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Side by Side Comparison of NRC's RAT's ID and Nebraska's Title 180

After 180 NAC was revised July 11, 2009

NOTE:

The right column "Nebraska" includes text from 180 NAC as written. Text is included for compatibility A, B, C and H&S. The text in the "Nebraska" column is what is in the draft that is in for review.

If the text is written similar to the NRC language "(NRC)" is written in the 180 NAC column.

If the text is written similar to the SSR language "(SSR)" is written in the 180 NAC column.

Additional comments are also written in the 180 NAC column concerning changes and differences.

The yellow highlighting show changes since September 2007.

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**National Source Tracking System Part 20**  
**(71 FR 65865; November 8, 2006) RATS ID 2006-3 Effective: February 6, 2007**  
**Date due for State adoption: January 31, 2009**

§20.100 3	Definition: Nationally tracked sources		B	<b>Added Definition:</b> Nationally tracked source means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E of this Part. 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.	180 NAC 1.002 No	<b>Nationally tracked source</b> means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix H of 180 NAC 4. 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. 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.
§20.220 7 (a)	Reports of transactions involving nationally tracked sources		B	<b>Added Section:</b> Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs (a) through (e) of this section for each type of	180 NAC 5-066 No	<b>4-066 REPORTS OF TRANSACTIONS INVOLVING NATIONALLY TRACKED SOURCES:</b> Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source must complete and submit a National Source Tracking Transaction Report as specified in 180 NAC 4-066.01 through 4-066.05 for each type of

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				<p>transaction.</p> <p>(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:</p> <ol style="list-style-type: none"> <li>(1) The name, address, and license number of the reporting licensee;</li> <li>(2) The name of the individual preparing the report;</li> <li>(3) The manufacturer, model, and serial number of the source;</li> <li>(4) The radioactive material in the source;</li> <li>(5) The initial source strength in becquerels (curies) at the time of manufacture; and</li> <li>(6) The manufacture date of the source.</li> </ol>		<p>transaction.</p> <p><u>4-066.01</u> Each licensee who manufactures a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:</p> <ol style="list-style-type: none"> <li>1. The name, address, and license number of the reporting licensee;</li> <li>2. The name of the individual preparing the report;</li> <li>3. The manufacturer, model, and serial number of the source;</li> <li>4. The radioactive material in the source;</li> <li>5. The initial source strength in becquerels (curies) at the time of manufacture; and</li> <li>6. The manufacture date of the source.</li> </ol>
§20.220 7 (b)	Reports of transactions involving nationally tracked sources		B	<p><b>Added Section:</b></p> <p>(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:</p> <ol style="list-style-type: none"> <li>(1) The name, address, and license number of the reporting licensee;</li> <li>(2) The name of the individual preparing the report;</li> <li>(3) The name and license number of the recipient facility and the shipping address;</li> <li>(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;</li> </ol>	180 NAC 4-066.02 No	<p><u>4-066.02</u> Each licensee that transfers a nationally tracked source to another person must complete and submit a National Source Tracking Transaction Report. The report must include the following information:</p> <ol style="list-style-type: none"> <li>1. The name, address, and license number of the reporting licensee;</li> <li>2. The name of the individual preparing the report;</li> <li>3. The name and license number of the recipient facility and the shipping address;</li> <li>4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely</li> </ol>

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				(5) The radioactive material in the source; (6) The initial or current source strength in becquerels (curies); (7) The date for which the source strength is reported; (8) The shipping date; (9) The estimated arrival date; and (10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source		identify the source; 5. The radioactive material in the source; 6. The initial or current source strength in becquerels (curies); 7. The date for which the source strength is reported; 8. The shipping date; 9. The estimated arrival date; and 10. For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.
§20.2207(c)	Reports of transactions involving nationally tracked sources		B	(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information: (1) The name, address, and license number of the reporting licensee; (2) The name of the individual preparing the report; (3) The name, address, and license number of the person that provided the source; (4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source; (5) The radioactive material in the source; (6) The initial or current source strength in becquerels (curies); (7) The date for which the source strength is reported;	180 NAC 4-066.03 No	4-066.03 Each licensee that receives a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information: 1. The name, address, and license number of the reporting licensee; 2. The name of the individual preparing the report; 3. The name, address, and license number of the person that provided the source; 4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source; 5. The radioactive material in the source; 6. The initial or current source strength in becquerels (curies);

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				8) The date of receipt; and 9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.		7. The date for which the source strength is reported; 8. The date of receipt, and 9. For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.
§20.220 7 (d)	Reports of transactions involving nationally tracked sources		B	<b>Added Section:</b> (d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information: (1) The name, address, and license number of the reporting licensee; (2) The name of the individual preparing the report; (3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source; (4) The radioactive material in the source; (5) The initial or current source strength in becquerels (curies); (6) The date for which the source strength is reported; (7) The disassemble date of the source.	180 NAC 4-066.04 No	<b>4-066.04</b> Each licensee that disassembles a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:  1. The name, address, and license number of the reporting licensee; 2. The name of the individual preparing the report; 3. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source; 4. The radioactive material in the source; 5. The initial or current source strength in becquerels (curies); 6. The date for which the source strength is reported; 7. The disassemble date of the source.
§20.220 7 (e)	Reports of transactions involving nationally tracked		B	<b>Added Section:</b> (e) Each Licensee who disposes of nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following	180 NAC 4-066.05 No	<b>4-066.05</b> Each licensee who disposes of a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

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	sources			information: (1) The name, address, and license number of the reporting licensee; (2) The name of the individual preparing the report; (3) The waste manifest number; (4) The container identification with the nationally tracked source; (5) The date of disposal; and (6) The method of disposal.		<ol style="list-style-type: none"> <li>1. The name, address, and license number of the reporting licensee;</li> <li>2. The name of the individual preparing the report;</li> <li>3. The waste manifest number;</li> <li>4. The container identification with the nationally tracked source;</li> <li>5. The date of disposal; and</li> <li>6. The method of disposal.</li> </ol>
§20.220.7(f)	Reports of transactions involving nationally tracked sources		B	<b>Added Section:</b> (f) The reports discussed in paragraphs (a) through (e) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using: (1) The on-line National Source Tracking System; (2) Electronically using a computer-readable format; (3) By facsimile; (4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or (5) By telephone with follow-up by facsimile or mail.	180 NAC 4-066.06 No	<p><u>4-066.06</u> The reports discussed in 180 NAC 4-066.01 through 4-066.05 must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:</p> <ol style="list-style-type: none"> <li>1. The on-line National Source Tracking System;</li> <li>2. Electronically using a computer readable format;</li> <li>3. By facsimile;</li> <li>4. By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or</li> <li>5. By telephone with followup by facsimile or mail.</li> </ol>
§20.220.7(g)	Reports of transactions involving nationally tracked		B	<b>Added Section:</b> (g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed	180 NAC 4-066.07 No	<p><u>4-066.07</u> Each licensee must correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such</p>

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	sources			transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (a) through (e) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.		errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee must reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified in 180 NAC 4-066.01 through 4-066.05. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.
§20.220 7 (h)	Reports of transactions involving nationally tracked sources		B	<b>Added Section:</b> (h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph (f)(1) through (f)(4) of this section. The initial inventory report must include the	180 NAC 4-066.06 No	<u>4-066.08</u> Each licensee that possesses Category 1 nationally tracked sources must report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources must report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified in 180 NAC 4-066.06, items 1 through 4. The initial inventory report must include the following information:

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				<p>following information:</p> <p>(1) The name, address, and license number of the reporting licensee;</p> <p>(2) The name of the individual preparing the report;</p> <p>(3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;</p> <p>(4) The radioactive material in the sealed source;</p> <p>(5) The initial or current source strength in becquerels (curies); and</p> <p>(6) The date for which the source strength is reported.</p>		<p>1. The name, address, and license number of the reporting licensee;</p> <p>2. The name of the individual preparing the report;</p> <p>3. The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;</p> <p>4. The radioactive material in the sealed source;</p> <p>5. The initial or current source strength in becquerels (curies); and</p> <p>6. The date for which the source strength is reported.</p>
20 Appendix E	Nationally tracked sources threshold		B	<p><b>Added Appendix:</b> See table at end of document</p>	180 NAC 4, Table 4H No	Table was added below to 180 NAC 4 as Appendix 4H

### Appendix E Part 20-Nationally Tracked Source Thresholds

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1600	0.6	16
Americium-241/Be	60	1600	0.6	16

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	Californium-252	20		540	0.2	5.4
	Cobalt-60	30		810	0.3	8.1
	Curium-244	50		1400	0.5	14
	Cesium-137	100		2700	1	27
	Gadolinium-153	1000		27000	10	270
	Iridium-192	80		2200	0.8	22
	Plutonium-238	60		1600	0.6	16
	Plutonium-239/Be	60		1600	0.6	16
	Polonium-210	60		1600	0.6	16
	Promethium-147	40000		1100000	400	11000
	Radium-226	40		1100	0.4	11
	Selenium-75	200		5400	2	54
	Strontium-90	1000		27000	10	270
	Thorium-228	20		540	0.2	5.4
	Thorium-229	20		540	0.2	5.4
	Thulium-170	20000		540000	200	5400
	Ytterbium-169	300		8100	3	81

**NEBRASKA's 180 NAC 4**

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**APPENDIX 4-H  
NATIONALLY TRACKED SOURCE THRESHOLDS**

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1.0	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

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**National Source Tracking System - Serialization Requirements**  
**(Part 32 with reference to Part 20 Appendix E)**  
**(71 FR 65685; November 8, 2006) RATS ID 2006-2 Effective 2/06/07**  
**Date due for State adoption: February 6, 2007**

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20 Appendix E	Nationally tracked sources threshold		B	<b>Added Appendix:</b> See table at end of document	180 NAC 4, Table 4H No	Table was added above to 180 NAC 4 as Appendix 4H
§32.2	Definitions -Nationally tracked sources		B	<b>Added Definition:</b> Nationally tracked source means a sealed source containing a quantity equal to or greater than Category 1 or 2 levels of any radioactive material listed in Appendix E to part 20 of this Chapter. 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.	180 NAC 1-002 No	<u>Nationally tracked source</u> means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix H of 180 NAC 4. 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. 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.

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**Minor Amendments- Part 20  
(71 FR 15005) RATS ID # 2006-1 Effective date 03/27/06  
Date Due For State Adoption 03/27/09**

20. Appendix B	<b>STANDARDS FOR PROTECTION AGAINST RADIATION</b>	No	A	In Appendix B to Part 20, "List of Elements," the Element "Thalium," Atomic Number 69, should be changed to read as "Thulium."	Appendix 4 B NO	Change was made
20. Appendix D	<b>STANDARDS FOR PROTECTION AGAINST RADIATION</b>	NA	D	N/A		

**Minor Amendments- Part 30  
(71 FR 15005) RATS ID # 2006-1 Effective date 03/27/06  
Date Due For State Adoption 03/27/09**

30.06	Communications		D	N/A		
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**Minor Amendments- Part 32  
(71 FR 15005) RATS ID # 2006-1 Effective date 03/27/06  
Date Due For State Adoption 03/27/09**

32.72	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.	No	B	In § 32.72, paragraph (b)(2)(ii) is revised to read as follows: (b) *** (2) *** (ii) This individual meets the requirements specified in 10 CFR 35.55(b) and 35.59 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or * ****	3-014.10, item 2.b.(2) (NRC)  NO	(2) This individual meets the requirements specified in 180 NAC 7-024.02 and 7-027 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or
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32.74	Manufacture and distribution of sources or devices containing byproduct material for medical use.		B	<b>In § 32.74, the introductory text of paragraph (a) is revised to read as follows:</b> (a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in §§ 35.400, 35.500, and 35.600 of this chapter will be approved if: * * * * *	<b>3-014.12 (NRC) NO</b>	<u>3-014.12. Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.</u> An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 180 NAC 7 for use as a calibration, <b>transmission</b> or reference source or for the uses listed in 180 NAC 7-055, 7-065 and 7-067 will be approved if:
35.2	<b>Definitions</b>		B B B F	<b>In § 35.2, paragraph (1) of the definitions for the terms “ Authorized medical physicist,” “Authorized nuclear pharmacist,” “Authorized user,” “Radiation Safety Officer” and for “Medical event” are revised to read as follows:</b> <i>Authorized medical physicist</i> means an individual who— (1) Meets the requirements in §§ 35.51(a) and 35.59; or * * * * * <i>Authorized nuclear pharmacist</i> means a pharmacist who—(1) Meets the requirements in §§ 35.55(a) and 35.59; or * * * * * <i>Authorized user</i> means a physician, dentist, or podiatrist who—(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or * * * * * <i>Radiation Safety Officer</i> means an individual who— (1) Meets the requirements in §§ 35.50(a) or (c)(1) and 35.59; or * * * * * <i>Medical event</i> N/A	<b>7-002 (NRC) NO (NRC) NO (No podiatrist or dentist)but will add (NRC) NO</b>	<u>Authorized medical physicist</u> means an individual who: 1. Meets the requirements in 180 NAC 7-023.01 and 7-027; or 2. Is identified as an authorized medical physicist <b>or teletherapy physicist</b> on a specific license or equivalent permit issued by the Department, Nuclear Regulatory Commission or Agreement State; or <u>Authorized nuclear pharmacist</u> means a pharmacist who: 1. Meets the requirements of 180 NAC 7-024.01 and 7-027; or <u>Authorized user</u> means a physician <b>dentist or podiatrists</b> who: 1. Meets the requirements in 180 NAC 7-027 and 7-043.01, 7-047.01, 7-052.01, 7-053.01, 7-054.01, 7-063.01, 7-066.01 or 7-084.01; or <u>Radiation Safety Officer (RSO)</u> means an individual who: 1. Meets the requirements in 180 NAC 7-022.01 and 7-026; E
35.8	<b>Information collection requirements: OMB approval</b>		D	N/A		
35.10	<b>Implementation</b>		D	N/A	<b>7-006</b>	
35.13	<b>License Amendments</b>		D	N/A	<b>7-010</b>	
35.14	<b>Notifications</b>		D	N/A	<b>7-011</b>	

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REG SECTION #	SECTION TITLE	Difference	COMP AT./ H&S CAT.	SUMMARY OF CHANGE	180 NAC& Significant Difference	Nebraska
35.50	Training for Radiation Safety Officer		B	In § 35.50, paragraph (a)(2)(ii)(B) is revised to read as follows: (a) * * * (2) * * * (ii) * * * (B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.290 or 35.390; * * * * *	7-022, item 1.b.(2) (NRC) NO	7-022.01, item 1.b.(2) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements or for authorized users in 180 NAC 7-047 or 7-052; and
35/51	Training for an authorized medical physicist		B	In § 35.51, paragraphs (a)(2)(ii) and (b)(2) are revised to read as follows: a) * * * (2) * * * (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 §§ 35.490 or 35.690; and * * * * * (b) * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, 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 must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, or equivalent 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 * * * * *	7-023.01, item 2.b. (NRC) NO  7-023.03 (NRC) NO	7-023.01, item 2.b. b. In a clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 180 NAC 7-063 or 7-084; and  <u>7-023.03</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-023.04 and 180 NAC 7-023.01, item 1 and 2, or 180 NAC 7-023.02, item 1 and 180 NAC 7-023.04, 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 must be signed by a preceptor authorized medical physicist who meets the requirements in 180 NAC 7-023, or equivalent U.S. Nuclear Regulatory Commission 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.

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35.59	Recentness of training		B	<b>Section 35.59 is revised to read as follows:</b> The training and experience specified in Subparts B, D, E, , G, and H of this part must have been obtained within the even years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.	<b>7-027 (NRC) NO</b>	<u>7-027 RECENTNESS OF TRAINING</u> The training and experience specified in 180 NAC 7 must have been obtained within seven years preceding the date of license application or the individual must have had related continuing education and experience since the required training and experience was completed.
35.65	Authorization for calibration, transmission, and reference sources		D	N/A		
35.100	Use of unsealed byproduct material for uptake, dilution and excretion studies for which a written directive is not required		H&S	<b>In § 35.100, paragraph (b)(2) is revised to read as follows:</b> b) * * * (2) A physician who is an authorized user and who meets he requirements specified in §§ 35.290, or 35.390 and 35..290(c)(1)(ii)(G); or * * * * *	<b>7-041.02 (NRC) NO</b>	7-041.02, item 2 A physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047 or 7-051 and 7-047.03, item 1.b.(7); or

REG SECTION #	SECTION TITLE	Difference	COMP AT./ H&S CAT.	SUMMARY OF CHANGE	180 NAC& Significant Difference	Nebraska
35.190	Training for uptake, dilution, and excretion studies.		B	<p>In § 35.190, paragraphs (b), (c)(1)(ii) and (c)(2) are revised to read as follows:</p> <p>(b) Is an authorized user under §§ 35.290, 35.390, or equivalent Agreement State requirements; or (c)(1)***</p> <p>(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving— *****</p> <p>(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.</p>	<p>7-043.02 (NRC) NO</p> <p>7-043.023, item 2 (NRC) NO</p> <p>7-043.04 (NRC) NO</p>	<p>7-043.02 Is an authorized user under 180 NAC 7-047 or 7-051 or equivalent U.S. Nuclear Regulatory or Agreement State requirements; or 7-043.03, item 2.</p> <p>2. Work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-043, 7-047 or 7-051 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving:</p> <p>7-043.04 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-043, 7-047, or 7-051, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirement in 180 NAC 7-043.01, item 1 or 7-043.03, item 1 and 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 180 NAC 7-041.</p>
35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.		H&S	<p>In § 35.200, paragraph (b)(2) is revised to read as follows:</p> <p>(b) ***</p> <p>(2) A physician who is an authorized user and who meets the requirements specified in § 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or *****</p>	<p>7-044.02, item 2 (NRC) NO</p>	<p>7-044.02, item 2</p> <p>A physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047, or 7-051 and 7-047.03, item 1.b.(7), or</p>

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REG SECTION #	SECTION TITLE	Difference	COMP AT./ H&S CAT.	SUMMARY OF CHANGE	180 NAC& Significant Difference	Nebraska
35.290	Training for imaging and localization studies		B	<p>In § 35.290, paragraphs (a)(1), (b), the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:</p> <p>(a) * * *</p> <p>(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and * * * * *</p> <p>(b) Is an authorized user under § 35.390 and meets the requirements in 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or (c)(1) * * *</p> <p>(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G), and 35.390, or equivalent Agreement State requirements, involving— * * * * *</p> <p>(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.</p>	<p>7-047.023, item 1 (NRC) NO</p> <p>7-047.02 (NRC) NO</p> <p>7-047.03, item 1.b. (NRC) NO</p> <p>7-047.04 (NRC) (NO)</p>	<p>7-047.02, item 1</p> <p>1. 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. <b>The training and experience must include at a minimum: that includes the topics listed in 180 NAC 7-047.03; and</b></p> <p>2-1.</p> <p>7-047.02 Is an authorized user in 180 NAC 7-051 and meets the requirements in 180 NAC 7-047.03, item 1.b.(7) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or 7-047.03, item 1.b.</p> <p>Work experience, under the supervision of an authorized user, who meets the requirements in 180 NAC 7-047 or 7-47.03, item 1.b.(7) and 180 NAC 7-051 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving;</p> <p>7-047.04 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-047, or 7-051 and 7-047.03, item 1.b.(7) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-047.01, item 1 or 180 NAC 7-047.03, item 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 180 NAC 7-041 and 7-044 .</p>
35.300	Use of unsealed byproduct material for which a written directive is required		H&S	<p>In § 35.300, paragraph (b)(2) is revised to read as follows:</p> <p>(b) * * *</p> <p>(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or * * * * *</p>	7-048.02 (NRC) NO	7-048.02 Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047 or 7-051, or an individual under the supervision of either as specified in 180 NAC 7-018; or

