pm-149		2.0	$5.4X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$1.5X10^4$	$4.0X10^5$
Pm-151		2.0	$5.4X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$2.7X10^4$	$7.3X10^5$
Po-210	Polonium (84)	$4.0X10^1$	$1.1X10^3$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.7X10^2$	$4.5X10^3$
Pr-142	Praseodymium (59)	$4.0X10^{-1}$	$1.1X10^1$	$4.0X10^{-1}$	$1.1X10^1$	$4.3X10^4$	$1.2X10^6$
Pr-143		3.0	$8.1X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$2.5X10^3$	$6.7X10^4$
Pt-188 (a)	Platinum (78)	1.0	$2.7X10^1$	$8.0X10^{-1}$	$2.2X10^1$	$2.5X10^3$	$6.8X10^4$
Pt-191		4.0	$1.1X10^2$	3.0	$8.1X10^1$	$8.7X10^3$	$2.4X10^5$
Pt-193		$4.0X10^1$	$1.1X10^3$	$4.0X10^1$	$1.1X10^3$	1.4	$3.7X10^1$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Pt-193m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pt-195m		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.2X10^{3}$	$1.7X10^{5}$
Pt-197		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{4}$	$8.7X10^{5}$
Pt-197m		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.7X10^{5}$	$1.0X10^{7}$
Pu-236	Plutonium (94)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.3X10^{2}$
Pu-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.5X10^{2}$	$1.2X10^{4}$
Pu-238		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.3X10^{-1}$	$1.7X10^{1}$
Pu-239		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$2.3X10^{-3}$	$6.2X10^{-2}$
Pu-240		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.4X10^{-3}$	$2.3X10^{-1}$
Pu-241 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-2}$	1.6	3.8	$1.0X10^{2}$
Pu-242		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.5X10^{-4}$	$3.9X10^{-3}$
Pu-244 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.7X10^{-7}$	$1.8X10^{-5}$
Ra-223 (a)	Radium (88)	$4.0X10^{-1}$	$1.1X10^{1}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$1.9X10^{3}$	$5.1X10^{4}$
Ra-224 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$5.9X10^{3}$	$1.6X10^{5}$
Ra-225 (a)		$2.0X10^{-1}$	5.4	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.5X10^{3}$	$3.9X10^{4}$
Ra-226 (a)		$2.0X10^{-1}$	5.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$3.7X10^{-2}$	1.0
Ra-228 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.0X10^{1}$	$2.7X10^{2}$
Rb-81	Rubidium (37)	2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{5}$	$8.4X10^{6}$
Rb-83 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$6.8X10^{2}$	$1.8X10^{4}$
Rb-84		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2X10^{-9}$	$8.6X10^{-8}$
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7X10^{6}$	$1.8X10^{8}$
Re-184	Rhenium (75)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Re-184m		3.0	$8.1X10^{1}$	1.0	$2.7X10^{1}$	$1.6X10^{2}$	$4.3X10^{3}$
Re-186		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.9X10^{3}$	$1.9X10^{5}$
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4X10^{-9}$	$3.8X10^{-8}$
Re-188		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.6X10^{4}$	$9.8X10^{5}$
Re-189 (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.8X10^{5}$
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	$2.4X10^{-8}$
Rh-99	Rhodium (45)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Rh-101		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Rh-102		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{1}$	$1.2X10^{3}$
Rh-102m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Rh-103m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.2X10^{6}$	$3.3X10^{7}$
Rh-105		$1.0X10^{1}$	$2.7X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{4}$	$8.4X10^{5}$
Rn-222 (a)	Radon (86)	$3.0X10^{-1}$	8.1	$4.0X10^{-3}$	$1.1X10^{-1}$	$5.7X10^{3}$	$1.5X10^{5}$
Ru-97	Ruthenium (44)	5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.7X10^{4}$	$4.6X10^{5}$
Ru-103 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Ru-105		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{5}$	$6.7X10^{6}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ru-106 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.3X10^{3}$
S-35	Sulfur (16)	$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{3}$	$4.3X10^{4}$
Sb-122	Antimony (51)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Sb-124		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.5X10^{2}$	$1.7X10^{4}$
Sb-125		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$3.9X10^{1}$	$1.0X10^{3}$
Sb-126		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Sc-44	Scandium (21)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.7X10^{5}$	$1.8X10^{7}$
Sc-46		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.3X10^{3}$	$3.4X10^{4}$
Sc-47		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.1X10^{4}$	$8.3X10^{5}$
Sc-48		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.5X10^{4}$	$1.5X10^{6}$
Se-75	Selenium (34)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	3.9	$1.1X10^{2}$
Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-1}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		9.0	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Sn-119m		$4.0X10^1$	$1.1X10^3$	$3.0X10^1$	$8.1X10^2$	$1.4X10^2$	$3.7X10^3$
Sn-121m (a)		$4.0X10^1$	$1.1X10^3$	$9.0X10^{-1}$	$2.4X10^1$	2.0	$5.4X10^1$
Sn-123		$8.0X10^{-1}$	$2.2X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$3.0X10^2$	$8.2X10^3$
Sn-125		$4.0X10^{-1}$	$1.1X10^1$	$4.0X10^{-1}$	$1.1X10^1$	$4.0X10^3$	$1.1X10^5$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^1$	$4.0X10^{-1}$	$1.1X10^1$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.3X10^3$	$6.2X10^4$
Sr-85		2.0	$5.4X10^1$	2.0	$5.4X10^1$	$8.8X10^2$	$2.4X10^4$