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35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicureis).		B	<p><b>In § 35.392, paragraph (b), the introductory text of paragraph ©(2) and paragraph (c)(3) are revised to read as follows:</b></p> <p>(b) Is an authorized user under § 35.390 for uses listed in §35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or equivalent Agreement State requirements; or (c) * * *</p> <p>(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b) must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve— * * * * *</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).</p>	<p><b>7-052.02 (NRC) NO</b></p> <p><b>Item 2 (NRC) NO</b></p> <p><b>7-052.04 (NRC) NO</b></p>	<p><u>7-052.02</u> Is an authorized user under 180 NAC 7-051.01, 7-051.02 for uses listed in 180 NAC 7-051.02, item 1.b.(6)(a) or (b), 180 NAC 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or 7-052.03, item 2 Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-051.01, 7-051.02, 7-052, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(a) or (b). The work experience must involve:</p> <p><u>7-052.04</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-052.03, item 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-051, 7-052, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(a) or (b).</p>

REG SECTION #	SECTION TITLE	Difference	COMP AT./ H&S CAT.	SUMMARY OF CHANGE	180 NAC& Significant Difference	Nebraska
35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)		B	<p><b>In § 35.394, paragraph (b), the introductory text of paragraph (c)(2), and paragraph (c)(3) are revised to read as follows:</b></p> <p>(b) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(2) or equivalent Agreement State requirements; or (c) * * *</p> <p>(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve— * * * * *</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under §35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).</p>	<p><b>7-053.02 (NRC) NO</b></p> <p><b>7-053.04 (NRC) NO</b></p>	<p><u>7-053.02</u> Is an authorized user under 180 NAC 7-051, for uses listed in 180 NAC 7-051.02, item 1.b.(6)(b), or equivalent Agreement State, or U.S. Nuclear Regulatory Commission requirements; or <b>7-053.03</b></p> <p>2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-051, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(b). The work experience must involve:</p> <p><u>7-053.04</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-053.03, item 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized in 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-051 or, 7-053, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.(6)(b).</p>

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35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive		B	<p><b>In § 35.396, the introductory paragraph, paragraphs (a), (b), (c), the introductory text of paragraphs (d)(1) and (d)(2), paragraph (d)(2)(vi), and paragraph (d)(3) are revised to read as follows:</b></p> <p>Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—</p> <p>(a) Is an authorized user under § 35.390 for uses listed in §§ 35.390(b)(1)(ii)(G)(3) or 35.390(b)(1)(ii)(G)(4), or equivalent Agreement State requirements; or (b) Is an authorized user under §§ 35.490, 35.690, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or (c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690, and who meets the requirements in paragraph (d) of this section.</p> <p>(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photonemitting 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 must include— * * * * *</p> <p>(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390, 35.396, or equivalent 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 in § 35.390 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve— * * * * *</p> <p>(vi) Administering dosages to patients of human research subjects, that include at least 3 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 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and (3) Has obtained written attestation that</p>	<p><b>7-054 (NRC) NO</b></p> <p><b>7-054.01 (NRC) NO</b></p> <p><b>7-054.02 (NRC) NO</b></p> <p><b>7-054.03 (NRC) NO</b></p> <p><b>7-054.04 (NRC) NO</b></p>	<p><u>7-054 TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE</u> Except as provided in 180 NAC 7-026, the licensee must require an authorized user for the parenteral administration requiring a written directive, to be a physician who:</p> <p><u>7-054.01</u> Is an authorized user under 180 NAC 7-051 for uses listed in 7-051.02, item 1.b. (6)(c) or (d), or equivalent Agreement State requirements; or</p> <p><u>7-054.02</u> Is an authorized user under 180 NAC 7-063 or 7-084, or equivalent Agreement State requirements and who meets the requirements in 180 NAC 7-054.04; or</p> <p><u>7-054.03</u> Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State under 180 NAC 7-063 or 7-084; and who meets the requirements in 180 NAC 7-054.04.</p> <p><u>7-054.04</u> The physician:</p> <p>1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, 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. The training must include:</p> <p>2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-051 or 7-054, or equivalent U.S. Nuclear Regulatory Commission 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 in 180 NAC 7-051, must have experience in</p>	Updated 11/10/09
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35.490	Training for use of manual brachytherapy sources		B	<p><b>In § 35.490, the introductory text of paragraph (b)(1)(ii), and paragraphs (b)(2), and (b)(3) are revised to read as follows:</b></p> <p>(b)(1) * * *</p> <p>(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving— * * * * *</p> <p>(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 or equivalent 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 or 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 paragraph (b)(1)(ii) of this section; and</p> <p>(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.</p>	<p><b>7-063.02, item 1.b. (NRC) NO</b></p> <p><b>7-063.02, Item 2 (NRC) NO</b></p> <p><b>7-063.03 (NRC) NO</b></p>	<p><b>7-063.02, item 1.b.</b></p> <p>b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements at a medical institution, involving:</p> <p>2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 180 NAC 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements, as a part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or 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 180 NAC 7-063.02, item 1.b.; and</p> <p>3. Meet the requirements of 180 NAC 7-063.03.</p> <p><u>7-063.03</u> Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-063, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-063.01, item 1 or 7-063.02, item 2 and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under 180 NAC 7-055.</p>

REG SECTION #	SECTION TITLE	Difference	COMP AT./ H&S CAT.	SUMMARY OF CHANGE	180 NAC& Significant Difference	Nebraska
35.491	Training for ophthalmic use of strontium-90		B	<p><b>In § 35.491, paragraphs (a) and (b)(3) are revised to read as follows:</b></p> <p>(a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or</p> <p>(b) * * *</p> <p>(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.</p>	<p><b>7-064.01 (NRC) NO</b></p> <p><b>7-064.02, item 3 (NRC) NO</b></p>	<p><u>7-064.01</u> Is an authorized user under 180 NAC 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements; or 7-064.02</p> <p>Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-063 or 7-064 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-064.01 and 7-064.02 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.</p>

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35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units		B	<p><b>In § 35.690, the introductory text of paragraph (b)(1)(ii), and paragraphs (b)(2), and (b)(3) are revised to read as follows:</b></p> <p>(b)(1) * * *</p> <p>(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or, equivalent Agreement State requirements at a medical institution, involving— * * * * *</p> <p>(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in § 35.690 or equivalent 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 or 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 paragraph (b)(1)(ii) of this section; and</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, 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 must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and * * * * *</p>	<p><b>7-084</b></p> <p><b>Item 1.b.</b></p> <p><b>(NRC)</b></p> <p><b>NO</b></p> <p><b>Item 2</b></p> <p><b>(NRC)</b></p> <p><b>NO</b></p>	<p>7-084.02, item 1.b.</p> <p>b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-084.01, 7-084.02 or equivalent U.S. Nuclear Regulatory or Agreement State requirements at a medical institution, involving:</p> <p>2. Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 180 NAC 7-084, or equivalent Agreement State or U.S. Nuclear Regulatory Commission 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 or 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 180 NAC 7-084.02, item 1.b.; and</p> <p>3. Meets the requirements of 180 NAC 7-084.03 and 7-084.04.</p> <p><u>7-084.03</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-084.01, item 1 or 7-084.02, item 1 and 2, and 7-084.04 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 must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-084 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and</p>

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Minor Amendments- Part 40  
(71 FR 15005) RATS ID # 2006-1 Effective date 03/27/06  
Date Due For State Adoption 03/27/09

40.5	Communication		D	N/A		
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Minor Amendments- Part 70  
(71 FR 15005) RATS ID # 2006-1 Effective date 03/27/06  
Date Due For State Adoption 03/27/09

70.5	Communication		D	N/A		
7-.14	Foreign military aircraft		D	N/A		

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**Security Requirements for Portable Gauges Containing Byproduct Material - Part 30**  
**(70 FR 2001) RATS ID # 2005-1 Effective date 7/11/05**  
**Date Due For State Adoption 7/11/08**

30.34	Terms and conditions of licenses.		C	<p>The final rule requires a portable gauge licensee to use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal whenever the portable gauges are not under the control and constant surveillance of the licensee. The primary intent of this rulemaking is to increase licensees' control of portable gauges to reduce the opportunity for unauthorized removal or theft.</p> <p>*****</p> <p>(i) Security requirements for portable gauges. 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.</p>	4-031.05 (NRC) NO	4-031.05 Security requirements for portable gauges. Each portable gauge licensee must 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.
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**Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35**  
(70 FR 16336) RATS ID # 2005-2 Effective date 4/29/05  
Date due for State Adoption : 4/29/08

§ 35.2	Definitions		B  B	<p>In § 35.2, the definition "Radiation Safety Officer" is amended by republishing the introductory text and revising paragraph (1) of the definition, and the definition of "Preceptor" is revised to read as follows:</p> <p>*****</p> <p><i>Preceptor</i> means an individual who provides, directs, or verifies 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.</p> <p>*****</p> <p><i>Radiation Safety Officer</i> means an individual who—</p> <p>(1) Meets the requirements in §§ 35.50(a) or (c)(1) and 35.59; or, before October 24, 2005, §§ 35.900(a) and 35.59; or</p> <p>*****</p>	7-002 (NRC) NO  7-002 NO	<p><u>Preceptor</u> means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a nuclear medicine technologist, a radiation therapy technologist or a Radiation Safety Officer.</p> <p><u>Radiation Safety Officer (RSO)</u> means an individual who:</p> <p><del>2.1</del> Meets the requirements in 180 NAC 7-022.01 and 7-026;</p> <p><del>3.2</del> Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Department for similar types and uses of radioactive material.</p>
§ 35.8	Information collection requirements: OMB approval		D	N/A	NA	
§ 35.10	Implementation		D	N/A	7-006	
§ 35.13	License amendments		D	N/A	7-010	
§ 35.14	Notifications		D	N/A	7-011	

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§ 35.50	Training for Radiation Safety Officer		B	<p><b>In § 35.50, paragraph (a), the introductory text of paragraph (b)(1)(I), paragraphs (b)(1)(ii)(G), and (c) are revised, paragraph (b)(2) is removed and reserved, and paragraphs (d) and (e) are added to read as follows:</b> *****</p> <p>(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:</p> <p>(1)(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;</p> <p>(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and</p> <p>(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</p>	<p>7-022.01 (NRC) NO</p> <p>Item 1 (NRC) NO</p>	<p><u>7-022 TRAINING FOR RADIATION SAFETY OFFICER</u> Except as provided in 180 NAC 7-026, the licensee must require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in 180 NAC 7-015 to be:</p> <p><u>7-022.01</u> An individual who is certified by a specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission and who meets the requirements in 180 NAC 7-022.04 and 7-022.05. (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's web page.)</p> <p>1. To have its certification process recognized, a specialty board will require all candidates for certification to:</p> <p>a. 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;</p> <p>b. 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</p> <p>c. 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</p>
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				<p>(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; or</p> <p>(2) 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 byproduct material for which the individual has Radiation Safety Officer responsibilities; and,</p> <p>(d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and</p>	<p>7-022.03 (NRC) NO</p> <p>7-022.04 (NRC) NO</p>	<p><u>7-022.03</u> The individual who is a:</p> <p>1. Medical physicist who has been certified by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State in 180 NAC 7-023.01 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 Radiation Safety Officer and who meets the requirement in 180 NAC 7-022.04 and 7-022.05; or</p> <p>2. 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 Radiation Safety Officer responsibilities and who meets the requirements in 180 NAC 7-022.04 and 7-022.05.</p> <p><u>7-022.04</u> An individual who has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in 180 NAC 7-022.05 and in 180 NAC 7-022.01, item 1.a. and b. or 180 NAC 7-022.01, item 2.a. and b, or 180 NAC 7-022.02 item 1 or 180 NAC 7-022.03 and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee.</p>
				<p>(e) 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 Radiation Safety Officer, 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</p>	<p>7-022.04 (NRC) NO</p>	<p><u>7-022.05</u> An individual who 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 radiation safety officer, 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</p>

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§ 35.51	Training for an authorized medical physicist		B	<p><b>In § 35.51, paragrapre revised, and paragraph (c) is added to read as follows:</b></p> <p>*****</p> <p>(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(2) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:</p> <p>(1) 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;</p> <p>(2) Have 2 years of full-time practical training and/or supervised experience in medical physics—</p> <p>(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or</p> <p>(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 §§ 35.490 or 35.690, or, before October 24, 2005, authorized users who meet the requirements in §§ 35.940 or 35.960; and</p> <p>(3) 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</p>	<p>7-023.01 (NRC) NO</p> <p>Item 1 NO</p> <p>Item 2 NO</p>	<p><u>7-023 TRAINING FOR AN AUTHORIZED MEDICAL PHYSICIST.</u> The licensee must require the authorized medical physicist to be:</p> <p><u>7-023.01</u> An individual who is certified by a specialty board whose certification process has been recognized by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements of 180 NAC 7-023.03 and 7-023.04. (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:</p> <p>1. 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;</p> <p>2. Have two years of full-time practical training and/or supervision experience in medical physics:</p> <p>a. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission, or</p> <p>b. In a clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 180 NAC 7-063 or 7-084; and</p> <p>3. Pass an examination, administered by diplomats of the specialty board, which 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</p>
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				<p>(b)(1) Holds 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 has completed 1 year of full-time training in medical physics and an additional year of fulltime 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 must 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 must include:</p> <ul style="list-style-type: none"> <li>(i) Performing sealed source leak tests and inventories;</li> <li>(ii) Performing decay corrections;</li> <li>(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and</li> <li>(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and</li> </ul> <p>(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, 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 must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, or, before October 24, 2005, § 35.961, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized</p>	<p>7-023.02 item 1 (NRC) NO</p> <p>7-023.03 (NRC) NO</p>	<p><u>7-023.02</u> An individual who:</p> <ol style="list-style-type: none"> <li>1. Holds 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 has completed 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 types(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include: <ol style="list-style-type: none"> <li>a. Performing sealed source leak tests and inventories;</li> <li>b. Performing decay corrections;</li> <li>c. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and</li> <li>d. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and</li> </ol> </li> <li>2. Meets the requirements of 180 NAC 7-023.03. and 7-023.04.</li> </ol> <p><u>7-023.03</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-023.04 and 180 NAC 7-023.01, item 1 and 2, or 180 NAC 7-023.02, item 1 and 180 NAC 7-023.04, 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 must be signed by a preceptor authorized medical physicist who meets the requirements in 180 NAC 7-023, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized <b>medical</b></p> <p style="text-align: center;">Updated 11/10/09</p> <p><u>7-023.04</u> 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</p>
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				<p>medical physicist status; and (c) 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.</p>	<p>7-023.04 (NRC)  NO</p>	<p>Medical physicist status and <del>7-023.04</del> 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.</p>

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§ 35.55	Training for an authorized nuclear pharmacist		B	<p><b>In § 35.55, paragraphs (a), (b)(1)(I) introductory text, and (b)(2) are revised to read as follows:</b></p> <p>*****</p> <p>(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (b)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:</p> <p>(1) 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;</p> <p>(2) Hold a current, active license to practice pharmacy;</p> <p>(3) 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</p> <p>(4) 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</p> <p>(b) ***</p> <p>(1) ***</p> <p>(i) 200 hours of classroom and laboratory training in the following areas—</p> <p>*****</p>	<p>7-024.01 (NRC) NO</p> <p>Item 1 NO</p> <p>Item 2 NO</p> <p>Item 3 NO</p> <p>Item 4 NO</p> <p>7-024.02 item 1.a NO</p>	<p><b>7-024 TRAINING FOR AN AUTHORIZED NUCLEAR PHARMACIST</b> The licensee will require the authorized nuclear pharmacist to be a pharmacist who:</p> <p><u>7-024.01</u> Is certified by a specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission who meets the requirements of 180 NAC 7-024.03. (The names of the board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) will be posted on the NRC's web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:</p> <p>1. 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;</p> <p>2. Hold a current, active license to practice pharmacy;</p> <p>3. Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience;</p> <p>4. Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, which 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</p> <p>7-024.02 item 1.a. 200 hours of classroom and laboratory training in the following areas:</p>

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				( (2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), (a)(2), and (a)(3) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.	7-024.03 NO	<u>7-024.03</u> Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements of 180 NAC 7-024.01, item 1, 2, and 3 or 7-024.02 and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.
§ 35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist		B	<b>Section 35.57 is revised to read as follows:</b>  (a)(1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. (2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.	7-026.01 (NRC) NO	<del>7-026 PROVISIONS FOR EXPERIENCED RADIATION SAFETY OFFICER, TELE THERAPY OR MEDICAL PHYSICIST, AUTHORIZED MEDICAL PHYSICIST, AUTHORIZED USER, NUCLEAR PHARMACIST AND AUTHORIZED NUCLEAR PHARMACIST</del> <u>7-026.01</u> An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist or an authorized medical physicist or a authorized nuclear pharmacist on a U.S. Nuclear Regulatory Commission, an Agreement State license or on a permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material permittee of broad scope that authorizes medical use or practice of nuclear pharmacy, before the effective date of these regulations need not comply with the training requirements of 180 NAC 7-022 through 7-024.

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				<p>(b)(1) Physicians, s, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D through H of this part.</p> <p>(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts D through H of this part.</p>	7-026.02 NO	7-026.02 Physicians, <b>dentists, or podiatrists</b> identified as authorized users for the medical, use of radioactive material on a license issued by the U.S. Nuclear Regulatory Commission or Agreement State, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope licensee, or on a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee before the effective date of these regulations who perform only those medical uses for which they were authorized on that date need not comply with the training requirements 180 NAC 7-041 through 7-084
§ 35.75	Release of individuals containing unsealed byproduct material or implants containing byproduct material		C, paragraphs (a) and (b) – paragraphs (c) and (d)	In § 35.75, paragraph (a), footnote 1, remove “(draft)”.	7-037 (NRC) NO	U.S. Nuclear Regulatory Commission’s - Regulatory Guide <b>NUREG-1556, Vol. 9</b> <b>“Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses:7.1,”</b> <b>“Release of Patients Administered Radioactive Materials.”</b> describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

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§ 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required		H&S	<p><b>In § 35.100, paragraph (b)(2) is revised to read as follows:</b></p> <p>*****</p> <p>(b) ***</p> <p>(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920; or</p> <p>*****</p>	7-041.02 (NRC) NO	<p><u>7-041.02</u> Prepared by:</p> <ol style="list-style-type: none"> <li>1. An authorized nuclear pharmacist;</li> <li>2. A physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047 or 7-051 and 7-047.03, item 1.b.(7); or</li> <li>3. An individual under the supervision, as specified in 180 NAC 7-018, of the authorized nuclear pharmacist in 180 NAC 7-041.02, item 1 or the physician who is authorized user in 180 NAC 7-041.02, item 2; or</li> </ol>



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				(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §35.100.	7-034.04 (NRC) NO	<u>7-043.04</u> Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-043, 7-047, or 7-051, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirement in 180 NAC 7-043.01, item 1 or 7-043.03, item 1 and 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 180 NAC 7-041.
§ 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.		H&S	<b>In § 35.200, paragraph (b)(2) is revised to read as follows:</b> ***** (b) *** (2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24,2005, § 35.920; or *****	7-044.02 (NRC) NO	<u>7-044.02</u> Prepared by:  2. A physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047, or 7-051 and 7-047.03, item 1.b.(7), or

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§ 35.290	Training for imaging and localization studies		B	<p><b>In § 35.290, paragraphs (a), (b), the introductory text of (c)(1) and (c)(1)(ii) introductory text, (c)(1)(ii)(B), and (c)(2) are revised to read as follows:</b></p> <p>*****</p> <p>(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:</p> <p>(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and</p> <p>(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or</p> <p>b) Is an authorized user under § 35.390 and meets the requirements in § 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements; or</p> <p>(c)(1) 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 byproduct material for imaging and localization studies. The training and experience must include, at a minimum—</p> <p>*****</p>	7-047.01 (NRC) NO	<p><u>7-047.01</u> Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) and who meets to requirement in 180 NAC 7-047.04. (The names of board certification which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:</p> <p><del>3-2.</del> 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 180 NAC 7-047.03; and</p> <p><del>4-3.</del> Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or</p> <p><u>7-047.02</u> Is an authorized user in 180 NAC 7-051 and meets the requirements in 180 NAC 7-047.03, item 1.b.(7) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or</p> <p><u>7-047.03 The physician:</u></p> <p>1. 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 must include at a minimum:</p>
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§ 35.390	Training for use of unsealed byproduct material for which a written directive is required.		B	<p><b>In § 35.390, paragraph (a), the introductory text of paragraphs (b)(1) and (b)(1)(ii) introductory text, paragraphs (b)(1)(ii)(B), (b)(1)(ii)(G)(1), (3) and (4), and (b)(2) are revised, and paragraph (b)(1)(ii)(F) is removed and reserved.</b></p> <p>*****</p> <p>(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) and (b)(2) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:</p> <p>(1) 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 must include 700 hours of training and experience as described in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must 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</p> <p>2) 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 byproduct material for which a written directive is required; or</p>	7-051.01 (NRC) NO	<p><u>7-051.01</u> Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) who meets the requirements in 180 NAC 7-051.02, item 1.b.(6) and 7-051.03. (Specialty Boards whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) To be recognized, a specialty board must require all candidates for certification to:</p> <p>1. Successfully complete <del>a minimum of three years of</del> residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 180 NAC 7-051.02, item 1.a. through 7-051.02, item 1.b.(5). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and</p> <p>2. 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</p>
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§ 35.390	Training for use of unsealed byproduct material for which a written directive is required.		B	<p>(b)(1) 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 byproduct material requiring a written directive. The training and experience must include— *****</p> <p>(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2005, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve— *****</p> <p>(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; *****</p> <p>(G) ***</p> <p>(1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required; *****</p> <p>(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or</p> <p>(4) Parenteral administration of any other radionuclide, for which a written directive is required; and *</p>	7--051.02 (NRC) NO	<p><u>7-051.02 The physician:</u></p> <p>1. 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 must include:</p> <p>b. Work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-051, or equivalent U.S. Nuclear Regulatory or Agreement State requirements. A supervising authorized user, who meets the requirements in 180 NAC 7-051.02, must also have experience in administering dosages in the same dosage category or categories (that is , 180 NAC 7-051.02, item 1., b.(6)) as the individual requesting authorized user status. The work experience must involve:</p> <p>(2) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;</p> <p><b>(6)</b></p> <p>(a) Oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131, for which a written directive is required;</p> <p>(c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or</p> <p>(d) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or</p>

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				<p>(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), or, before October 24, 2005, § 35.930(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.</p>	<p>7-051.03 NO</p>	<p><u>7-051.03</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-051.01, item 1 and 7-051.02, item 1.b.(6) or 7-051.02, item 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-051, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirement in 180 NAC 7-051.02 must have experience in administering dosages in the same dosage category or categories (that is, 180 NAC 7-051.02, item 1.b.(6)) as the individual requesting authorized user status.</p>
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§ 35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).		B	<p><b>In § 35.392, paragraphs (a), (c)(2)(ii) and (c)(3) are revised to read as follows:</b> *****</p> <p>(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or *****</p> <p>(c) *** (2) *** (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; *****</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.392, or 35.394, or, before October 24, 2005, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).</p>	<p>7-052.01 (NRC) NO</p> <p>7-052.03 (NRC) NO</p> <p>7-052.04 (NRC) NO</p>	<p><u>7-052.01</u> Is certified by a medical specialty board whose certification process includes all of the requirements in 180 NAC 7-052.03, item 1. and 2. and whose certification has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission who meets the requirements of 180 NAC 7-052.04. (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) or</p> <p><b>7-052.03 2.</b> b. Performing quality control procedures on instruments used to determine the activity of dosages and performing check for proper operation of survey meters;</p> <p><u>7-052.04</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-052.03, item 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-051, 7-052, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(a) or (b).</p>
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§ 35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).		B	<p><b>In § 35.394, paragraphs (a), (c)(2)(ii) and (c)(3) are revised to read as follows:</b> *****</p> <p>(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or *****</p> <p>(c) *** (2) *** (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; *****</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390 or 35.394, or, before October 24, 2005, §§ 35.930 or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).</p>	<p>7-053.01 (NRC) NO</p> <p>7-053.03 NO</p> <p>7-053.04 NO</p>	<p><u>7-053.01</u> Is certified by a medical specialty board whose certification process includes all of the requirements in 180 NAC 7-053.03, item 1. and 2. and whose certification has been recognized an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) and who meets the requirements in 180 NAC 7-053.04. (The name of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) or</p> <p>7-053.03 2.b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;</p> <p><u>7-053.04</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-053.03, item 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized in 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-051 or, 7-053, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.(6)(b).</p>
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§ 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive		B	<p><b>Section 35.396 is added to read as follows:</b></p> <p>Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who-</p> <p>(a) Is an authorized user under § 35.390 or, before October 24, 2005, § 35.930 for uses listed in §§ 35.390(b)(1)(ii)(G)(3) or 35.390(b)(1)(ii)(G)(4), or equivalent Agreement State requirements; or</p> <p>(b) Is an authorized user under §§ 35.490 or 35.690, or, before October 24, 2005, §§ 35.940 or 35.960, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or</p> <p>(c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690, or, before October 24, 2005, §§ 35.940 or 35.960; and who meets the requirements in paragraph (d) of this section.</p> <p>(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, 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. The training must include—</p> <p>(i) Radiation physics and instrumentation;</p> <p>(ii) Radiation protection;</p> <p>(iii) Mathematics pertaining to the use and measurement of radioactivity;</p> <p>(iv) Chemistry of byproduct material for medical use; and</p> <p>(v) Radiation biology; and</p>	<p>7-054 (NRC) NO</p> <p>7-054.02 (NRC) NO</p> <p>7-054.03 (NRC) NO</p> <p>7-054.04 (NRC) NO</p>	<p><u>7-054 TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE</u></p> <p>Except as provided in 180 NAC 7-026, the licensee must require an authorized user for the parenteral administration requiring a written directive, to be a physician who:</p> <p><u>7-054.01</u> Is an authorized user under 180 NAC 7-051 for uses listed in 7-051.02, item 1.b. (6)(c) or (d), or equivalent Agreement State requirements; or</p> <p><u>7-054.02</u> Is an authorized user under 180 NAC 7-063 or 7-084, or equivalent Agreement State requirements and who meets the requirements in 180 NAC 7-054.04; or</p> <p><u>7-054.03</u> Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State under 180 NAC 7-063 or 7-084; and who meets the requirements in 180 NAC 7-054.04.</p> <p><u>7-054.04</u> The physician:</p> <p>1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, 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. The training must include:</p> <p>(1) Radiation physics and instrumentation;</p> <p>(2) Radiation protection;</p> <p>(3) Mathematics pertaining to the use and measurement of radioactivity;</p> <p>(4) Chemistry of radioactive material for medical use; and</p> <p>1. Radiation biology; and</p>

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				<p>(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390 or 35.396, or, before October 24, 2005, § 35.930, or equivalent 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 in §§ 35.390 or 35.930 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve—</p> <ul style="list-style-type: none"> <li>(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;</li> <li>(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;</li> <li>(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;</li> <li>(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;</li> <li>(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;</li> <li>(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and</li> <li>(vi) Administering dosages to patients or human research subjects, that include at least 3 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 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and</li> </ul>		<p>2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-051 or 7-054, or equivalent U.S. Nuclear Regulatory Commission 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 in 180 NAC 7-051, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(c) and/or (d). The work experience must involve:</p> <ul style="list-style-type: none"> <li>a. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;</li> <li>b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;</li> <li>c. Calculating, measuring, and safely preparing patient or human research subject dosages;</li> <li>d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;</li> <li>e. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and</li> <li>f. 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</li> </ul>
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				<p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.396, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4).</p>		<p>3. Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-054.02 or 7-054.03, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-051, or 7-054, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 180 NAC 7-051, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(c) and/or (d).</p>
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				(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in § 35.490, or, before October 24, 2005, § 35.940, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.	<b>7-063.03 (NRC) NO</b>	<u>7-063.03</u> Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-063, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-063.01, item 1 or 7-063.02, item 2 and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under 180 NAC 7-055.
§ 35.491	Training for ophthalmic use of strontium-90		B	<b>In § 35.491, paragraph (b)(3) is revised to read as follows:</b>  ***** (b) *** (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.490 or 35.491, or, before October 24, 2005, §§ 35.940 or 35.941, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use	7-064.02 (NRC) NO	<b>7-064.02</b> 3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-063 or 7-064 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-064.01 and 7-064.02 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

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§ 35.590	Training for use of sealed sources for diagnosis		B	<p><b>In § 35.590, paragraphs (a) and (b) are revised and paragraph (c) is added to read as follows:</b></p> <p>*****</p> <p>(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or</p> <p>(b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—</p> <p>(1) Radiation physics and instrumentation;</p> <p>(2) Radiation protection;</p> <p>(3) Mathematics pertaining to the use and measurement of radioactivity; and</p> <p>(4) Radiation biology; and</p> <p>(c) Has completed training in the use of the device for the uses requested.</p>	<p>7-066.01 (NRC) NO</p> <p>7-066.02 (NRC) NO</p> <p>7-066.03 (NRC) NO</p>	<p><u>7-066.01</u> Is certified by a specialty board whose certification includes all of the requirements in 180 NAC 7-066.02 and 7-066.03 whose certification has been recognized by, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC). (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's web page.); or</p> <p><u>7-066.02</u> The physician, <b>dentist or podiatrist</b>:</p> <p>1. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:</p> <p>a. Radiation physics and instrumentation;</p> <p>b. Radiation protection;</p> <p>c. Mathematics pertaining to the use and measurement of radioactivity; and</p> <p>d. Radiation biology; and</p> <p><u>7-066.03</u> Has completed training in the use of the device for the uses requested.</p>
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				<p>the supervised work experience required by paragraph (b)(1)(ii) of this section; and</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, 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 must be signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and</p> <p>(c) 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</p>	<p>7-084.03 (NRC) NO</p> <p>7-084.04 (NRC) NO</p>	<p><u>7-084.03</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-084.01, item 1 or 7-084.02, item 1 and 2, and 7-084.04 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 must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-084 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and</p> <p><u>7-084.04</u> Has received training in device operation, safety procedures, and clinical use of 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.</p>
§ 35.980	Training for an authorized nuclear pharmacist		D	N/A	NA	

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<b>Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090</b>						
<b>(70 FR 72128, (12/1/05)</b>						
<b>RATS IF 2005-03 (Due Date 12/01/05 Per letter dated 9-2/05 from Paul H. Lohaus – NRC Order EA-o5-090)</b>						
Nebraska completed this 12/2/2005						

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**compatibility With IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments  
(69 FR 3697, January 26, 2004)**

**RATS ID 2004-1 Effective date October 1, 2004**

**Due for State adoption: October 1, 2007**

**Please Note: The bracket “ [ ] “ around a compatibility category designation means that the Section may have been adopted elsewhere in a State rules and it is not necessary to adopt it again.**

**Please Note : Sections of Part 71 reserved for NRC use are not listed in this amendment notice. Please check the Federal Register (69 FR 3697) for those sections.**

§71.0	Purpose and scope		D, except paragraph C is [B]	<p>(a) This part establishes—</p> <p>(1) Requirements for packaging, preparation for shipment, and transportation of licensed material; and</p> <p>(2) Procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of other licensed material in excess of a Type A quantity.</p> <p>(b) The packaging and transport of licensed material are also subject to other parts of this chapter (e.g., 10 CFR parts 20, 21, 30, 40, 70, and 73) and to the regulations of other agencies (e.g., the U.S. Department of Transportation (DOT) and the U.S. Postal Service)1 having jurisdiction over means of transport. The requirements of this part are in addition to, and not in substitution for, other requirements.</p> <p>(c) The regulations in this part apply to any licensee authorized by specific or general license issued by the Commission to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport Transports the material outside the site of usage as specified in the NRC license, or transports that material on public highways. No provision of this part authorizes possession of licensed material.</p> <p>(d)(1) Exemptions from the requirement for license in § 71.3 are specified in § 71.14. General licenses for which no NRC package approval is required are issued in §§ 71.20 through 71.23. The general license</p>	13-001.03 (NRC NO)	13-001.03 The regulations in 180 NAC 13 apply to any licensee authorized by specific or general license issued by this Department to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transport the material outside the site of usage as specified in the Department's license, or transport that material on public highways. No provision of 180 NAC 13 authorizes possession of licensed material.
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				<p>in § 71.17 requires that an NRC certificate of compliance or other package approval be issued for the package to be used under this general license.</p> <p>(2) Application for package approval must be completed in accordance with subpart D of this part, demonstrating that the design of the package to be used satisfies the package approval standards contained in subpart E of this part, as related to the tests of subpart F of this part.</p> <p>(3) A licensee transporting licensed material, or delivering licensed material to a carrier for transport, shall comply with the operating control requirements of subpart G of this part; the quality assurance requirements of subpart H of this part; and the general provisions of subpart A of this part, including DOT regulations referenced in § 71.5.</p> <p>(e) The regulations of this part apply to any person holding, or applying for, a certificate of compliance, issued pursuant to this part, for a package intended for the transportation of radioactive material, outside the confines of a licensee's facility or authorized place of use.</p> <p>pursuant to part 76 of this chapter, if the person delivers radioactive material to a common or contract carrier for transport or transports the material outside the confines of the person's plant or other authorized place of use.</p> <p>(g) This part also gives notice to all persons who knowingly provide to any licensee, certificate holder, quality assurance program approval holder, applicant for a license, certificate, or or quality assurance program approval, or to a contractor, or subcontractor of any of them, components, equipment, materials, or other goods or services, that relate to a licensee's, certificate holder's, quality assurance program approval holder's, or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 71.8.</p>		
71.1	Communication s and records		D	NA	NA	
71.2	Interpretations		D	NA	NA	

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71.3	Requirement for license		[B]	Except as authorized in a general license or a specific license issued by the Commission, or as exempted in this part, no licensee may— (a) Deliver licensed material to a carrier for transport; or (b) Transport licensed material.	13-003 (NRC) NO	<u>13-003 REQUIREMENT FOR LICENSE:</u> Except as authorized in a general or specific license issued by the Department, or as exempted in 180 NAC 13-004, no licensee may: 1. Deliver radioactive material to a carrier for transport; or Transport radioactive material.
71.4	Definitions		[B]	The following terms are as defined here for the purpose of this part. To ensure compatibility with international transportation standards, all limits in this part are given in terms of dual units: The International System of Units (SI) followed or preceded by 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 part, either unit may be used.	13-002	
			[B]	A1 means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix A, Table A-1, of this part, or may be derived in accordance with the procedures prescribed in Appendix A of this part.	1-002 (NRC) NO	A <sub>1</sub> means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix A of 180 NAC 13, Table A-1, or may be derived in accordance with the procedure prescribed in Appendix A of 180 NAC 013.
			[B]	A2 means the maximum activity of radioactive material, other than special form material, LSA, and SCO material, permitted in a Type A package. This value is either listed in Appendix A, Table A-1, of this part, or may be derived in accordance with the procedures prescribed in Appendix A of this part.	1-002 (NRC) NO	A <sub>2</sub> means 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. These values are either listed in Appendix A of 180 NAC 13, Table A-1, or may be derived in accordance with the procedure prescribed in Appendix A of 180 NAC 013.
			[B]	<i>Carrier</i> means 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.	13-002 (NRC) NO	<u>Carrier</u> means 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.
			D-for those State which have no licensees			

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			<p>that use Type B package or [B]-for those States which have licensees that use Type B packages</p> <p>D-for those State which have no licensees that use Type B package or [B]-for those States which have licensees that use Type B packages</p> <p>D</p> <p>[B]</p>	<p><u>Certificate holder</u> means a person who has been issued a certificate of compliance or other package approval by the Commission.</p> <p><u>Certificate of Compliance (CoC)</u> means the certificate issued by the Commission under subpart D of this part which approves the design of a package for the transportation of radioactive material.</p> <p><u>Close reflection by water</u> means immediate contact by water of sufficient thickness for maximum reflection of neutrons.</p> <p><u>Consignment</u> means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.</p> <p><u>Containment system</u> means the assembly of components of the packaging intended to retain the radioactive material during transport.</p>	<p>13-002 (NRC) NO</p> <p>13-002 (NRC) NO</p> <p>13-002 (NRC) NO</p> <p>13-002 (NRC) NO</p>	<p><u>Certificate holder</u> means a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Com</p> <p><u>Certificate of Compliance (CoC)</u> means the certificate issued by the U.S. Nuclear Regulatory Commission under 10 CFR 71 Subpart D which approves the design of a package for the transportation of radioactive material.</p> <p><u>Close reflection by water</u> means immediate contact by water of sufficient thickness for maximum reflection of neutrons.</p> <p><u>Consignment</u> means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.</p> <p><u>Containment system</u> means the assembly of components of packaging intended to retain the radioactive material during transport.</p>
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			[B]	<i>Conveyance</i> means: (1) For transport by public highway or rail any transport vehicle or large freight container; (2) For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and (3) For transport by any aircraft.	13-002 (NRC) NO	<i>Conveyance</i> means: (1) For transport by public highway or rail any transport vehicle or large freight container; (2) For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and (3) For transport by aircraft any aircraft.
			B	<i>Criticality Safety Index (CSI)</i> means 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 §§ 71.22, 71.23, and 71.59.	13-002 (NRC) NO	<i>Criticality Safety Index (CSI)</i> means 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 180 NAC 13-011 and 13-012, and 10 CFR 71.59.
			B	<i>Deuterium</i> means, for the purposes of §§ 71.15 and 71.22, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000. <i>DOT</i> means the U.S. Department of Transportation.	13-002 (NRC) NO	<i>Deuterium</i> means, for the purposes of 180 NAC 13-004.04 and 13-011, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.
			D	<i>Exclusive use</i> means 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 must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must 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.	13-002 (NRC) NO	<i>DOT</i> means the U.S. Department of Transportation. <i>Exclusive use</i> means the sole use of a conveyance by a single consignor 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 must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must 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.
			[B]		13-002 (NRC) NO	

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			[B]	<i>Fissile material</i> means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, 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. Certain exclusions from fissile material controls are provided in § 71.15.	13-002 (NRC) NO	<u>Fissile material</u> means 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. <sup>1</sup> Certain exclusions from fissile material control are provided in 180 NAC 13-004.04.
			B	<i>Graphite</i> means, for the purposes of §§ 71.15 and 71.22, graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.	13-002 (NRC) NO	<u>Graphite</u> means, for the purposes of 180 NAC 13-004.04 and 13-011, graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.
			[D]	<i>Licensed material</i> means byproduct, source, or special nuclear material received, possessed, used, or transferred under a general or specific license issued by the Commission pursuant to the regulations in this chapter.	1-002 (NRC) NO	<u>Licensed material</u> means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Department.
			[B]	<i>Low Specific Activity (LSA) material</i> means radioactive material with limited specific activity which is nonfissile or is excepted under § 71.15, and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups: (1) LSA—I. (i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclides which are not intended to be processed for the use of these radionuclides; (ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; (iii) Radioactive material for which the A2 value is unlimited; or	13-002 (NRC) NO	<u>Low specific activity (LSA) Material</u> means radioactive material with limited specific activity which is nonfissile or is excepted under 180 NAC 13-004.04, and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups: (1) LSA-I: (a) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclides which are not intended to be processed for the use of these radonucleides; (b) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; (c) Radioactive material for which the A2value is unlimited; or;

<sup>1</sup>Department jurisdiction extends only to "special nuclear material in quantities not sufficient to form a critical mass" as defined in 180 NAC 1-002.