Sr-85m		5.0	$1.4X10^2$	5.0	$1.4X10^2$	$1.2X10^6$	$3.3X10^7$
Sr-87m		3.0	$8.1X10^1$	3.0	$8.1X10^1$	$4.8X10^5$	$1.3X10^7$
Sr-89		$6.0X10^{-1}$	$1.6X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$1.1X10^3$	$2.9X10^4$
Sr-90 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	5.1	$1.4X10^2$
Sr-91 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^5$	$3.6X10^6$
Sr-92 (a)		1.0	$2.7X10^1$	$3.0X10^{-1}$	8.1	$4.7X10^5$	$1.3X10^7$
T(H-3)	Tritium (1)	$4.0X10^1$	$1.1X10^3$	$4.0X10^1$	$1.1X10^3$	$3.6X10^2$	$9.7X10^3$
Ta-178 (long-lived)	Tantalum (73)	1.0	$2.7X10^1$	$8.0X10^{-1}$	$2.2X10^1$	$4.2X10^6$	$1.1X10^8$
Ta-179		$3.0X10^1$	$8.1X10^2$	$3.0X10^1$	$8.1X10^2$	$4.1X10^1$	$1.1X10^3$
Ta-182		$9.0X10^{-1}$	$2.4X10^1$	$5.0X10^{-1}$	$1.4X10^1$	$2.3X10^2$	$6.2X10^3$
Tb-157	Terbium (65)	$4.0X10^1$	$1.1X10^3$	$4.0X10^1$	$1.1X10^3$	$5.6X10^{-1}$	$1.5X10^1$
Tb-158		1.0	$2.7X10^1$	1.0	$2.7X10^1$	$5.6X10^{-1}$	$1.5X10^1$
Tb-160		1.0	$2.7X10^1$	$6.0X10^{-1}$	$1.6X10^1$	$4.2X10^2$	$1.1X10^4$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Tc-95m (a)	Technetium (43)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$
Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		5.0	$1.4X10^{2}$	3.0	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		8.0	$2.2X10^{2}$	1.0	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m (a)		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$
Te-132 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Th-229		5.0	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.6X10^{2}$	$2.3X10^{4}$
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	6.4	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$
Tl-204		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.7X10^{1}$	$4.6X10^{2}$
Tm-167	Thulium (69)	7.0	$1.9X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{3}$	$8.5X10^{4}$
Tm-170		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{2}$	$6.0X10^{3}$
Tm-171		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$
U-230 (fast lung absorption) (a)(d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-1}$	2.7	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (medium lung absorption) (a)(e)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (slow lung absorption) (a)(f)		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$1.0X10^{3}$	$2.7X10^{4}$
U-232 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
U-232 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-233 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-234 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-235 (all lung absorption types) (a),(d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$8.0X10^{-8}$	$2.2X10^{-6}$
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (slow lung		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
absorption) (f)							
U-238 (all lung absorption types) (d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$1.2X10^{-8}$	$3.4X10^{-7}$
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6X10^{-8}$	$7.1X10^{-7}$
U (enriched to 20% or less) (g)		Unlimited	Unlimited	Unlimited	Unlimited	See Table 257-6	See Table 257-6
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	See Table 257-6	(See Table 257-5)
V-48	Vanadium (23)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$6.3X10^{3}$	$1.7X10^{5}$
V-49		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{2}$	$8.1X10^{3}$
W-178 (a)	Tungsten (74)	9.0	$2.4X10^{2}$	5.0	$1.4X10^{2}$	$1.3X10^{3}$	$3.4X10^{4}$
W-181		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.2X10^{2}$	$6.0X10^{3}$
W-185		$4.0X10^{1}$	$1.1X10^{3}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
W-187		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
W-188 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{-1}$	8.1	$3.7X10^{2}$	$1.0X10^{4}$
Xe-122 (a)	Xenon (54)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.8X10^{4}$	$1.3X10^{6}$
Xe-123		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.4X10^{5}$	$1.2X10^{7}$
Xe-127		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$1.0X10^{3}$	$2.8X10^{4}$
Xe-131m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$
Xe-133		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$6.9X10^{3}$	$1.9X10^{5}$
Xe-135		3.0	$8.1X10^{1}$	2.0	$5.4X10^{1}$	$9.5X10^{4}$	$2.6X10^{6}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Y-87 (a)	Yttrium (39)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.7X10^{4}$	$4.5X10^{5}$
Y-88		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$5.2X10^{2}$	$1.4X10^{4}$
Y-90		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{4}$	$5.4X10^{5}$
Y-91		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.1X10^{2}$	$2.5X10^{4}$
Y-91m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.5X10^{6}$	$4.2X10^{7}$
Y-92		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.6X10^{5}$	$9.6X10^{6}$
Y-93		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.2X10^{5}$	$3.3X10^{6}$
Yb-169	Ytterbium (70)	4.0	$1.1X10^{2}$	1.0	$2.7X10^{1}$	$8.9X10^{2}$	$2.4X10^{4}$
Yb-175		$3.0X10^{1}$	$8.1X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.6X10^{3}$	$1.8X10^{5}$
Zn-65	Zinc (30)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Zn-69		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{6}$	$4.9X10^{7}$
Zn-69m (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Zr-88	Zirconium (40)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	$9.3X10^{-5}$	$2.5X10^{-3}$
Zr-95 (a)		2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Zr-97 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