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			[B]	<p>(iv) Other radioactive material in which the activity 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 Appendix A.</p> <p>(2) LSA—II.</p> <p>(i) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or</p> <p>(ii) Other material in which the activity is distributed throughout and the average specific activity does not exceed 10<sup>-4</sup> A<sub>2</sub>/g for solids and gases, and 10<sup>-5</sup>A<sub>2</sub>/g for liquids.</p> <p>(2) LSA—III.</p> <p>Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of § 71.77, in which:</p> <p>(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.);</p> <p>(ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed 0.1 A<sub>2</sub>; and</p> <p>(iii) The estimated average specific activity of the solid does not exceed 2 × 10<sup>-3</sup> A<sub>2</sub>/g.</p> <p><i>Low toxicity alpha emitters</i> means 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 10 days.</p>	13-002 (NRC) NO	<p>(d) Other radioactive material in which the activity 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 Appendix 13-A.</p> <p>(2) LSA-II:</p> <p>(a) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or</p> <p>(b) Other material in which the activity is distributed throughout, and the average specific activity does not exceed 10<sup>-4</sup> A<sub>2</sub>/g for solids and gases, and 10<sup>-5</sup> A<sub>2</sub>/g for liquids.</p> <p>(3) LSA-III solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77 in which:</p> <p>(a) 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</p> <p>(b) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package leaching, when placed in water for 7 days, would not exceed 0.1 A<sub>2</sub>; and</p> <p>(c) The estimated average specific activity of the solid does not exceed 2 E-3 A<sub>2</sub>/g.</p> <p><u>Low toxicity alpha emitters</u> means 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 10 days.</p>
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			D	<p><i>Maximum normal operating pressure</i> means the maximum gauge pressure that would develop in the containment system in a period of 1 year under the heat condition specified in § 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.</p> <p><i>Natural thorium</i> means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).</p> <p>[B] <i>Normal form radioactive material</i> means radioactive material that has not been demonstrated to qualify as "special form radioactive material."</p> <p>D <i>Optimum interspersed hydrogenous moderation</i> means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.</p> <p>[B] <i>Package</i> means the packaging together with its radioactive contents as presented for transport.  (1) Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents.  (2) Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR part 173.  (3) Type B package means a Type B packaging together with its radioactive contents. On approval, 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 kPa (100 lbs/in<sup>2</sup>) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in § 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</p>	<p>NA</p> <p>13-002 (NRC) NO</p> <p>13-002 (NRC) NO</p> <p>13-002 (NRC) NO</p> <p>13-002 (NRC) NO</p>	<p><u>Natural thorium</u> means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).</p> <p><u>Normal form radioactive material</u> means radioactive material which has not been demonstrated to qualify as "special form radioactive material" as defined 180 NAC 1-002.</p> <p><u>Optimum interspersed hydrogenous moderation</u> means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.</p> <p><u>Package</u> means the packaging together with its radioactive contents as presented for transport.  (1) Fissile material package or Type AF package, Type BF package, Type B(U)F package or Type B(M)F package means a fissile material packaging together with its fissile material contents.  (2) Type A package means a Type A packaging together with its radioactive contents. A type A package is defined and must comply with the DOT regulations in 49 CFR part 173.  (3) Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by U. S. Nuclear Regulatory Commission (NRC) as B(U) unless the package has a maximum normal operating pressure or more than 700 kPa (100 lb/in<sup>2</sup>) gauge or pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR Part 71.73 (hypothetical accident conditions), in which 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</p>
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			[B]	determine their distinction for international transportation, see DOT regulations in 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 § 71.19. <i>Packaging</i> means the assembly of components necessary to ensure compliance with the packaging requirements of this part. 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, tiedown system, and auxiliary equipment may be designated as part of the packaging.	13-002 (NRC) NO	determine their distinction for international transportation, see U. S. Department of Transportation (DOT) regulations, 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 10 CFR 71.19. <u>Packaging</u> means the assembly of components necessary to ensure compliance with the packaging requirements of 180 NAC 13. 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.
			[B]	<i>Special form radioactive material</i> means radioactive material that satisfies the following conditions: (1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule; (2) The piece or capsule has at least one dimension not less than 5 mm (0.2 in); and (3) It satisfies the requirements of § 71.75. A special form encapsulation designed in accordance with the requirements of § 71.4 in effect on June 30, 1983 (see 10 CFR part 71, revised as of January 1, 1983), and constructed before July 1, 1985, and a special form encapsulation designed in accordance with the requirements of § 71.4 in effect on March 31, 1996 (see 10 CFR part 71, revised as of January 1, 1983), and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.	1-002 (NRC) NO	<u>Special form radioactive material</u> means radioactive material that satisfies the following conditions: (1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule; (2) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and (3) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.
			[B]	<i>Specific activity of a radionuclide</i> means 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.	13-002 (NRC) NO	<u>Specific activity</u> of a radionuclide means the radioactivity of a 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.

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			D	<p><i>Spent nuclear fuel or Spent fuel</i> means fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least 1 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.</p>	1-002 (NRC) NO	<p><u>Spent nuclear fuel</u> means fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one year of 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 nuclear fuel includes the special nuclear material, byproduct material, source material, and other radioactive material associated with fuel assemblies.</p>
			D	<p><i>State</i> means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.</p>	NA	
			[B]	<p><i>Surface Contaminated Object (SCO)</i> means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:</p> <p>(1) SCO-1: A solid object on which:</p> <p>(i) The nonfixed contamination on the accessible surface averaged over 300 Cm2 (or the area of the surface if less than 300 Cm2) does not exceed 4 Bq/Cm2 (10-4 microcurie/Cm2) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/Cm2 (10-5 microcurie/Cm2) for all other alpha emitters;</p> <p>(ii) The fixed contamination on the accessible surface averaged over 300 Cm2 (or the area of the surface if less than 300 Cm2) does not exceed <math>4 \times 10^{-4}</math> Bq/Cm2 (1.0 microcurie/Cm2) for beta and gamma and low toxicity alpha emitters, or <math>4 \times 10^3</math> Bq/Cm2 (0.1 microcurie/Cm2) for all other alpha emitters; and</p> <p>(iii) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 Cm2 (or the area of the surface if less than 300 Cm2) does not exceed <math>4 \times 10^4</math> Bq/Cm2 (1 microcurie/Cm2) for beta and gamma and low toxicity alpha emitters, or <math>4 \times 10^3</math> Bq/Cm2 (0.1 microcurie/Cm2) for all other alpha emitters.</p>	13-002 (NRC) NO	<p><u>Surface contaminated object (SCO)</u> means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:</p> <p>(1) SCO-1: A solid object on which:</p> <p>(a) The non-fixed contamination on the accessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 4 Bq/cm<sup>2</sup> (10<sup>-4</sup> μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm<sup>2</sup> (10<sup>-5</sup> μCi/cm<sup>2</sup>) for all other alpha emitters.</p> <p>(b) The fixed contamination on the accessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 4E+4 Bq/cm<sup>2</sup> (1.0 μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters, or 4E+3 Bq/cm<sup>2</sup> (0.1 μCi/cm<sup>2</sup>) for all other alpha emitters; and</p> <p>(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 4E+4 Bq/cm<sup>2</sup> (1.0 μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters, or 4E+3 Bq/cm<sup>2</sup> (0.1 μCi/cm<sup>2</sup>) for all other alpha emitters.</p>

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			[B]	<p>(2) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:</p> <p>(i) The nonfixed contamination on the accessible surface averaged over 300 Cm2 (or the area of the surface if less than 300 Cm2) does not exceed 400 Bq/Cm2 (10-2 microcurie/Cm2) for beta and gamma and low toxicity alpha emitters or 40 Bq/Cm2 (10-3 microcurie/Cm2) for all other alpha emitters;</p> <p>(ii) The fixed contamination on the accessible surface averaged over 300 Cm2 (or the area of the surface if less than 300 Cm2) does not exceed <math>8 \times 10^5</math> Bq/Cm2 (20 microcuries/Cm2) for beta and gamma and low toxicity alpha emitters, or <math>8 \times 10^4</math> Bq/Cm2 (2 microcuries/Cm2) for all other alpha emitters; and</p> <p>(iii) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 Cm2 (or the area of the surface if less than 300 2) does not exceed <math>8 \times 10^5</math> Bq/ Cm2 (20 microcuries/Cm2) for beta and gamma and low toxicity alpha emitters, or <math>8 \times 10^4</math> Bq/Cm2 (2 microcuries/Cm2) for all other alpha emitters.</p> <p><i>Transport index (TI)</i> means the dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at 1 meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at 1 meter (3.3 ft)).</p>	13-002 (NRC) NO	<p>(2) SCO-II: A solid object on which the limits for SCO-1 are exceeded and on which:</p> <p>(a) The non-fixed contamination on the accessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 400 Bq/cm<sup>2</sup> (10<sup>-2</sup> μCi/cm<sup>2</sup>) or beta and gamma and low toxicity alpha emitters or 40 Bq/cm<sup>2</sup> (10<sup>-3</sup> μCi/cm<sup>2</sup>) for all other alpha emitters;</p> <p>(b) The fixed contamination on the accessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 8E+5 Bq/cm<sup>2</sup> (20 μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters, or 8E+4 Bq/cm<sup>2</sup> (2 μCi/cm<sup>2</sup>) for all other alpha emitters;</p> <p>(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 8E+5 Bq/cm<sup>2</sup> (20 μCi/cm<sup>2</sup>) for beta and gamma and low toxicity alpha emitters, or 8E+4 Bq/cm<sup>2</sup> (2 μCi/cm<sup>2</sup>) for all other alpha emitters.</p> <p><u>Transport index</u> means the dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at 1 meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at 1 meter (3.3 ft))</p>
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			[B]	<i>Type A quantity</i> means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A <sub>1</sub> for special form radioactive material, or A <sub>2</sub> for normal form radioactive material, where A <sub>1</sub> and A <sub>2</sub> are given in Table A-1 of this part, or may be determined by procedures described in Appendix A of this part.	13-002 (NRC) NO	<u>Type A quantity</u> means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A <sub>1</sub> for special form radioactive material, or A <sub>2</sub> for normal form radioactive material, where A <sub>1</sub> and A <sub>2</sub> are given in Appendix 13-A, Table A-1, or may be determined by procedures described in Appendix 13-AA.
			[B]	<i>Type B quantity</i> means a quantity of radioactive material greater than a Type A quantity.	13-002 (NRC) NO	<u>Type B quantity</u> means a quantity of radioactive material greater than a Type A quantity.
			[B]	<i>Unirradiated uranium</i> means uranium containing not more than 2 × 10 <sup>3</sup> Bq of plutonium per gram of uranium-235, not more than 9 × 10 <sup>6</sup> Bq of fission products per gram of uranium-235, and not more than 5 × 10 <sup>-3</sup> g of uranium-236 per gram of uranium-235. <i>Uranium—natural, depleted, enriched:</i>	13-002 (NRC) NO	<u>Unirradiated uranium</u> means uranium containing not more than 2 × 10 <sup>3</sup> Bq of plutonium per gram of uranium-235, not more than 9 × 10 <sup>6</sup> Bq of fission products per gram of uranium-235, and not more than 5 × 10 <sup>-3</sup> g of uranium-236 per gram of uranium-235.
			[B]	(1) Natural uranium means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238). (2) Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes. (3) Enriched uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes. § 71.5 Transportation of licensed material.	13-002 (NRC) NO	<u>Uranium - natural, depleted, enriched</u> (1) <u>Natural uranium</u> means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238). (2) <u>Depleted uranium</u> means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes. (3) <u>Enriched Uranium</u> means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

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71.5	Transportation of licensed material		[B]	<p>a) Each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 170 through 189 appropriate to the mode of transport.</p> <p>(1) The licensee shall particularly note DOT regulations in the following areas:</p> <p>(i) Packaging—49 CFR part 173: subparts A, B, and I.</p> <p>(ii) Marking and labeling—49 CFR part 172: subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.440, and subpart E.</p> <p>(iii) Placarding—49 CFR part 172: subpart F, especially §§ 172.500 through 172.519, 172.556, and appendices B and C.</p> <p>(iv) Accident reporting—49 CFR part 171: §§ 171.15 and 171.16.</p> <p>v) Shipping papers and emergency information—49 CFR part 172: subparts C and G.</p> <p>(vi) Hazardous material employee training—49 CFR part 172: subpart H.</p> <p>(vii) Hazardous material shipper/carrier registration—49 CFR part 107: subpart G.</p> <p>(i) Rail—49 CFR part 174: subparts A through D and K.</p> <p>(ii) Air—49 CFR part 175.</p> <p>(iii) Vessel—49 CFR part 176: subparts A through F and M.</p> <p>(iv) Public Highway—49 CFR part 177 and parts 390 through 397.</p>	<p>13-005.01 (NRC) Typo error. "49 CFR part 170" should be "49 CFR part 107" Will change in next revision.</p>	<p><u>13-005 TRANSPORTATION OF LICENSED MATERIAL</u> <u>13-005.01</u> Each licensee who transports licensed material outside of the site of usage, as specified in the Department license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, must comply with the applicable requirements of the DOT regulation in 49 CFR part 170, <del>171</del> through 189, <del>and 390 through 397</del> appropriate to mode of transport</p> <p>1. The licensee must comply with the applicable DOT regulations in the following areas:</p> <p>a. Packaging - 49 CFR Part 173: Subparts A and B and I.</p> <p>b. Marking and labeling - 49 CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.440, and Subpart E.</p> <p>c. Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.</p> <p>d. Accident Reporting - 49 CFR Part 171: §§ 171.15 and 171.16.</p> <p>e. Shipping papers and emergency information - 49 CFR Part 172: Subparts C and G.</p> <p>f. Hazardous material employee training - 49 CFR Part 172: Subpart H.</p> <p>g. Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.</p> <p>2. The licensee must also comply with applicable DOT regulations pertaining to the following modes of transportation:</p> <p>a. Rail - 49 CFR Part 174: Subparts A through D and K.</p> <p>b. Air - 49 CFR Part 175</p> <p>c. Vessel - 49 CFR Part 176: Subparts A through F and M.</p> <p>d. Public Highway - 49 CFR Part 177 and Parts 390 through 397.</p> <p>3. Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with 180 NAC 4-038.</p>
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				(b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section 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, and any notification referred to in those requirements, must be filed with, or made to, the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.	13-005.02 NO	<u>13-005.02</u> If, for any reason, the regulations of the DOT are not applicable to a shipment of licensed material, the licensee must conform to the standards and requirements of 49 CFR Parts 170 through 189 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations.
71.6	Information collection requirements: OMB approval		D	NA	NA	
71.7	Completeness and accuracy of information		D	NA	NA	

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71.8	Deliberate misconduct		C	<p>(a) This section applies to any—</p> <p>(1) Licensee;</p> <p>(2) Certificate holder;</p> <p>(3) Quality assurance program approval holder;</p> <p>(4) Applicant for a license, certificate, or quality assurance program approval;</p> <p>(5) Contractor (including a supplier or consultant) or subcontractor, to any person identified in paragraph (a)(4) of this section; or</p> <p>(6) Employees of any person identified in paragraphs (a)(1) through (a)(5) of this section.</p> <p>(b) A person identified in paragraph (a) of this section who knowingly provides to any entity, listed in paragraphs (a)(1) through (a)(5) of this section, any components, materials, or other goods or services that relate to a licensee's, certificate holder's, quality assurance program approval holder's, or applicant's activities subject to this part may not:</p>	17-010 NO	<p><u>17-0010 DELIBERATE MISCONDUCT:</u></p> <p><u>17-0010.01</u> Any licensee, registrant, applicant for a license or registration, employee of a licensee or registrant, contractor or subcontractor to a licensee, registrant, or applicant for a license or registration, or employee of any contractor or subcontractor to a licensee, registrant, or applicant for a license or registration, who knowingly provides to any licensee, registrant, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's or applicant's activities covered by the Radiation Control Act, will not:</p> <p>1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or registration issued by the Department; or</p> <p>2. Intentionally submit to the Department, a licensee, a registrant, an applicant, or a licensee's, registrant's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.</p> <p><u>17-0010.02</u> Any person who violates 180 NAC 17-0010, is subject to the provisions of 180 NAC 17-005.</p>

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				<p>1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate holder, quality assurance program approval holder, or any applicant to be in violation of any rule, regulation, or order; or any term, condition or limitation of any license, certificate, or approval issued by the Commission; or</p> <p>(2) Deliberately submit to the NRC, a licensee, a certificate holder, quality assurance program approval holder, an applicant for a license, certificate or quality assurance program approval, or a licensee's, applicant's, certificate holder's, or quality assurance program approval holder's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.</p> <p>(c) A person who violates paragraph (b)(1) or (b)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.</p> <p>(d) For the purposes of paragraph (b)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:</p> <p>(1) Would cause a licensee, certificate holder, quality assurance program approval holder, or applicant for a license, certificate, or quality assurance program approval to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or certificate issued by the Commission; or</p> <p>(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate holder, quality assurance program approval holder, applicant, or the contractor or subcontractor of any of them.</p>		
71.9	Employee protection		D	NA	NA	
71.10	Public inspection of application		D	NA	NA	
71.11				[Reserved]		
71.12	Specific exemptions		D	NA	NA	

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71.13	Exemption of physicians		[B]	Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from § 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 must be licensed under 10 CFR part 35 or the equivalent Agreement State regulations.	13.004.02 (NRC) NO	<u>13-004.02</u> Exemption of physicians: Any physician licensed by the State of Nebraska to dispense drugs in the practice of medicine is exempt from 180 NAC 13-003 with respect to transport by the physician of radioactive material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under 180 NAC 7 or equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations.

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71.14	Exemption for low-level material		[B] paragraph (a) NRC-paragraph (b)	<p>(a) A licensee is exempt from all the requirements of this part with respect to shipment or carriage of the following low-level materials:</p> <p>(1) 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 Appendix A, Table A-2, of this part.</p> <p>(2) Materials for which the activity concentration is not greater than the activity concentration values specified in Appendix A, Table A-2 of this part, or for which the consignment activity is not greater than the limit for an exempt consignment found in Appendix A, Table A-2, of this part.</p> <p>(b) A licensee is exempt from all the requirements of this part, other than §§ 71.5 and 71.88, with respect to shipment or carriage of the following packages, provided the packages do not contain any fissile material, or the material is exempt from classification as fissile material under § 71.15 (1) A package that contains no more than a Type A quantity of radioactive material;</p> <p>(2) A package transported within the United States that contains no more than 0.74 TBq (20 Ci) of special form plutonium-244; or</p> <p>(3) The package contains only LSA or SCO radioactive material, provided—</p> <p>(i) That the LSA or SCO material has an external radiation dose of less than or equal to 10 mSv/h (1 rem/h), at a distance of 3 m from the unshielded material; or</p> <p>(ii) That the package contains only LSA-I or SCO-I material</p>	13-004.03 (NRC) NO	<p><u>13-004.03 Exemption for low-level materials:</u> Any licensee is exempt from the requirements of 180 NAC 13 with respect to shipment or carriage of the following low-level materials:</p> <p>1. 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 Appendix 13-A, Table A-2.</p> <p>2. Materials for which the activity concentration is not greater than the activity concentration values specified in Appendix 13-A, Table A-2, or for which the consignment activity is not greater than the limit for an exempt consignment found in Appendix 13-A, Table A-2.</p>

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71.15	Exemption from classification as fissile material		[B]	<p>Fissile material meeting the requirements of at least one of the paragraphs (a) through (f) of this section are exempt from classification as fissile material and from the fissile material package standards of §§ 71.55 and 71.59, but are subject to all other requirements of this part, except as noted.</p> <p>(a) Individual package containing 2 grams or less fissile material.</p> <p>(b) 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 must not be included in determining the required mass for solid nonfissile material.</p> <p>(c)(1) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:</p> <p>(i) There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and</p> <p>(ii) There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.</p> <p>(2) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.</p> <p>d) Uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with total plutonium and uranium-233 content of up to 1 percent 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.</p>	13-004.04 (NRC) NO	<p><u>13-004.04 Exemption from classification as fissile material:</u> Fissile material meeting the requirements of at least one of the items of 180 NAC 13-004.04, item 1 through 6 are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 71.59, but are subject to all other requirements of 180 NAC 13, except as noted.</p> <ol style="list-style-type: none"> <li>1. Individual package containing 2 grams or less fissile material.</li> <li>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 must not be included in determining the required mass for solid nonfissile material.</li> <li>3. Packages containing: <ol style="list-style-type: none"> <li>a. Low concentrations of solid fissile material commingled with solid nonfissile material, provided that: <ol style="list-style-type: none"> <li>(1) There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and</li> <li>(2) There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.</li> </ol> </li> <li>b. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.</li> </ol> </li> <li>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 percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5% of the uranium mass.</li> </ol>

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				(e) 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 must be contained in at least a DOT Type A package. (f) 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.		5. Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2% by mass, with a total plutonium and uranium-233 content not exceeding 0.002% of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must 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% by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.
71.16				[Reserved]		
71.17	General license: NRC-approved package		[B]	(a) A general license is issued to any licensee of the Commission to transport, or to deliver to a carrier for transport, licensed 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 Commission as satisfying the provisions of subpart H of this part. (c) This general license applies only to a licensee who— (1) Has a copy of the CoC, or other approval 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; (2) Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G, and H of this part; and	13-007.01 (NRC) NO  13-007.02 (NRC) NO	<u>13-007 GENERAL LICENSE: U.S. NUCLEAR REGULATORY COMMISSION NRC APPROVED PACKAGES</u> <u>13-007.01</u> A general license is hereby issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the NRC. <u>13-007.02</u> This general license applies only to a licensee who: 1. Has a copy of the specific license, certificate of compliance, 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 prior to shipment; 2. Complies with the terms and conditions of the license, certificate, or other approval by the NRC, as applicable, and the applicable requirements of 180 NAC 13;

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				<p>(3) 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 § 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.</p> <p>(d) This general license applies only when the package approval authorizes use of the package under this general license.</p> <p>(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 § 71.19.</p>	<p>13-007.03 (NRC) NO 13-007.04 (NRC) NO</p>	<p>3. Prior to the licensee's first use of the package, has registered with the NRC; and</p> <p>4. Has a quality assurance program required by 180 NAC 13-021.</p> <p><u>13-007.03</u> The general license in 180 NAC 13-007.01 applies only when the package approval authorizes use of the package under this general license.</p> <p><u>13-007.04</u> For a Type B or fissile material package, the design of which was approved before April 1, 1996 the general license is subject to the additional restrictions of 10 CFR 71.19.</p>
71.18				[Reserved]		

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71.20	General license: DOT specification container		[B]	<p>(a) A general license is issued to any licensee of the Commission 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 DOT regulations at 49 CFR parts 173 and 178.</p> <p>(b) This general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of this part.</p> <p>(c) This general license applies only to a licensee who—  (1) Has a copy of the specification; and  (2) Complies with the terms and conditions of the specification and the applicable requirements of subparts A, G, and H of this part.</p> <p>(d) This general license 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 DOT regulations at 49 CFR 173.403.</p> <p>(e) This section expires October 1, 2008.</p>	<p>13-009.01 (NRC) NO</p> <p>13-009.02 (NRC) NO</p> <p>13-009.03 (NRC) NO</p> <p>13-009.04 (NRC) NO</p>	<p><del>13-009 RESERVED</del>  <del>13-009 GENERAL LICENSE: DOT SPECIFICATION CONTAINER</del>  <del>13-009.01 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 49 CFR Parts 173 and 178.</del>  <del>13-009.02 Except as otherwise provided in 180 NAC 13, the general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the applicable provision of 180 NAC 13-021.</del>  <del>13-009.03 This general license applies only to a licensee who:</del>  <del>1. Has a copy of the specification;</del>  <del>2. Complies with the terms and conditions of the specification and the applicable requirements of 180 NAC 13; and</del>  <del>3. Has a quality assurance program required by 180 NAC 13-021.</del>  <del>13-009.04 The general license in 180 NAC 13-009.01 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 49 CFR 173.403.</del></p>

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71.21	General license: Use of foreign approved package		[B]	<p>(a) A general license is issued to any licensee of the Commission 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 DOT as meeting the applicable requirements of 49 CFR 171.12.</p> <p>(b) Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the applicable provisions of subpart H of this part.</p> <p>(c) This general license applies only to shipments made to or from locations outside the United States.</p> <p>(d) This general license applies only to a licensee who—</p> <p>(1) 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 before shipment; and</p> <p>(2) Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of subparts A, G, and H of this part. With respect to the quality assurance provisions of subpart H of this part, the licensee is exempt from design, construction, and fabrication considerations.</p>	<p>13-010.1 (NRC) Yes Need add in next revision</p>	<p><del>13-010 Reserved</del> <del>13-010 GENERAL LICENSE: USE OF FOREIGN APPROVED PACKAGE</del> <del>13-010.01 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 which has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.12.</del> <del>13-010.02 Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the U.S. Nuclear Regulatory Commission as satisfying the applicable provisions of 10 CFR 71, subpart H.</del> <del>13-010.03 This general license applies only to international shipments.</del> <del>13-010.04 This general license applies only to a licensee who:</del> <del>1. 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</del> <del>2. Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of 180 NAC 13.</del> <del>3. Has a quality assurance program approved by the Department.</del> <del>**With respect to the quality assurance provision of 180 NAC 7-021, the licensee is exempt from design, construction, and fabrication considerations.</del></p>

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71.22	General license: Fissile material		[B]	<p><b>REFERENCE 10CFR71 for Tables 71-1 and 71-2</b></p> <p>(a) A general license is issued to any licensee of the Commission 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 which meets the standards of subparts E and F of this part; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).</p> <p>(b) The general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of this part.</p> <p>(c) The general license applies only when a package's contents:</p> <p>(1) Contain less than a Type A quantity of fissile material; and</p> <p>(2) Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.</p> <p>(d) The general license applies only to packages containing fissile material that are labeled with a CSI which:</p> <p>(1) Has been determined in accordance with paragraph (e) of this section;</p> <p>(2) Has a value less than or equal to 10; and</p> <p>(3) For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use</p>	<p>13-011.01 (NRC) NO</p> <p>13-011.02 (NRC)</p> <p>13-011.03 (NRC)</p> <p>13-011.04 (NRC)</p>	<p><b>13-011 GENERAL LICENSE: FISSILE MATERIAL</b></p> <p><u>13-011.01</u> A general license is hereby 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 <del>this</del> 180 NAC 13-011. The fissile material need not be contained in a package which meets the standards of 10 CFR 71 subparts E and F; however the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).</p> <p><u>13-011.02</u> The general license applies only to a licensee who has a quality assurance program approved by the Department.</p> <p><u>13-11.03</u> he general license applies only when a package's contents:</p> <p>1. Contains less than a Type A quantity of fissile material; and</p> <p>2. Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium</p> <p><u>13-011.04</u> The general license applies only to packages containing fissile material that are labeled with a CSI which</p> <p>1. Has been determined in accordance with 180 NAC 13-011.05;</p> <p>2. Has a value less than or equal to 10; and</p> <p>3. For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance)</p>

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				<p>conveyance).</p> <p>(e)(1) The value for the CSI must be greater than or equal to the number calculated by the following equation:</p> <div style="border: 1px solid black; background-color: red; width: 200px; height: 20px; margin: 10px auto;"></div> <p>(2) The calculated CSI must be rounded up to the first decimal place;</p> <p>(3) The values of X, Y, and Z used in the CSI equation must be taken from Tables 71-1 or 71-2, as appropriate;</p> <p>(4) If Table 71-2 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and</p> <p>(5) Table 71-1 values for X, Y, and Z must be used to determine the CSI if:</p> <p>(i) Uranium-233 is present in the package;</p> <p>(ii) The mass of plutonium exceeds 1 percent of the mass of uranium-235;</p> <p>(iii) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or</p> <p>(iv) Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H<sub>2</sub>O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.</p>	13-011.05 (NRC) NO	<p><u>13-011.05 CSI determination:</u></p> <p>1. The value for the CSI must be greater than or equal to the number calculated by the following equation:</p> $CSI = 10 \left[ \frac{\text{grams of } ^{235}\text{U}}{X} + \frac{\text{grams of } ^{233}\text{U}}{Y} + \frac{\text{grams of Pu}}{Z} \right];$ <p>2. The calculated CSI must be rounded up to the first decimal place;</p> <p>3. The values of X, Y, and Z used in the CSI equation must be taken from Table 13 -1 or Table 13-2, as appropriate;</p> <p>4. If Table 13-2 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and</p> <p>5. Table 13-1 values for X, Y., and Z must be used to determine the CSI if:</p> <p>a. Uranium-233 is present in the package;</p> <p>b. The mass of the plutonium exceeds 1% of the mass of uranium-235;</p> <p>c. The uranium is unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or</p> <p>d. Substances having a moderating effectiveness (that is, an average hydrogen density greater than H<sub>2</sub>O (for example, certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.</p>
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71.23	General license: Plutoniumberyllium special form material		[B]	(a) A general license is issued to any licensee of the Commission 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 which meets the standards of subparts E and F of this part; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).	13-012  13-012.01 (NRC) NO	<del>13-012 GENERAL LICENSE: PLUTONIUM-BERYLLIUM SPECIAL FORM MATERIAL</del> <u>13-012.01</u> A general license is hereby issued to any licensee to transport fissile material, or to deliver 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 subsection. This material need not be contained in package which meets the standards of 10 CFR 71 subpart E and F; however the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 40 CFR 173.417(a).

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				<p>(b) The general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of this part.</p> <p>(c) The general license applies only when a package's contents:</p> <p>(1) Contain less than a Type A quantity of material; and</p> <p>(2) Contain less than 1000 g 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.</p> <p>(d) The general license applies only to packages labeled with a CSI which:</p> <p>(1) Has been determined in accordance with paragraph (e) of this section;</p> <p>(2) Has a value less than or equal to 100; and</p> <p>(3) For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and and less than or equal to 100 (for shipment on an exclusive use conveyance).</p> <p>(e)(1) The value for the CSI must be greater than or equal to the number calculated by the following equation:</p> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 5px auto;"> <del> <math display="block">\frac{100 \times \text{Total Weight of Pu-Be Sources}}{\text{Total Weight of Pu-Be Sources} + 100}</math> </del> </div> <p>(2) The calculated CSI must be rounded up to the first decimal place.</p>	<p>13-012.03 (NRC) NO</p> <p>13-012.04 (NRC) NO</p> <p>13-012.05 (NRC) NO</p>	<p><u>13-012.03</u> The general license applies only to a licensee who has a quality assurance program approved by the Department.</p> <p>13-012.04 The general license applies only to packages labeled with a CSI which:</p> <ol style="list-style-type: none"> <li>1. Has been determined per 180 NAC 13-012.05;</li> <li>2. Has a value less than or equal to 100; and</li> <li>3. For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).</li> </ol> <p>13-012.05 CSI determination:</p> <ol style="list-style-type: none"> <li>1. The value for the CSI must be greater than or equal to the number calculated by the following equation: ;and (see equation in text of 180 NAC 13-0`1.05)</li> <li>2. The calculated CSI must be <u>rounded up to the first decimal place.</u></li> </ol>
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71.24				[Reserved]		
71.25				[Reserved]		
71.47	External radiation standards for all packages		[B]	<p>(a) Except as provided in paragraph (b) of this section, each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed 10.</p> <p>(b) A package that exceeds the radiation level limits specified in paragraph (a) of this section must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:</p> <p>(1) 2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):</p> <p>(i) The shipment is made in a closed transport vehicle;</p> <p>(ii) The package is secured within the vehicle so that its position remains fixed during transportation; and</p> <p>(iii) There are no loading or unloading operations between the beginning and end of the transportation;</p> <p>(2) 2 mSv/h (200 mrem/h) 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</p> <p>(3) 0.1 mSv/h (10 mrem/h) at any point 2 meters (80 in) 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 meters (6.6 feet) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and</p>	13-015.11 NO	<p><u>13-015.101</u> For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in 180 NAC 13-015.09 but must not exceed any of the following:</p> <p>1. 2 mSv/h (200 mrem/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/hr);</p> <p>a. The shipment is made in a closed transport vehicle,</p> <p>b. Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and</p> <p>c. There are no loading or unloading operations between the beginning and end of the transportation.</p> <p>2. 2 mSv/h (200 mrem/hr) at any point on the outer surface of the vehicle, including the upper and top and underside of the vehicle, or, in the case of a flat-bed style vehicle, with a personnel barrier<sup>2</sup>, 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<sup>2</sup>;</p> <p>3. 0.1 mSv/h (10 mrem/hr) at any point 2 meters 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 meters from the vertical planes projected from the outer edges of the vehicle; and</p>

<sup>2</sup>A flat-bed style vehicle with a personnel barrier must have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 2 mSv/h (200 mrem/hr) at the surface.\*

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				<p>(4) 0.02 mSv/h (2 mrem/h) 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 10 CFR 20.1502.</p> <p>(c) For shipments made under the provisions of paragraph (b) of this section, the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.</p> <p>(d) The written instructions required for exclusive use shipments must 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.</p>		<p>4. 0.02 mSv/h (2 mrem/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 180 NAC 10-003; and 13-015.1<del>12</del><sup>12</sup>. A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 185 degrees Fahrenheit (85 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures must not exceed these limits at any time during transportation.</p> <p>13-015.1<del>23</del><sup>23</sup>. A package may not incorporate a feature intended to allow continuous venting during transport.</p>
71.53				[Reserved]		
71.81	Applicability of operating controls and procedures		D	NA	NA	
71.83	Assumptions as to unknown properties		[B]	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.	<del>13-013</del> <sup>13</sup> -013 (NRC) NO	<del>13-013</del> <sup>13</sup> 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 must package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

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71.85	Preliminary determinations		[B]	<p>Before the first use of any packaging for the shipment of licensed material --</p> <p>(a) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;</p> <p>(b) Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in<sup>2</sup>) gauge, the licensee shall 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</p> <p>(c) The licensee shall 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 Commission.</p>	<p><del>713-014.01</del> (NRC) NO</p> <p><del>713-014.02</del> (NRC) NO</p> <p><del>713-014.0</del> NO</p>	<p><del>13-014 PRELIMINARY DETERMINATIONS:</del> Prior to the first use of any packaging for the shipment of licensed material:</p> <p><del>13-014.01</del> The licensee must ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects which could significantly reduce the effectiveness of the packaging;</p> <p><del>13-014.02</del> Where the maximum normal operating pressure will exceed 35 kilopascal (5 lbf/in<sup>2</sup>) gauge, the licensee must test the containment system at an internal pressure at least 50% higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;</p> <p><del>13-014.03</del> The licensee must determine that the packaging has been fabricated in accordance with the design approved by the NRC; and</p> <p><del>13-014.04</del> The licensee must conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by the NRC.</p>
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71.87	Routine determinations		[B]	<p>Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this part and of the license. The licensee shall determine that --</p> <p>(a) The package is proper for the contents to be shipped;</p> <p>(b) The package is in unimpaired physical condition except for superficial defects such as marks or dents;</p> <p>(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;</p> <p>(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;</p> <p>(e) Any pressure relief device is operable and set in accordance with written procedures;</p> <p>(f) The package has been loaded and closed in accordance with written procedures;</p> <p>(g) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;</p>	<p>13-015 (NRC) NO</p> <p>7-015.01 NO</p> <p>7-015.02 NO</p> <p>7-015.03 NO</p> <p>7-015.04 NO</p> <p>13-015.05 (NRC) NO</p> <p>13-015.06 NO</p>	<p><u>13-015 ROUTINE DETERMINATIONS:</u> Prior to each shipment of licensed material, the licensee must ensure that the package with its contents satisfies the applicable requirements of 180 NAC 13-015 and of the licensee. The licensee must determine that:</p> <p><u>13-015.01</u> The package is proper for the contents to be shipped;</p> <p><u>13-015.02</u> The package is in unimpaired physical condition except for superficial defects such as marks or dents;</p> <p><u>13-015.03</u> Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;</p> <p><u>13-015.04</u> Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;</p> <p><u>13-015.05</u> Any pressure relief device is operable and set in accordance with written procedures;</p> <p><u>13-015.06</u> The package has been loaded and closed in accordance with written procedures;</p> <p><u>13-015.07</u> For fissile material, any moderator or neutron absorber, if required, is present and in proper condition.</p>

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71.87	Routine determinations		[B]	<p>(h) 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 § 71.45;</p> <p>(i) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in DOT regulations in 49 CFR 173.443;</p> <p>(j) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in § 71.47 at any time during transportation; and</p>	<p>13-015.07 (NRC) NO</p> <p>13-015.08 (NRC) NO</p> <p>13-015.09 (NRC) NO</p>	<p><del>13-015.078</del> Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;</p> <p><del>13-015.089</del> The level of removable radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable. The level of removable radioactive contamination may be determined by wiping an area of 300 square centimeters 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 180 NAC 13-015.08, item (1), the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in TABLE 13-3 of 180 NAC 13-015 at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When 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 TABLE 13-3.</p> <p>1. 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 180 NAC 13-015.08. The levels at the beginning of transport must not exceed the levels in 180 NAC 13-015.08;</p> <p><del>13-015.0910</del> External radiation levels around the package and around the vehicle, if applicable, will not exceed 2 mSv/h (200 mrem/hr) at any point on the external surface of the package at any time during transportation. The transport index must not exceed 10.;</p>

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				(k) Accessible package surface temperatures will not exceed the limits specified in § 71.43(g) at any time during transportation.	13-015.11 NO	13-015.11 <sup>12</sup> A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 185 degrees Fahrenheit (85 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures must not exceed these limits at any time during transportation.