[a] A_1 and/or A_2 values include contributions from daughter nuclides with half-lives less than 10 days.
[b] The values of A_1 and A_2 in Curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq), (subsection (ff)(1) of this section - Determination of A_1 and A_2, Section I.).

[c] The quantity may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.
[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.
[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.
[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.
[g] These values apply to unirradiated uranium only.
[h] A_1 = 0.1 TBq (2.7 Ci) and A_2 = 0.001 TBq (0.027 Ci) for Cf-252 for domestic use.
[i] A_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

(7) Exempt material activity concentrations and exempt consignment activity limits for radionuclides. The following Table 257-4 contains exempt material activity concentrations and exempt consignment activity limits for radionuclides:

Table 257-4

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ac-225	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ac-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-105	Silver (47)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-108m (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-110m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-111		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Al-26	Aluminum (13)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Am-241	Americium (95)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ar-37	Argon (18)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ar-39		$1.0X10^{7}$	$2.7X10^{-4}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ar-41		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
As-72	Arsenic (33)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-73		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
As-74		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
As-76		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-77		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
At-211	Astatine (85)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-193	Gold (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-194		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-195		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-198		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-199		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-131	Barium (56)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-140 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Be-7	Beryllium (4)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Be-10		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-205	Bismuth (83)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-206		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-207		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Bi-210m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bk-247	Berkelium (97)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Bk-249		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-76	Bromine (35)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Br-77		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-82		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-11	Carbon (6)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-14		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-41	Calcium (20)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-45		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-47		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-109	Cadmium (48)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-113m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-139	Cerium (58)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-141		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ce-143		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ce-144 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-248	Californium (98)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-249		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-250		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-251		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-252		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-253		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-254		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cl-36	Chlorine (17)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cl-38		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-240	Curium (96)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cm-242		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-243		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-244		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-245		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-246		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-247		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-248		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Co-55	Cobalt (27)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Co-57		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Co-60		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cr-51	Chromium (24)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-129	Cesium (55)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-131		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cs-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cs-134m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-135		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-136		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-137 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cu-64	Copper (29)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cu-67		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-159	Dysprosium (66)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Dy-165		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Dy-166		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Er-169	Erbium (68)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Er-171		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-147	Europium (63)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-150 (short lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-150 (long lived)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-154		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-155		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-156		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
F-18	Fluorine (9)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-52	Iron (26)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-55		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-59		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-60		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-67	Gallium (31)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ga-68		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-72		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Gd-146	Gadolinium (64)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Gd-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Gd-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Gd-159		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ge-68	Germanium (32)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ge-71		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ge-77		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Hf-172	Hafnium (72)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-175		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-181		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-182		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-194	Mercury (80)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-197		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Hg-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166	Holmium (67)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ho-166m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-123	Iodine (53)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
I-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-125		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-126		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-131		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-133		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-135		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-111	Indium (49)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-113m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-114m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189	Iridium (77)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ir-190		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-192		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ir-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
K-40	Potassium (19)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-42		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-43		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Kr-81	Krypton (36)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Kr-85		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{4}$	$2.7X10^{-7}$
Kr-85m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Kr-87		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
La-137	Lanthanum (57)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
La-140		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Lu-172	Lutetium (71)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Lu-173		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-177		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Mg-28	Magnesium (12)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-52	Manganese (25)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-53		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{9}$	$2.7X10^{-2}$
Mn-54		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Mn-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Mo-93	Molybdenum (42)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Mo-99		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