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71.88	Air transport of plutonium		[B]	<p>(a) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this part or included indirectly by citation of 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:</p> <p>(1) The plutonium is contained in a medical device designed for individual human application; or</p> <p>(2) 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 Appendix A, Table A-2, of this part, and in which the radioactivity is essentially uniformly distributed; or</p> <p>(3) The plutonium is shipped in a single package containing no more than an A2 quantity of plutonium in any isotope or form, and is shipped in accordance with § 71.5; or</p> <p>(4) 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 Commission.</p> <p>(b) Nothing in paragraph (a) of this section is to be interpreted as removing or diminishing the requirements of § 73.24 of this chapter.</p> <p>(c) For a shipment of plutonium by air which is subject to paragraph (a)(4) of this section, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.</p>	<p>13-016.01 (NRC) NO</p> <p>13-016.02 (NRC) NO</p> <p>13-015.03 (NRC) NO</p>	<p><u>13-016 AIR TRANSPORT OF PLUTONIUM</u> <u>13-016.01</u> Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Section or included indirectly by citation of the DOT regulations, as may be applicable, the licensee must assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:</p> <p>1. The plutonium is contained in a medical device designed for individual human application; or</p> <p>2. 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 Appendix 13-A, Table A-2, and in which the radioactivity is essentially uniformly distributed; or</p> <p>3. The plutonium is shipped in a single package containing no more than an A<sub>2</sub> quantity of plutonium in any isotope or form and is shipped in accordance with 180 NAC 13-005; or</p> <p>4. 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.</p> <p><u>13-016.02</u> Nothing in 180 NAC 13-016.01 is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.</p> <p><u>13-016.03</u> For a shipment of plutonium by air which is subject to 180 NAC 13-015.04, the licensee must, through special arrangement with the carrier, require compliance with 49 CFR 175.704, the DOT regulations applicable to the air transport of plutonium.</p>

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71.89	Opening instructions		[B]	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 10 CFR 20.1906(e).	3-017 (NRC) NO	<u>13-017 OPENING INSTRUCTIONS:</u> Before delivery of a package to a carrier for transport, the licensee must 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 180 NAC 4-038.
71.91	Records		D	NA	13-018	
71.93	Inspection and tests		D	NA		
71.95	Reports		D	NA	13-019	

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71.97	Advance notification of shipment of irradiated reactor fuel and nuclear waste		B	<p>(a) As specified in paragraphs (b), (c) and (d) of this section, each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, through, or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.</p> <p>(b) Advance notification is required under this section for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of § 73.37(f) of this chapter. Advance notification is also required under this section for shipment of licensed material, other than irradiated fuel, meeting the following three conditions:</p> <p>(1) The licensed material is required by this part to be in Type B packaging for transportation;</p> <p>(2) The licensed material 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</p> <p>(3) The quantity of licensed material in a single package exceeds the least of the following:</p> <p>(i) 3000 times the A<sub>1</sub> value of the radionuclides as specified in appendix A, Table A-1 for special form radioactive material;</p> <p>(ii) 3000 times the A<sub>2</sub> value of the radionuclides as specified in appendix A, Table A-1 for normal form radioactive material; or</p> <p>(iii) 1000 TBq (27,000 Ci).</p> <p>(c) Procedures for submitting advance notification. (1) The notification must be made in writing to the office of each appropriate governor or governor's designee and to the Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response.</p> <p>(2) A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.</p>	13-020	<p><u>13-020 ADVANCE NOTIFICATION OF TRANSPORT OF NUCLEAR WASTE</u></p> <p><u>13-020.01</u> Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee must provide advance notification of such transport to the governor, or governor's designee, of each state within or through which the waste will be transported.<sup>3</sup></p> <p><u>13-020.02</u> Advance notification is required only when:</p> <ol style="list-style-type: none"> <li>1. The nuclear waste is required to be in Type B packaging for transportation;</li> <li>2. The nuclear waste is being transported into, within, or through, a state enroute to a disposal facility or to a collection point for transport to a disposal facility; and</li> <li>3. The quantity of licensed material in a single package exceeds: <ol style="list-style-type: none"> <li>a. 3000 times the A<sub>1</sub> value of the radionuclides as specified in Appendix 13-A, Table I for special form radioactive material;</li> <li>b. 3000 times the A<sub>2</sub> value of the radionuclides as specified in Appendix 13-A, Table I for normal form radioactive material; or</li> <li>c. 1000 TBq (27,000 Ci).</li> </ol> </li> </ol>
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<sup>3</sup>A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State Programs, NRC, Washington, D.C. 20555. The list will be published annually in the Federal register on or about June 30 to reflect any changes in information.

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				<p>(3) A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.</p> <p>(i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).</p> <p>(ii) The list will be published annually in the Federal Register on or about June 20 to reflect any changes in information.</p> <p>(iii) A list of the names and mailing addresses of the governors' designees is available on requests from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001</p> <p>(4) The licensee shall retain a copy of the notification as a record for 3 years.</p> <p>(d) Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:</p> <p>(1) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;</p> <p>(2) A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of DOT in 49 CFR 172.202 and 172.203(d);</p>	13-020.03 NO	<p><u>13-020.03</u> Each advance notification required by 180 NAC 13-020.01 must contain the following information:</p> <p>1. The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;</p> <p>2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);</p>
				<p>(3) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;</p> <p>(4) The 7-day period during which arrival of the shipment at State boundaries is estimated to occur;</p> <p>(5) The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and</p> <p>(6) A point of contact, with a telephone number, for current shipment information.</p>		<p>3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;</p> <p>4. The seven-day period during which arrival of the shipment at state boundaries is estimated to occur;</p> <p>5. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and</p> <p>6. A point of contact with a telephone number for current shipment information.</p>

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						<p><u>13-020.04</u> The notification required by 180 NAC 13-020.01 must be made in writing to the office of each appropriate governor, or governor's designee, and to the <b>Agency U.S. Nuclear Regulatory Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response</b>. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or 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. A copy of the notification must be retained by the licensee for <b>one three</b> years.</p> <p><u>13-020.05</u> The licensee must notify each appropriate governor, or governor's designee, and the Department of any changes to schedule information provided pursuant to 180 NAC 13-020.01. Such notification must be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee must maintain for one year a record of the name of the individual contacted.</p> <p><u>13-020.06</u> Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, must send a cancellation notice, identifying the advance notification that is being canceled, to the governor, or governor's designee, of each appropriate state and to the Agency Department. A copy of the notice must be retained by the licensee for <b>one three</b> years.</p>
71.100	Criminal penalties.		D	NA		

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71.101	Quality assurance requirements		D- Paragraphs (a), (b), and (c)(1) are designated D for those States which have no users of Type B packages other than Industrial Radiography** C- Paragraphs (a), (b)	(a) Purpose. This subpart 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. As used in this subpart, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. 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. The licensee, certificate holder, and applicant for a CoC are responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging. Each licensee is responsible for the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to this subpart.	13-021 NO	<p><b>No licensees that use type B containers</b></p> <p><b>13-021 QUALITY ASSURANCE REQUIREMENTS</b></p> <p><b>13-021.01</b> Unless otherwise authorized by the Department, each licensee, certificate holder and applicant for a CoC must establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.</p> <p><b>13-021.02</b> The licensee, certificate holder and applicant for a CoC must identify the material and components to be covered by the quality assurance program.</p> <p><b>13-021.03</b> Each licensee, certificate holder and applicant for a CoC must document the quality assurance program by written procedures or instructions and must carry out the program in accordance with those procedures throughout the period during which packaging is used.</p>
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			and (c)(1) are designated C for those States which have users of Type B packages other than Industrial Radiography.** D-paragraph (f) C-paragraph (g) NRC-paragraphs (c)(2), (d) and (e) **Note: 10 CFR Part 71.101 (g) indicates that QA programs for industrial radiography Type B Package users are covered	(b) Establishment of program. Each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of §§ 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee, certificate holder, and applicant for a CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety. (c) Approval of program (1) Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Commission approval of its quality assurance program. Using an appropriate method listed in § 71.1(a), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards. (2) Before the fabrication, testing, or modification of any package for the shipment of licensed material subject to this subpart, each licensee, certificate holder, or applicant for a CoC shall obtain Commission approval of its quality assurance program. Each certificate holder or applicant for a CoC shall, in accordance with § 71.1, file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied. (d) Existing package designs. The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979, and which have been designed in accordance with the provisions of this part in effect at	<u>13-021.04</u> Prior to the use of any package for the shipment of radioactive material, each licensee, certificate holder and applicant for a CoC must obtain approval by the Department of its quality assurance program.  <u>13-021.05</u> The licensee, certificate holder and applicant for a CoC must maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material must be maintained for a period of three years after shipment.	
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			by 10 CFR 34.31(b). It is also indicated that this section satisfies § 71.12 (b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137)	<p>the time of application for package approval. Those packages will be accepted as having been designed in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.</p> <p>(e) Existing packages. The provisions of this paragraph deal with packages that have been approved for use in accordance with this part (before January 1, 1979, have been at least partially fabricated before that date, and for which the fabrication is in accordance with the provisions of this part in effect at the time of application for approval of package design. These packages will be accepted as having been fabricated and assembled in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.</p> <p>(f) Previously approved programs. A Commission-approved quality assurance program that satisfies the applicable criteria of subpart H of this part, Appendix B of part 50 of this chapter, or subpart G of part 72 of this chapter, and that is established, maintained, and executed regarding transport packages, will be accepted as satisfying the requirements of paragraph (b) of this section. Before first use, the licensee, certificate holder, and applicant for a CoC shall notify the NRC, in accordance with § 71.1, of its intent to apply its previously approved subpart H, Appendix B, or subpart G quality assurance program to transportation activities. The licensee, certificate holder, and applicant for a CoC shall identify the program by date of submittal to the Commission, Docket Number, and date of Commission approval.</p> <p>(g) 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 § 34.31(b) of this chapter or equivalent Agreement State requirement, is deemed to satisfy the requirements of §§ 71.17(b) and 71.101(b).</p>	13-021.06 (NRC) NO	<p>▲ - - - - -</p> <p><b>13-021.06</b> The licensee, certificate holder and applicant for a CoC must maintain a program for transport container inspection and maintenance limited to radiographic exposure devices, source changer, or packages transporting these devices and meeting the requirements of 180 NAC 5-011 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements.</p>
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71.103	Quality assurance organization		D- for those States which have no users of Type B packages- other than Industrial Radiography** [C]- Paragraph h (a) is designated [C] for those States which have users of Type B packages other than Industrial Radiography**	(a) The licensee , certificate holder, and applicant for a CoC shall 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. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions. (b) The quality assurance functions are— (1) Assuring that an appropriate quality assurance program is established and effectively executed; and (2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed. (c) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to— (1) Identify quality problems; (2) Initiate, recommend, or provide solutions; and (3) Verify implementation of solutions. (d) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided. or subpart G quality assurance program to transportation activities. The licensee, certificate holder, and applicant for a CoC shall identify the program by date of submittal to the Commission, Docket Number, and date of Commission approval. (g) Radiography containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or	N-A	

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			<p>C- Paragraph h (b) is designated C for those States which have users of Type B packages- other than Industrial Radiography**</p> <p>D- paragraphs (d), (e), and (f)</p> <p>**Note: 10 CFR Part 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by 10 CFR 34.31 (b). It also indicated that this section</p>	<p>(e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.</p> <p>(f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.</p> <p>-----</p> <p>2 While the term "licensee" is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued.</p>		<p>▲</p>
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			satisfies §71.12 (b) and thus would satisfy those sections referenced in this provision (§§71.101 through 71.137.)			
71.105	Quality assurance program		D- for those States which have no users of Type B packages- other than Industrial Radiography** or C- Paragraphs (a), (c), and (d) and [C] - paragraph b for those States which have users of	a) The licensee, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of §§ 71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC shall 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. The licensee, certificate holder, and applicant for a CoC shall 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. b) The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall 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. The licensee,	NA	<b>No licensees that use type B containers</b>

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			<p>Type B packages-other than Industrial Radiography**</p> <p>**Note: 10 CFR Part 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by 10 CFR 34.31 (b). It also indicated that this section satisfies §71.12 (b) and thus would satisfy those sections referenced in this provision (§§71.101 through 71.137.)</p>	<p>certificate holder, and applicant for a CoC shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied.</p> <p>The licensee, certificate holder, and applicant for a CoC shall 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.</p> <p>(c) 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:</p> <ol style="list-style-type: none"> <li>(1) The impact of malfunction or failure of the item to safety;</li> <li>(2) The design and fabrication complexity or uniqueness of the item;</li> <li>(3) The need for special controls and surveillance over processes and equipment;</li> <li>(4) The degree to which functional compliance can be demonstrated by inspection or test; and</li> <li>(5) The quality history and degree of standardization of the item.</li> </ol> <p>(d) 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. 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.</p>		
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71.127	Handling, storage, and shipping control		D- for those States which have no users of Type B packages-other than Industrial Radiography** [C]- for those States which have users of Type B packages-other than Industrial Radiography** **Note: 10 CFR Part 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by 10 CFR 34.31 (b).	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.	NO	<b>No licensees that use type B containers</b> <b>13-021.07 Handling, storage, and shipping control:</b> The licensee, certificate holder, and applicant for a CoC must 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.
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			It also indicated that this section satisfies §71.12 (b) and thus would satisfy those sections referenced in this provision (§§71.101 through 71.137.			
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71.129	Inspection, test, and operating status		D- for those States which have no users of Type B packages- other than Industrial Radiography** [C]- for those States which have users of Type B packages- other than Industrial	(a) 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. (b) 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	NO	<p><b>No licensees that use type B containers</b>  <b>13-021.08 Inspection, test, and operating status.</b></p> <p>The licensee, certificate holder, and applicant for a CoC must 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.</p> <p>The licensee must establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.</p> <p><b>13-021.09 Nonconforming materials, parts, or components:</b> The licensee, certificate holder, and applicant for a CoC must 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, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organization. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.</p>

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			Radiography** **Note: 10 CFR Part 71.101 (g) programs for industrial radiography Type B package users are covered by 10 CFR 34.31 (b). It also indicated that this section satisfies §71.12 (b) and thus would satisfy those sections referenced in this provision (§§71.101 through 71.137.)			
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71.131	Nonconforming materials, parts, or components		D- for those States which have no users of Type B packages-other than Industrial Radiography** [C]- for those States which have users of Type B packages-other than Industrial Radiography** **Note: 10 CFR Part 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by 10 CFR 34.31 (b).	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, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.	NO	<p><b>No licensees that use type B containers</b></p> <p><b>13-021.10 Corrective Actions:</b> The licensee, certificate holder, and applicant for a CoC must establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. 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. 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.</p>

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			It also indicated that this section satisfies §71.12(b) and thus would satisfy those sections referenced in this provision (§§71.101 through 71.137.)			
71-135	Quality assurance records		D- for those States which have no users of Type B packages other than Industrial Radiography** C- for those States which have users of Type B packages other than	The licensee, certificate holder, and applicant for a CoC shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions, procedures, and drawings required by §71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the 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. The licensee, certificate holder, and applicant for a CoC shall retain these records 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.	NO	<b>No licensees that use type B containers</b> <u>13-021.11 Quality assurance records:</u> The licensee, certificate holder, and applicant for a CoC must maintain sufficient written records to describe the activities affecting quality. The records must include the instruction, procedures, and drawings to prescribe quality assurance activities and must include closely related specifications such as required qualification of personnel, procedures, and equipment. The records must include the 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. The licensee, certificate holder, and applicant for a CoC must retain these records for three years beyond the date which 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 instruction is superseded, the licensee, certificate holder, and applicant for a CoC must retain the superseded material for three years after it is superseded.

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			<p>Industrial Radiography**  **Note: 10 CFR Part 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by 10 CFR 34.31 (b). It also indicated that this section satisfies §71.12 (b) and thus would satisfy those sections referenced in this provision( §§71.101 through 71.137.)</p>			
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71.137	Audits		<p>D- for those States which have no users of Type B packages-other than Industrial Radiography**</p> <p>C - for those States which have users of Type B packages-other than Industrial Radiography**</p> <p>**Note: 10 CFR Part 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by 10 CFR</p>	<p>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 audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.</p>	NO	<p><b>No licensees that use type B containers</b></p> <p>13-021.12 Audits: The licensee, certificate holder, and applicant for a CoC must 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 audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.</p>
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			34.31 (b). It also indicated that this section satisfies §71.12 (b) and thus would satisfy those sections reference d in this provision (§§71.101 through 71.137.)			
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Appendix A to Part 71	Determination of A1 and A2		[B]	<p><b>REFERENCE 10CFR71 FOR TABLES A-1, A-2, A-3, and A-4</b></p> <p>I. Values of A1 and A2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations, are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A1 and A2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.</p> <p>II. a. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the A1 and A2 values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Commission approval of the A1 and A2 values for radionuclides not listed in Table A-1, before shipping the material.</p> <p>b. For individual radionuclides whose identities are known, but which are not listed in Table A-2, the exempt material activity concentration and exempt consignment activity values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Commission approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table A-2, before shipping the material.</p> <p>c. The licensee shall submit requests for prior approval, described under paragraphs II.a. and II.b. of this Appendix, to the Commission, in accordance with § 71.1 of this part.</p>	180 NAC 13 Appendix 13-A (NRC) NO	<p><b>See Appendix 13- DETERMINATION OF A<sub>1</sub> AND A<sub>2</sub></b></p> <p>I. Values of A<sub>1</sub> and A<sub>2</sub> for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) value. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A<sub>1</sub> or A<sub>2</sub> are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.</p> <p>II. a. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the A<sub>1</sub> and A<sub>2</sub> values contained in Table A-3 may be used. Otherwise the licensee must obtain prior Department approval of the A<sub>1</sub> and A<sub>2</sub> values for radionuclides not listed in Table A-1, before shipping the material.</p> <p>b. For individual radionuclides whose identities are known, but which are not listed in Table A-2, the exempt material activity concentration and exempt consignment activity values contained in Table A-3 may be used. Otherwise, the licensee must obtain prior Department approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table A-2, before shipping the material.</p> <p>c. The licensee must submit requests for prior approval, described under paragraphs II.a. and II.b. of this Appendix, to the Department, in accordance with 180 NAC 1-012.</p>

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				<p>III. In the calculations of A<sub>1</sub> and A<sub>2</sub> for a radionuclide not in Table A-1, 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 10 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<sub>1</sub> and A<sub>2</sub> 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 10 days, or greater than that of the parent radionuclide, the parent and those daughter radionuclides shall be considered as mixtures of different radionuclides.</p>		<p>III. In the calculations of A<sub>1</sub> and A<sub>2</sub> for a radionuclide not in Table A-1, 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 10 days, or longer than that of the parent radionuclide, must be considered as a single radionuclide, and the activity to be taken into account, and the A<sub>1</sub> and A<sub>2</sub> value to be applied must be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter radionuclide has a half-life either longer than 10 days, or greater than that of the parent radionuclide, the parent and those daughter radionuclides must be considered as mixtures of different nuclides.</p>
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				<p>IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:</p> <p>a. For special form radioactive material, the maximum quantity transported in a Type A package is as follows:</p> <div style="text-align: center;"></div> <p>where B(i) is the activity of radionuclide i and A<sub>1</sub>(i) is the A<sub>1</sub> value for radionuclide i.</p> <p>b. For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:</p> <div style="text-align: center;"></div> <p>where B(i) is the activity of radionuclide i and A<sub>2</sub>(i) is the A<sub>2</sub>(i) value for radionuclide i.</p> <p>c. Alternatively, the A<sub>1</sub> value for mixtures of special form material may be determined as follows:</p> <div style="text-align: center;"></div> <p>where f(i) is the fraction of activity for radionuclide i in the mixture, and A<sub>1</sub>(i) is the appropriate A<sub>1</sub> value for radionuclide i.</p> <p>d. Alternatively, the A<sub>2</sub> value for mixtures of normal form material may be determined as follows:</p> <div style="text-align: center;"></div> <p>where f(i) is the fraction of activity for radionuclide i in the mixture, and A<sub>2</sub>(i) is the appropriate A<sub>2</sub> value for radionuclide i.</p>		<p>IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:</p> <p>a. For special form radioactive material, the maximum quantity transported in a Type A package is as follows:</p> $\sum_i \frac{B(i)}{A_1(i)}$ <p>where B(i) is the activity of radionuclide i, and A<sub>1</sub>(i) is the A<sub>1</sub> value for radionuclide i.</p> <p>b. For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:</p> $\sum B(i)/A_2(i) \leq$ <p>where B(i) is the activity of radionuclide i and A<sub>2</sub>(i) is the A<sub>2</sub>(i) value for radionuclide i.</p> <p>c. Alternatively, the A<sub>1</sub> value for mixtures of special form material may be determined as follows:</p> $A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$ <p>where f(i) is the fraction of activity for radionuclide i in the mixture and A<sub>1</sub>(i) is the appropriate A<sub>1</sub> value for radionuclide i.</p> <p>d. Alternatively, the A<sub>2</sub> value for mixtures of normal form material may be determined as follows:</p> $A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$ <p>where f(i) is the fraction of activity of radionuclide i in the mixture and A<sub>2</sub>(i) is the appropriate A<sub>2</sub> value for radionuclide i.</p>
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REG SECTION #	SECTION TITLE	Difference	COMP AT./ H&S CAT.	SUMMARY OF CHANGE	180 NAC& Significant Difference	Nebraska
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				<p>e. The exempt activity concentration for mixtures of nuclides may be determined as follows: Exempt activity concentration for mixture</p> <div style="text-align: center;">  </div> <p>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.</p> <p>f. The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows: Exempt consignment activity limit for mixture</p> <div style="text-align: center;">  </div> <p>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.</p> <p>V. 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<sub>1</sub> or A<sub>2</sub> value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A<sub>1</sub> or A<sub>2</sub> values for the alpha emitters and beta/gamma emitters.</p>		<p>e. The exempt activity concentration for mixture of nuclides may be determined as follows:</p> $\text{Exempt activity concentration for mixture} = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$ <p>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.</p> <p>f. The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:</p> $\text{Exempt consignment activity limits for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$ <p>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.</p> <p>V. 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<sub>1</sub> or A<sub>2</sub> value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A<sub>1</sub> or A<sub>2</sub> values for the alpha emitters and beta/gamma emitters.</p>
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**Summary of Change for Amendment 2003-1**