N-13	Nitrogen (7)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Na-22	Sodium (11)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Na-24		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Nb-93m	Niobium (41)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Nb-94		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-97		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-147	Neodymium (60)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ni-59	Nickel (28)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-63		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-65		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Np-235	Neptunium (93)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (long-lived)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Np-237 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Np-239		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Os-185	Osmium (76)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-191m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-193		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-32	Phosphorus (15)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-33		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pa-230	Protactinium (91)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pa-231		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pa-233		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-201	Lead (82)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-202		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-205		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-210 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pb-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pd-103	Palladium (46)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-107		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-109		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Pm-143	Promethium (61)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-144		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-145		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-147		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-148m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-149		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-151		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Po-210	Polonium (84)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pr-142	Praseodymium (59)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pr-143		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-188	Platinum (78)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-193		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-193m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pu-236	Plutonium (94)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-237		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Pu-238		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-239		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-240		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pu-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pu-242		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-244		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-223 (b)	Radium (88)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-224 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-225		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-226 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-228 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-81	Rubidium (37)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-83		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-84		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-86		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-87		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rb(nat)		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Re-184	Rhenium (75)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-184m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Re-186		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-187		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Re-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Re-189		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re(nat)		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Rh-99	Rhodium (45)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-101		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rh-102		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-102m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-103m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Rh-105		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rn-222 (b)	Radon (86)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ru-97	Ruthenium (44)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ru-103		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-105		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-106 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
S-35	Sulfur (16)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sb-122	Antimony (51)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sb-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Sb-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-44	Scandium (21)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-46		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-47		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-48		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Se-75	Selenium (34)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Se-79		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Si-31	Silicon (14)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Si-32		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sm-145	Samarium (62)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sm-147		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sm-151		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sm-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-113	Tin (50)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-117m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-119m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-121m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-123		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Sn-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sn-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-82	Strontium (38)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-85		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-85m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sr-87m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-89		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-90 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sr-91		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-92		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
T(H-3)	Tritium (1)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Ta-178 (long-lived)	Tantalum (73)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ta-179		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ta-182		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tb-157	Terbium (65)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tb-158		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tb-160		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-95m	Technetium (43)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Tc-96m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-97		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Tc-97m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-98		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-99		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-99m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-121	Tellurium (52)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-121m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Te-123m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-125m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-127m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-129m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-131m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-132		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-229 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Th-230		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-231		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-232		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-234 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Th (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ti-44	Titanium (22)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Tl-200	Thallium (81)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-201		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-202		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-204		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tm-167	Thulium (69)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-170		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-171		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
U-230 (fast lung absorption) (b),(d)	Uranium (92)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-230 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-230 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (fast lung		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
absorption) (b),(d)					
U-232 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-233 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-234 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-235 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (medium lung		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
absorption) (e)					
U-236 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-238 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (enriched to 20% or less) (g)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (dep)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
V-48	Vanadium (23)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
V-49		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-178	Tungsten (74)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-181		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-185		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-187		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-122	Xenon (54)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-123		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Xe-131m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-133		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-135		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Y-87	Yttrium (39)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-88		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-90		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-91		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-91m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-92		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-93		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Yb-169	Ytterbium (70)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Yb-175		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zn-65	Zinc (30)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-88	Zirconium (40)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-93 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zr-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-97 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

[a][Reserved]
[b] Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-20
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242

Am-243 Np-239

[c][Reserved]

[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

[g] These values apply to unirradiated uranium only.

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(8) General values for A_1 and A_2. The following Table 257-5 contains general values for A_1 and A_2:

Table 257-5: General Values For A_1 And A_2

Contents	A_1		A_2		Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consignments (Bq)	Activity limits for exempt consignments (Ci)
	(TBq)	(Ci)	(TBq)	(Ci)				
Only beta or gamma emitting radionuclides are known to be present	1×10^{-1}	2.7×10^{0}	2×10^{-2}	5.4×10^{-1}	1×10^{1}	2.7×10^{-10}	1×10^{4}	2.7×10^{-7}
Only alpha emitting radionuclides are known to be present	2×10^{-1}	5.4×10^{0}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}
No relevant data are available	1×10^{-3}	2.7×10^{-2}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}

(9) Activity-mass relationships for uranium. The following Table 257-6 contains activity-mass relationships for uranium:

Table 257-6: Activity-mass Relationships for Uranium

Uranium Enrichment* wt % U-235 present	Specific Activity TBq/g	Specific Activity Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72	2.6×10^{-8}	7.1×10^{-7}
1.0	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5.0	1.0×10^{-7}	2.7×10^{-6}
10.0	1.8×10^{-7}	4.8×10^{-6}
20.0	3.7×10^{-7}	1.0×10^{-5}
35.0	7.4×10^{-7}	2.0×10^{-5}
50.0	9.3×10^{-7}	2.5×10^{-5}
90.0	2.2×10^{-6}	5.8×10^{-5}
93.0	2.6×10^{-6}	7.0×10^{-5}
95.0	3.4×10^{-6}	9.1×10^{-5}

(ff) Appendices for the requirements for transfers of LLRW intended for disposal at licensed land disposal facilities and manifests.

(1) Manifest. A waste generator, collector, or processor who transports, or offers for transportation, LLRW intended for ultimate disposal at a licensed LLRW land disposal facility shall prepare a manifest reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)) or their equivalent. NRC Forms 540 and 540A shall be completed and shall physically accompany the pertinent LLRW shipment. Upon agreement between shipper and consignee, NRC Forms 541, 541A, and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by the agency to comply with the manifesting requirements of this section when they ship:

(A) LLRW for processing and expect its return (i.e., for storage in accordance with their license) prior to disposal at a licensed land disposal facility;

(B) LLRW that is being returned to the licensee who is the waste generator or generator, as defined in this section; or

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* The figures for uranium include representative values for the activity of the uranium-235 which is concentrated during the enrichment process.

(C) radioactively contaminated material to a waste processor that becomes the processor's residual waste.

(2) Form instructions. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this subsection may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

(3) Forms. NRC Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, may be obtained from the NRC at www.nrc.gov/reading-rm/doc-collections/forms/#NRC.

(4) Information requirements of the DOT. This subsection includes information requirements of the DOT, as codified in Title 49, CFR, Part 172. Information on hazardous, medical, or other waste, required to meet EPA regulations, as codified in Title 40, CFR, Parts 259 and 261 or elsewhere, is not addressed in this section, and shall be provided on the required EPA forms. However, the required EPA forms shall accompany the uniform manifest required by this section.

(5) General information. The shipper of the LLRW, shall provide the following information on the uniform manifest:

(A) the name, facility address, and telephone number of the licensee shipping the waste;

(B) an explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

(C) the name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

(6) Shipment information. The shipper of the LLRW shall provide the following information regarding the waste shipment on the uniform manifest:

(A) the date of the waste shipment;

(B) the total number of packages/disposal containers;

(C) the total disposal volume and disposal weight in the shipment;

(D) the total radionuclide activity in the shipment;

(E) the activity of each of the radionuclides hydrogen-3, carbon-14, technetium-99, and iodine-129 contained in the shipment; and

(F) the total masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

(7) Disposal container and waste information. The shipper of the LLRW shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

(A) an alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

(B) a physical description of the disposal container, including the manufacturer and model of any high integrity container;

(C) the volume displaced by the disposal container;

(D) the gross weight of the disposal container, including the waste;

(E) for waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

(F) a physical and chemical description of the waste;

(G) the total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(H) the approximate volume of waste within a container;

(I) the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

(J) the identities and activities of individual radionuclides contained in each container, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

(K) the total radioactivity within each container; and

(L) for wastes consigned to a disposal facility, the classification of the waste in accordance with §289.202(ggg)(4)(A) of this title. Waste not meeting the structural stability requirements of §289.202(ggg)(4)(B)(ii) of this title shall be identified.