**Financial Assurance for Materials Licensees – Parts 30, 40, 70  
(68 FR 57327, October 3, 2003)  
RATS ID 2003-1 Effective December 3, 2003  
Due for State adoption on December 3, 2006**

30.35		Financial assurance and recordkeeping for decommissioning	D-- paragraphs (c), (e), (f) H&S-- paragraphs (a), (b), (d), and (g).	<p>In Sec. 30.35, paragraphs (a), (c)(2), (d), and (e) are revised and a new paragraph (c)(5) is added to read as follows:</p> <p>(a)(1) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding <math>10^5</math> times the applicable quantities set forth in appendix B to part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if <math>R</math> divided by <math>10^5</math> is greater than 1 (unity rule), where <math>R</math> is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in appendix B to part 30. (2) Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding <math>10^{12}</math> times the applicable quantities set forth in appendix B to part 30 (or when a combination of isotopes is involved if <math>R</math>, as defined in Sec. 30.35(a)(1), divided by <math>10^{12}</math> is greater than 1), shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must be submitted to NRC by December 2, 2005. ***** (c) *** (2) Each holder of a specific license issued before July 27, 1990, and of a type described in</p>	<p>3-018.01 item 1 (NRC) NO</p> <p>3-018.03 (NRC)</p>	<p><u>3-018 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING 3-018.01</u> Each:</p> <p>1. Applicant for a specific license authorizing the possession and use of unsealed <b>byproduct radioactive</b> material of half-life greater than 120 days and in quantities <b>exceeding</b> <math>10^5</math> times the applicable quantities set forth in 180 NAC 4, Appendix 4-F must submit a decommissioning funding plan as described in 180 NAC 3-018.05. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if <math>R</math> divided by <math>10^5</math> is greater than 1 (unity rule), where <math>R</math> is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix 4-F of 180 NAC 4.</p> <p>2. Holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding <math>10^{12}</math> times the applicable quantities set forth in 180 NAC 4, Appendix 4-F (or when a combination of isotopes is involved if <math>R</math>, as defined in 180 NAC 3-018.01, item 1, divided by <math>10^{12}</math> is greater than 1), must submit a decommissioning funding plan as described in 180 NAC 3-018.05. The decommissioning funding plan must be submitted to the Department by (two years from effective date of these regulations).</p> <p><u>3-018.02</u> Each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in 180 NAC 3-018.04 must</p>
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REG SECTION #	SECTION TITLE	Difference	COMP AT./ H&S CAT.	SUMMARY OF CHANGE	180 NAC& Significant Difference	Nebraska
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40.36	Financial assurance and recordkeeping for decommissioning		D-- paragraphs (c) and (e). H&S- - paragraphs (a), (b), (d), and (f).	<p><b>In Sec. 40.36, paragraphs (b)(2), (c)(2), and (d) are revised to read as follows:</b></p> <p>*****</p> <p>(b) ***</p> <p>(2) Submit a certification that financial assurance for decommissioning has been provided in the amount of \$225,000 by June 2, 2005 using one of the methods described in paragraph (e) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section must be submitted to NRC prior to receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to NRC, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section.</p> <p>(c) ***</p> <p>(2) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (a) of this section shall submit a decommissioning funding plan as described in paragraph (d) of this section or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal. Licensees required to submit the \$1,125,000 amount must do so by December 2, 2004.</p> <p>*****</p> <p>(d) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for</p>	NA	<p><u>3-018.07</u> Each person licensed under 180 NAC 3, 5, 7, 12, 14 and 19 must keep records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with 180 NAC 3-017.02, licensees must transfer all records described in 180 NAC 3-018.07 to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Department considers important to decommissioning consists of:</p> <ol style="list-style-type: none"> <li>1. 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 must include any known information on identification of involved nuclides, quantities, forms, and concentrations.</li> <li>2. 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 which 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 must substitute appropriate records of available information concerning these areas and locations.</li> <li>3. Except for areas containing only sealed sources (provided the 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</li> </ol>
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				<p>decommissioning from paragraph (e) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed 3 years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section.* *</p> <p>***</p>		<p>and updated every 2 years, of the following:</p> <ol style="list-style-type: none"> <li>a. All areas designated and formerly designated as restricted areas as defined under 180 NAC 1-002 ;</li> <li>b. All areas outside of restricted areas that require documentation under 180 NAC 3-018.07, item 1.;</li> <li>c. All areas outside of restricted areas where current and previous wastes have been buried as documented under 180 NAC 4-054; and</li> </ol> <p>. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 180 NAC 4-040.</p> <ol style="list-style-type: none"> <li>4. 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 if either a funding plan or certification is used.</li> </ol>
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REG SECTION #	SECTION TITLE	Difference	COMP AT./ H&S CAT.	SUMMARY OF CHANGE	180 NAC& Significant Difference	Nebraska
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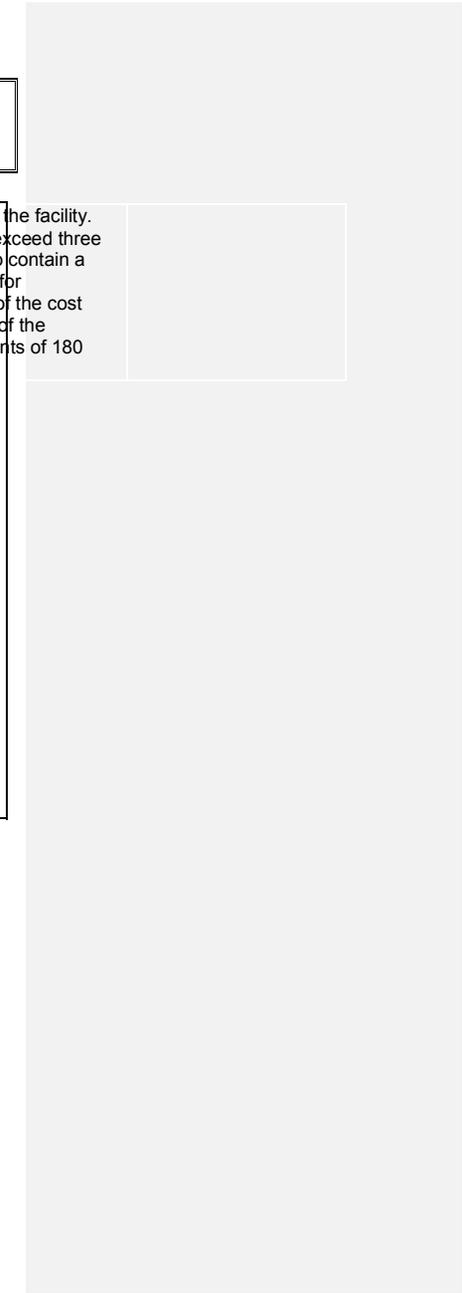
70.25	Financial assurance and recordkeeping for decommissioning		D-- paragraphs (c), (e), and (f) NRC-- paragraph (a) H&S-- paragraphs (b), (d), and (g).	In Sec. 70.25, paragraphs (c)(2), (d), and (e) are revised to read as follows: * * * * * (c) * * * (2) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (a) of this section shall submit a decommissioning funding plan as described in paragraph (e) of this section or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal. * * * * * (d) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the \$1,125,000 amount must do so by December 2, 2004. Licensees required to submit the \$225,000 amount must do so by June 2, 2005. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan. Greater than 10 <sup>4</sup> but less than or equal to 10 <sup>5</sup> times the applicable quantities of appendix B to part 30. (For a combination of isotopes, if R, as defined in Sec. 70.25(a), divided by 10 <sup>4</sup> is greater than 1 but R divided by 10 <sup>5</sup> is less than or equal to 1.).....\$1,125,000 Greater than 10 <sup>3</sup> but less than or equal to 10 <sup>4</sup> times the applicable quantities of appendix B to part 30. (For a combination of isotopes, if R, as defined in Sec. 70.25(a), divided by 10 <sup>3</sup> is greater than 1 but R divided by 10 <sup>4</sup> is less than or equal to 1.)..... \$225,000 (e) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from paragraph (f) of this	NA	3-018.03 Each: 2. <b>Holder of a specific license</b> issued before May 30, 1994, and of a type described in 180 NAC 3-018.01 must submit, on or before May 30, 1994, <b>and of type described in 180 NAC 3-018.01 must submit a decommissioning funding plan as described in 180 NAC 3-018.05</b> or a certification of financial assurance for decommissioning in an amount at least equal to <b>\$1,125,000</b> in accordance with the criteria set forth in 180 NAC 3-018.03, item 2. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee must include a decommissioning funding plan in any application for license renewal. 3-018.04 Table of required amounts of financial assurance for decommissioning by quantity of material. <b>Licensees required to submit the \$1,125,000 amount must do so by (one year from effective date of these regulations). Licensees required to submit the \$113,000 or \$225,000 amount must do so by (one and a half years from effective date of these regulations). Licensees having possession limits exceeding the upper bound of this table must base financial assurance on a decommissioning funding plan.</b> Greater than 10 <sup>4</sup> but less than or equal to 10 <sup>5</sup> times the applicable quantities of 180 NAC 4, Appendix 4-F in unsealed form. (For a combination of isotopes, if R, as defined in 180 NAC 3-018.01, item 1 divided by 10 <sup>4</sup> is greater than 1 but R divided by 10 <sup>5</sup> is less than or equal to 1.) . \$1,125,000  Greater than 10 <sup>3</sup> but less than or equal to 10 <sup>4</sup> times the applicable quantities of 180 NAC 4, Appendix 4-F in unsealed form. (For a combination of isotopes, if R, as defined in 180 NAC 3-018.01, item 1 divided by 10 <sup>3</sup> is greater than 1 but R divided by 10 <sup>4</sup> is less than or equal to 1.) . \$225,000  3-018.05 Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 180 NAC 3-018.06, including means of adjusting cost estimates and	
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	\$1,125,000
	\$225,000

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				<p>section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed 3 years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section. * *</p>		<p>associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed three years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial statement obtained to satisfy the requirements of 180 NAC 3-018.06.</p>
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**Revision of the Skin Dose Limit, 10 CFR Part 20 (67 FR 16298)**  
**Effective: June 4, 2002 Implementation Date: April 5, 2005**  
**RATS ID: 2002-1**

20.1003	Definitions		A	<p>The definition of shallow-dose equivalent (Hs) is revised to read as follows:</p> <p>Shallow-dose equivalent (Hs), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm<sup>2</sup>).</p>	<p>180 NAC 1-002 (NRC) NO - Moved from 4-002 to 1-002</p>	<p>Shallow-dose equivalent (Hs) which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm<sup>2</sup>)</p>
20.1201(a)(2), (a)(2)(ii) and (c)	Occupational Dose Limits for Adults		A	<p>The introductory text of paragraph (a)(2), and paragraphs (a)(2)(ii) and (c), are revised to read as follows:</p> <p>(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:</p> <p>(ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.</p> <p>(c) The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. 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.</p>	<p>180 NAC 4-005.01, item 2 (NRC) NO</p> <p>4-005.03 (NRC) NO</p>	<p>2. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:</p> <p>b. A shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.</p> <p><u>4-005.03</u> The assigned deep dose equivalent must be for the part of the body receiving the highest exposure.</p> <p>1. The assigned shallow-dose equivalent must be the dose averaged over the contiguous ten square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and the 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.</p>

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**Medical Use of Byproduct Material, 10 CFR 20, 32, and 35 (67 FR 20249)**  
**Effective: April 24, 2002 Implementation Date: April 24, 2005**  
**RATS ID: 2002-2**

Part 35 was completely revised and due to the extensive changes, each section will not be listed separately in the chronology. The States should adopt the new Part 35 in accordance with the compatibility chart published in the Federal Register with the final rule. **FOR DETAILS SEE I:\REGS\RATS\NRC-CHRONOLOGY\_PART35\_20002-2.DOC**

**5/9/02**  
**COMPATIBILITY DESIGNATIONS FOR FINAL 10 CFR PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL, PART 20 & PART 32**

§20.100 2	Scope		D	Does not meet any of the criteria of Category A, B, C, or H&S.	4-001.03	4-001.03
§20.100 3	Definitions					
	Occupational dose		A		1-002 (NRC) NO	1-002 <u>Occupational dose</u> means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation from licensed/registered or unlicensed/unregistered sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 180 NAC 7-037, from voluntary participation in medical research programs, or as a member of the public.
	Public dose		A		1-002 (NRC) NO	1-002 <u>Public dose</u> means the dose received by a member of the public from exposure to sources of radiation released by a licensee or registrant, or to any other source of radiation under the control of a licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive

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						material and released in accordance with 180 NAC 7-037, or from voluntary participation in medical research programs,
§20.130 1 (a) and (c)	Dose limits for individual members of the public		A		4-013.01 (NRC) NO	<p><u>4-013.01</u> Each licensee or registrant must conduct operations so that:</p> <p>1. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 180 NAC 7-037, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with 180 NAC 4-041, and <del>4-013.03</del> Notwithstanding 180 NAC 4-013.01, item 1 a licensee may permit visitors to an individual who cannot be released, under 180 NAC 7-037, to receive a radiation dose greater than 1 mSv (0.1 rem) if:</p> <p>1. The radiation dose received does not exceed 5 mSv (0.5 rem); and</p> <p>2. The authorized user, as defined in 180 NAC 7, has determined before the visit that it is appropriate.</p>
§32.72 (b)(1) and (b)(2)(ii)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35		B		3-014.10, item 2a, NO  item 2.b.(2) NO	<p>3-014.10, item 2a.</p> <p>a. May prepare radioactive drugs for medical use, as defined in 180 NAC 7-002, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 180 NAC 3-014.10, item 1.b. and d, or an individual under the supervision of an authorized nuclear pharmacist as specified in 180 NAC 7-018.</p> <p>3-014.10, item 2b(2) (2) This individual meets the requirements specified in 180 NAC 7-024.02 and 7-027 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or</p>

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§32.74 (a) and (a)(3)	Manufacture and distribution of sources or devices containing byproduct material for medical use		B		3-014.12 (NRC) NO  3-014.12 .item 3 (NRC)	3-014.12. <u>Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.</u> An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 180 NAC 7 for use as a calibration <b>transmission</b> or reference source or for the uses listed in 180 NAC 7-055, 7-065 and 7-067 will be approved if:  3-014.012, item 3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the Department has approved distribution of the (name of the source or device) to persons licensed to use radioactive material identified in 180 NAC 7-032, 7-055, 7-065 and 7-067 as appropriate, and to persons who hold an equivalent license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.
§35.1	Purpose and scope		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-001	7-001
§35.2	Definitions					
	Address of use		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Agreement State		[B]	This definition also appears in 10 CFR §150.3(b). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category B.	1-002 (NRC) NO	1-002 <u>Agreement State</u> means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).
	Area of use		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002

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	*Authorized medical physicist		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-002 (SSR) NO	7-002 <u>Authorized medical physicist</u> means an individual who: 2. Meets the requirements in 180 NAC 7-023.01 and 7-027; or 3. Is identified as an authorized medical physicist <u>or teletherapy physicist on a specific license or equivalent permit issued by the Department, Nuclear Regulatory Commission or Agreement State; or</u> 4. Is identified as an authorized medical physicist on a permit issued by an Department, Nuclear Regulatory Commission or Agreement State specific medical use license of broad scope that is authorized to permit the use of radioactive material.
	* Authorized nuclear pharmacist		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-002 (SSR) NO	7-002 <u>Authorized nuclear pharmacist</u> means a pharmacist who: 1. Meets the requirements of 180 NAC 7-024.01 and 7-027; or 2. Is identified as an authorized nuclear pharmacist on a specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Department, Nuclear Regulatory Commission or Agreement State; or 3. Is identified as an authorized nuclear pharmacist on a permit issued by the Department, Nuclear Regulatory Commission or Agreement State specific medical use license of broad scope that is authorized to permit the use of radioactive material.
	* Authorized user		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-002 NO	7-002 <u>Authorized user</u> means a physician, <u>dentist or podiatrist</u> who: 1. Meets the requirements in 180 NAC 7-027 and 7-043.01, 7-047.01, 7-052.01, 7-053.01, 7-054.01, 7-063.01, 7-066.01 or 7-084.01; or 2. Is identified as an authorized user on a specific license or equivalent permit issued by the Department, Nuclear Regulatory Commission or Agreement State; or 3. Is identified as an authorized user on a permit issued by an Department, Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the medical

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						use of radioactive material
	Brachytherapy		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Brachytherapy source		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Client's address		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Dedicated check source		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Dentist		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	High dose-rate remote afterloader		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Low dose-rate remote afterloader		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Management		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Manual Brachytherapy		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Medical		D	Does not meet any of the criteria of Category A, B, C, or H&S since the term was not defined in this	7-002	7-002

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	event			section, but is defined in 35.3045(a).		
	Medical institution		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	* Medical use		C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(e), this definition was identified as a Category C. The essential objectives of this definition should be adopted because the lack of it could potentially impair effective communication. The essential objective of this definition is to establish a common understanding regarding the application of radioactive materials and the radiation therefrom to humans as directed by an authorized user.	7-002 (SSR) NO	7-002 <u>Medical use</u> means 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
	Medium dose-rate remote afterloader		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Mobile medical service		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Output		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Patient intervention		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Pharmacist		D	Does not meet any of the criteria of Category A, B, C, or H&S.	1-002	7-002
	Physician		D	Does not meet any of the criteria of Category A, B, C, or H&S.	1-002	7-002
	Podiatrist		D	Does not meet any of the criteria of Category A, B,	1-002	7-002

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				C, or H&S.		
	Preceptor		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	
	* Prescribed dosage		C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(c) and (2)(e), this definition was identified as a Category C. The essential objectives of this definition should be adopted because the lack of it could potentially preclude an effective review or evaluation by the Commission and Agreement State programs for agreement materials with respect to protection of public health and safety and impair effective communication. The essential objective of this definition is to establish a common understanding regarding the correct quantity of radiopharmaceutical activity prescribed by the authorized user for administration to a patient.	7-002 (CFR) NO	7-002 <u>Prescribed dosage</u> means the specified activity or range of activity of radioactive drug as documented: <ol style="list-style-type: none"> <li>1. In a written directive as specified in 180 NAC 7-019; or</li> <li>2. In accordance with the directions of the authorized user for procedures performed per 180 NAC 7-041, 7-044 and 7-048.</li> </ol>
	* Prescribed dose		C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(c) and (2)(e), this definition was identified as a Category C. The essential objective of this definition should be adopted because the lack of it could potentially preclude an effective review or evaluation by the Commission and Agreement State programs for agreement materials with respect to protection of public health and safety and impair effective communication. The essential objective of this definition is to establish a common understanding regarding the correct quantity of radiopharmaceutical activity prescribed by the authorized user for administration to a patient.	7-002 (CFR) NO	7-002 <u>Prescribed dose</u> means: <ol style="list-style-type: none"> <li>1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;</li> <li>2. For teletherapy, the total dose and dose per fraction as documented in the written directive;</li> <li>3. For manual brachytherapy, either the total source strength and exposure time or the total dose as documented in the written directive; or</li> <li>4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive</li> </ol>
	Pulsed dose-rate remote afterloader		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	* Radiation		B	To be included in Category B, an NRC program element is to be one that applies to activities that	7-002 (CFR) NO	7-002 <u>Radiation Safety Officer (RSO)</u> means an individual who: <ol style="list-style-type: none"> <li>4.3. Meets the requirements in 180 NAC 7-022.04</li> </ol>