(8) Uncontainerized waste information. The shipper of the LLRW shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

(A) the approximate volume and weight of the waste;

(B) a physical and chemical description of the waste;

(C) the total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

(D) for waste consigned to a disposal facility, the classification of the waste in accordance with §289.202(ggg)(4)(A) of this title. Waste not meeting the structural stability requirements of §289.202(ggg)(4)(B)(ii) of this title shall be identified;

(E) the identities and activities of individual radionuclides contained in the waste, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

(F) for wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

(9) Multi-generator disposal container information. This paragraph applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLRW resulting from a processor's activities may be attributable to one or more generators (including waste generators) as defined in this section). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

(A) For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

(B) For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(i) the volume of waste within the disposal container;

(ii) a physical and chemical description of the waste, including the solidification agent, if any;

(iii) the total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(iv) the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in §289.202(ggg)(4)(B)(ii) of this title; and

(v) radionuclide identities and activities contained in the waste, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

(10) Certification. An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the DOT and the agency. A collector in signing the certification is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

(11) Control and tracking.

(A) Any licensee who transfers LLRW to a land disposal facility or a licensed waste collector shall comply with the requirements in clauses (i) - (ix) of this subparagraph. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of clauses (iv) - (ix) of this subparagraph. A licensee shall:

(i) prepare all wastes so that the waste is classified according to §289.202(ggg)(4)(A) of this title and meets the waste characteristic requirements in §289.202(ggg)(4)(B) of this title;

(ii) label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with §289.202(ggg)(4)(A) of this title;

(iii) conduct a quality assurance program to assure compliance with §289.202(ggg)(4)(A) and (B) of this title;

(iv) prepare the uniform manifest as required by this subsection;

(v) forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

(I) receipt of the manifest precedes the LLRW shipment; and

(II) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclauses (I) and (II) of this clause are also acceptable;

(vi) include the uniform manifest with the shipment regardless of the option chosen in clause (v) of this subparagraph;

(vii) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(viii) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this title and §289.252 of this title; and

(ix) for any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this subsection, conduct an investigation in accordance with subparagraph (D) of this paragraph.

(B) Any waste collector licensee who handles only prepackaged waste shall:

(i) acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of the uniform manifest;

(ii) prepare a new uniform manifest to reflect consolidated shipments that meet the requirements of this subsection. The waste collector shall ensure that, for each container of waste in the shipment, the uniform manifest identifies the generator of that container of waste;

(iii) forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

(I) receipt of the uniform manifest precedes the LLRW shipment; or

(II) the uniform manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclauses (I) and (II) of this clause are also acceptable;

(iv) include the uniform manifest with the shipment regardless of the option chosen in clause (iii) of this subparagraph**;**

(v) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(vi) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this title and §289.252 of this title;

(vii) for any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in accordance with this clause, conduct an investigation in accordance with subparagraph (D) of this paragraph; and

(viii) notify the shipper and the agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance uniform manifest, unless notified by the shipper that the shipment has been cancelled.

(C) Any licensed waste processor who treats or repackages waste shall:

(i) acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of the uniform manifest;

(ii) prepare a new uniform manifest that meets the requirements of this subsection. Preparation of the new uniform manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in clause (i) of this subparagraph;

(iii) prepare all wastes so that the waste is classified according to §289.202(ggg)(4)(A) of this title and meets the waste characteristics requirements in §289.202(ggg)(4)(B) of this title;

(iv) label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with §289.202(ggg)(4)(A) and (C) of this title;

(v) conduct a quality assurance program to assure compliance with §289.202(ggg)(4)(A) and (B) of this title;

(vi) forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

(I) receipt of the uniform manifest precedes the LLRW shipment; or

(II) the uniform manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclause (I) of this clause and this subclause is also acceptable;

(vii) include the uniform manifest with the shipment regardless of the option chosen in clause (vi) of this subparagraph;

(viii) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(ix) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this title and §289.252 of this title;

(x) for any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in accordance with this clause, conduct an investigation in accordance with clause (v) of this subparagraph; and

(xi) notify the shipper and the agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance uniform manifest, unless notified by the shipper that the shipment has been cancelled.

(D) Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in accordance with this section shall undergo the following:

(i) be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

(ii) be traced and reported. The investigation shall include tracing the shipment and filing a report with the agency. Each licensee who conducts a trace investigation shall file a written report with the agency within two weeks of completion of the investigation.