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	safety officer			have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.		and 7-026; 5-4. Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Department for similar types and uses of radioactive material.
	Sealed source		[B]	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (B), paragraph (2)(c), this definition was identified as a Category B because it is a definition of a product that licensees routinely transport in multiple jurisdictions. This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category B.	1-002 NO	1-002 <u>Sealed source</u> means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material .
	Sealed source and device registry		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Stereotactic radiosurgery		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Structured educational program		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Teletherapy		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Temporary jobsite		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Therapeutic			Does not meet any of the criteria of Category A, B,	7-002	7-002

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	dosage		D	C, or H&S.		
	Therapeutic dose		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	* Treatment site		C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(c) and (2)(e), this definition was identified as a Category C. The essential objective of this definition should be adopted because the lack of it could potentially preclude an effective review or evaluation by the Commission and Agreement State programs for agreement materials with respect to protection of public health and safety and impair effective communication. The essential objective of this definition is to establish a common understanding of the correct anatomical description of the area intended to receive a radiation dose.	7-002 (CFR) NO	7-002 <u>Treatment site</u> means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.
	Type of use		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Unit dosage		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-002	7-002
	Written directive		D	Does not meet any of the criteria of Category A, B, C, or H&S since the term was not defined in this section, but is defined in 35.40.	7-002	7-002
§35.5	Maintenance of records		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-003	7-002
§35.6	Provisions for the protection of human research subjects		C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (1), this requirement was designated a Category C. The lack of this requirement could create a gap whereby the Federal Policy for the Protection of Human Subjects would not be applied. The essential objective of this requirement is to assure	7-004 NO	<u>7-004 PROVISIONS FOR RESEARCH INVOLVING HUMAN SUBJECTS:</u> A licensee may conduct research involving human subjects using radioactive material provided:  <u>7-004.01</u> That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of

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				the consistent application of the Federal Policy.		Human Subjects. Otherwise, a licensee may apply for and receive approval of a specific amendment to its Department license before conducting such research. Both types of licensees must, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;  <u>7-004.02</u> The research involving human subjects authorized in 180 NAC 7-004.01 maybe conducted using radioactive material authorized for medical use in the license; and  <u>7-004.03</u> Nothing in 180 NAC 7-004 relieves the licensee from complying with the requirements in 180 NAC 7.
§35.7	FDA, other Federal, and State requirements		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-005	7-005
§35.8	Information collection requirements : OMB Approval		D	Does not meet any of the criteria of Category A, B, C, or H&S.	NA	
§35.10	Implementation		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-006	7-006
§35.11	License required		[C]	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(f), this requirement was designated a Category C because Agreement States should adopt the Part 30 provision as a minimum requirement for their licensees. The general requirement for activities to be licensed appears in 10 CFR § 30.3 which has	7-007 (NRC) NO	<u>7-007 7-007 LICENSE REQUIRED</u> <u>7-007.01</u> A person may only manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State, or as allowed by 180 NAC 7-007.02 or 7-007.03.

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				been designated compatibility category C. If an Agreement State has adopted 10 CFR § 30.3, it is not necessary to adopt this section since the requirements are covered in Part 30.3 and this section would be a duplication of those provisions.		<p><u>7-007.02</u> An individual may receive, possess, use or transfer radioactive material in accordance with 180 NAC 7 under the supervision of an authorized user as provided in 180 NAC 7-018, unless prohibited by license condition.</p> <p><u>7-007.03</u> An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in 180 NAC 7 under the supervision of an authorized nuclear pharmacist or authorized user as provided in 180 NAC 7-018, unless prohibited by license condition.</p>
§35.12	Application for license, amendment, or renewal		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-008	7-008
§35.13	License amendments		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-010	7-010
§35.14	Notifications		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-011	
§35.15	Exemptions regarding Type A specific licenses of broad scope		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-012	
§35.18	License issuance		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-013	7-013
§35.19	Specific exemptions		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-014	7-014
§35.24	Authority and responsibilities for the		D - paragraphs	Paragraphs (a)(1), (a)(2), (a)(3), (d) and (g), do not meet any of the criteria of Category A, B, C, or H&S. In addition, paragraph (a)(2) was not	7-015.04 (NRC) NO	7-015.04 <del>7-015.04</del> A licensee's management must appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through

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	radiation protection program		(a) (1), (a) (2), (a)(3), (c), (d), (e), (g) (h)  H&S- paragr aph (b) and (f)	required because the definitions and training of authorized users, authorized nuclear pharmacists, radiation safety officers and authorized medical physicists are required as a matter of compatibility and would prevent an unqualified individual from working in these positions. Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (E), paragraphs (b) and (f) were designated Category H&S because they assist in establishing a minimum level of safety for the medical use of agreement materials since they deal with the implementation of the radiation protection program. The essential objective of paragraph (b) is to assure that the RSO agrees to implement the radiation safety program. The essential objective of paragraph (f) is to require that management provides the RSO with sufficient authority, time and resources to identify radiation problems, initiate corrective actions, stop unsafe operations and verify the implementation of corrective actions.  The H&S two or fewer failure test scenario: If unapproved changes are made to the radiation safety program, or if unsafe operations are not stopped, the public and workers could receive radiation exposures in excess of the radiation protection limits in Parts 20 & 35 and a medical event may occur.	7-015.04 (NRC) NO	the Radiation Safety Officer, must ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. <u>7-015.08</u> Licensees that are authorized for one or more different types of use under 180 NAC 7-048, 7-055, 7-067 and 7-085, or one or more types of units under 180 NAC 7-067, will establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members the licensee deems appropriate.
§35.26	Radiation protection program changes		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-016	7-016
§35.27	Supervision		H&S	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S because it assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a worker overexposure and medical event. The essential objectives of this requirement are to assure the instruction of the supervised individuals in radiation safety procedures and policies, and for	7-018 (SSR) NO	<u>7-018.01</u> A licensee permitting the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 180 NAC 7-007.02, must: 1. In addition to the requirements of 180 NAC 10-003, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of 180 NAC 7, and the license conditions with respect to the use of radioactive material; and

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				<p>the supervised individuals to request clarification from authorized users as needed.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee fails to instruct supervised individuals in radiation safety procedures, regulations and license conditions and radioactive material is mishandled, the public and workers could receive radiation exposures in excess of limits and a medical event could occur.</p>	<p>2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of 180 NAC 7, and license conditions with respect to the medical use of radioactive material.</p> <p>3. Require that only those individuals specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.</p> <p>4. Require the authorized user to audit the performance of each supervised individual initially and at least annually. The audit must include verification that the supervised individual is meeting the requirements of 180 NAC 7-018.01, item 2 and physical observation of the individual performing the duties the authorized user has delegated to them.</p> <p><u>7-18.02</u> A licensee permitting the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 180 NAC 7-007.03, must:</p> <p>1. Train and instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and</p> <p>2. 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 radiation protection procedures, the regulations of 180 NAC 7, and license conditions.</p> <p><u>7-018.03</u> Unless physical presence as described in other sections of 180 NAC 7 is required, a licensee who permits supervised activities under 180 NAC 7-018.01 and 7-018.02 must require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and</p>	

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						<p><u>7-018.04</u> A licensee that permits supervised activities under 180 NAC 7-018.01 and 7-018.02 is responsible for the acts and omissions of the supervised individual.</p>
§35.40	Written directives		H&S, (a) and (b) except paragraph (c) and (d) are D	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&amp;S because it assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that correct information on the prescribed dose is communicated to the licensee's staff.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not use written directives for therapeutic medical use and a misinterpretation of the authorized users' orders occurs, a medical event could occur.</p>	7-019 (SSR) NO	<p>7-019 <u>7-019.01</u> A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (30 microcuries (µCi)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.</p> <p>1. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.</p> <p><u>7-019.02</u> The written directive must contain the patient or human research subject's name and the following information:  For any administration of dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and the route of administration;  For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;  For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;  For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or  For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:</p> <p>a. Prior to implantation: treatment site, the radionuclide, and dose; and  b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or the total dose).</p>

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§35.41	Procedures for administrations requiring a written directive		H&S, except paragraph (b) and (c) are D	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&amp;S because it assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure patient identification and dose verification prior to administration to human beings.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not verify patient identity, radioactive material or radiation could be administered to the wrong person, and an exposure in excess of limits could occur. In addition, if the prescribed dose is not verified before administration, the prescribed dose could be exceeded and a medical event could occur.</p>	7-020 (SSR) NO	<p>7-020 <u>7-020.01</u> For any administration requiring a written directive, the licensee will develop, implement, and maintain written procedures to provide high confidence that:</p> <ol style="list-style-type: none"> <li>1. The patient's or human research subject's identity is verified before each administration; and</li> <li>2. Each administration is in accordance with the written directive.</li> </ol> <p><u>7-020.02</u> The procedures required by 180 NAC 7-020.01 must, at a minimum, address the following items that are applicable to the licensee's use of radioactive material:</p> <ol style="list-style-type: none"> <li>1. Verifying the identity of the patient or human research subject;</li> <li>2. Verifying that the specific details of the administration is in accordance with the treatment plan, if applicable, and the written directive.</li> <li>3. Checking both manual and computer-generated dose calculations; and Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 180 NAC 7-067</li> </ol>
§35.49	Suppliers for sealed sources or devices for medical use		[C]	<p>This section is a bracketed Category C, because it is already required by 10 CFR § 30.32 (g) and § 32.74. Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(f), 10 CFR § 30.32 (g) was designated a Category C. This section requires that licensees, authorized to possess and use sealed sources or devices for medical use, obtain these products from a licensed vendor. In addition, 10 CFR § 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," is designated a Category B. This designation was based upon Handbook 5.9 Part II, "Categorization Criteria," Section (B), paragraph (b), requirements for approval of products that are distributed nationwide. If an Agreement State has adopted 10 CFR § 30.32 (g) and 10 CFR § 32.74, it is not necessary to adopt this section since the</p>	7-021 (SSR) NO	<p>7-021 <u>7-021.01</u> Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 180 NAC 3 or the equivalent regulations of the U.S. Nuclear Regulatory Commission, or another Agreement State;</p> <p><u>7-021.02</u> Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 180 NAC 3, or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.</p>

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				requirements are covered by these provisions.		
§35.50	Training for Radiation Safety Officer		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-022 (NRC) NO	<p><u>7-022 TRAINING FOR RADIATION SAFETY OFFICER</u> Except as provided in 180 NAC 7-026, the licensee must require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in 180 NAC 7-015 to be:</p> <p><u>7-022.01</u> An individual who is certified by a specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission and who meets the requirements in 180 NAC 7-022.04 and 7-022.05. (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's web page.)</p> <p>1. To have its certification process recognized, a specialty board will require all candidates for certification to:</p> <p>d. 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;</p> <p>e. 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</p> <p>f. Pass an examination administered by diplomats 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</p> <p>2. Require all candidates for certification to:</p> <p>c. 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;</p> <p>d. Have two years of full-time practical training and/or supervised experience in medical physics:</p> <p>(3) Under the supervision of a medical physicist who is certified in medical physicist by a specialty board recognized by an agreement state of the U.S.</p>

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						<p>Nuclear Regulatory Commission.</p> <p>(4) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements or for authorized users in 180 NAC 7-047 or 7-052; and</p> <p>e. Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or</p> <p><u>7-022.02</u> An individual who:</p> <ol style="list-style-type: none"> <li>1. Has completed a structured educational program consisting of both: <ol style="list-style-type: none"> <li>a. 200 hours of classroom and laboratory training in the following areas: <ol style="list-style-type: none"> <li>(1) Radiation physics and instrumentation;</li> <li>(2) Radiation protection;</li> <li>(3) Mathematics pertaining to the use and measurement of radioactivity;</li> <li>(4) Radiation biology; and</li> <li>(5) Radiation dosimetry; and</li> </ol> </li> <li>b. One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a U.S. Nuclear Regulatory Commission or Agreement State license or permit issued by the a U.S. Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following: <ol style="list-style-type: none"> <li>(1) Shipping, receiving, and performing related radiation surveys;</li> <li>(2) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;</li> <li>(3) Securing and controlling radioactive material;</li> <li>(4) Using administrative controls to avoid mistakes in the administration of radioactive material;</li> <li>(5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;</li> <li>(6) Using emergency procedures to control radioactive material; and</li> <li>(8) Disposing of radioactive material; and</li> </ol> </li> </ol> </li> <li>2. Meets the requirements in 180 NAC 7-</li> </ol>
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						<p>022.04 and 7-022.05; or 7-022.03  <u>7-022.03</u> The individual who is a:  3. Medical physicist who has been certified by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State in 180 NAC 7-023.01 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 Radiation Safety Officer and who meets the requirement in 180 NAC 7-022.04 and 7-022.05; 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 Radiation Safety Officer responsibilities and who meets the requirements in 180 NAC 7-022.04 and 7-022.05.  <u>7-022.04</u> An individual who has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in 180 NAC 7-022.05 and in 180 NAC 7-022.01, item 1.a. and b. or 180 NAC 7-022.01, item 2.a. and b, or 180 NAC 7-022.02 item 1 or 180 NAC 7-022.03 and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee.  <u>7-022.05</u> An individual who 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 radiation safety officer, 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.</p>
§35.51	Training for an authorized medical		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the	7-023 (NRC) NO	<p><u>7-023 TRAINING FOR AN AUTHORIZED MEDICAL PHYSICIST</u> The licensee must require the authorized medical physicist to be:  <u>7-023.01</u> An individual who is certified by a specialty board whose certification process has been recognized by the Department, the U.S. Nuclear</p>

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	physicist			training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.		<p>Regulatory Commission or an Agreement State and who meets the requirements of 180 NAC 7-023.03 and 7-023.04. (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:</p> <p>3. 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;</p> <p>4. Have two years of full-time practical training and/or supervision experience in medical physics:</p> <p>a. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission, or</p> <p>b. In a clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 180 NAC 7-063 or 7-084; and</p> <p>3. Pass an examination, administered by diplomats of the specialty board, which 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</p> <p><u>7-023.02</u> An individual who:</p> <p>1. Holds 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 has completed 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 types(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy (photons</p>

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						<p>and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include:</p> <ul style="list-style-type: none"> <li>a. Performing sealed source leak tests and inventories;</li> <li>b. Performing decay corrections;</li> <li>c. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and</li> <li>f. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable, and</li> </ul> <p>2. Meets the requirements of 180 NAC 7-023.03. and 7-023.04.</p> <p><u>7-023.03</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-023.04 and 180 NAC 7-023.01, item 1 and 2, or 180 NAC 7-023.02, item 1 and 180 NAC 7-023.04, 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 must be signed by a preceptor authorized medical physicist who meets the requirements in 180 NAC 7-023, or equivalent U.S. Nuclear Regulatory Commission 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.</p> <p><u>7-023.04</u> 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.</p>
	Training for			To be included in Category B, an NRC program	7-024 (NRC)	<u>7-024 TRAINING FOR AN AUTHORIZED NUCLEAR PHARMACIST</u> The licensee will require the

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§35.55	an authorized nuclear pharmacist		B	element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	NO	<p>authorized nuclear pharmacist to be a pharmacist who:</p> <p><u>7-024.01</u> Is certified by a specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission who meets the requirements of 180 NAC 7-024.03. (The names of the board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) will be posted on the NRC's web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:</p> <ol style="list-style-type: none"> <li>1. 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;</li> <li>2. Hold a current, active license to practice pharmacy;</li> <li>3. Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience;</li> <li>4. Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, which 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</li> </ol> <p><u>7-024.02</u> Completed all of the following requirements:</p> <ol style="list-style-type: none"> <li>1. 700 hours in a structured educational program consisting of both: <ol style="list-style-type: none"> <li>a. 200 hours of classroom and laboratory training in the following areas: <ol style="list-style-type: none"> <li>(1) Radiation physics and instrumentation;</li> <li>(2) Radiation protection;</li> <li>(3) Mathematics pertaining to the use and measurement of radioactivity;</li> <li>(4) Chemistry of radioactive material for medical use; and</li> </ol> </li> </ol> </li> </ol>

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						<p>(5) Radiation biology; and  b. Supervised practical experience in nuclear pharmacy involving:  (1) Shipping, receiving, and performing related radiation surveys;  (2) 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;  (3) Calculating, assaying, and safely preparing dosages for patients or human research subjects;  (4) Using administrative controls to avoid medical events in the administration of radioactive material; and  (5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and  2. Meets the requirement of 180 NAC 7-024.03.  7-024.03 Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements of 180 NAC 7-024.01, item 1, 2, and 3 or 7-024.02 and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.</p>
§35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-026 (NRC) NO	<p><del>7-026 PROVISIONS FOR EXPERIENCED RADIATION SAFETY OFFICER, TELE THERAPY OR MEDICAL PHYSICIST, AUTHORIZED MEDICAL PHYSICIST, AUTHORIZED USER, NUCLEAR PHARMACIST AND AUTHORIZED NUCLEAR PHARMACIST</del>  7-026.01 An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist <b>or a authorized medial physicist, or a authorized nuclear pharmacist</b> on a U.S. Nuclear Regulatory Commission, an Agreement State license or on a permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material permittee of broad scope that authorizes medical use or practice of nuclear pharmacy, before</p>

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						the effective date of these regulations need not comply with the training requirements of 180 NAC 7-022 through 7-024. <u>7-026.02</u> Physicians, dentists, or podiatrists identified as authorized users for the medical, use of radioactive material on a license issued by the U.S. Nuclear Regulatory Commission or Agreement State, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope licensee, or on a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee before the effective date of these regulations who perform only those medical uses for which they were authorized on that date need not comply with the training requirements 180 NAC 7-041 through 7-084 .
§35.59	Recentness of training		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-027 (NRC) NO	<u>7-027 RECENTNESS OF TRAINING</u> The training and experience specified in 180 NAC 7 must have been obtained within seven years preceding the date of license application or the individual must have had related continuing education and experience since the required training and experience was completed.
§35.60	Possession, use, and calibration of instruments to measure the activity of unsealed byproduct material		H&S, except paragraph (c) is D.	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure the measurement of the dosage with proper instrumentation prior to administration.  The H&S two or fewer failure test scenario: If a licensee does not properly measure the dosage with the appropriate instrumentation, the	7-029 (NRC) NO	<u>7-029 POSSESSION, USE, AND CALIBRATION OF INSTRUMENTS USED TO MEASURE THE ACTIVITY OF UNSEALED RADIOACTIVE MATERIAL</u> <u>7-029.01</u> For direct measurements performed in accordance with 180 NAC 7-031, a licensee must possess and use instrumentation to measure the activity of unsealed radioactive material prior to administration to each patient or human research subject. <u>7-029.02</u> A licensee must test the instrumentation required in 180 NAC 7-029.01 in accordance with nationally recognized standards or the manufacturer's instructions.

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				administered dose could differ from the prescribed dose and a medical event could occur.		<p><u>7-029.03</u> The tests required in 180 NAC 7-029.02 must at minimum include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument.</p> <p><u>7-029.04</u> A licensee will must a record of each instrument test required by 180 NAC 7-029 in accordance with 180 NAC 7-091.</p>
§35.61	Calibration of survey instruments		H&S, except paragraphs (a)(3) & (c) are D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&amp;S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials. Without properly calibrated survey instruments over exposures could occur and is needed to demonstrate compliance with Part 20 requirements. The essential objective of this requirement is to assure the possession of calibrated survey instruments.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not calibrate or check survey instruments as required by this rule, and a contamination event occurs, radiation levels in excess of Part 20 limits could occur.</p>	7-030 (NRC & SSR) NO	<p><u>7-030 CALIBRATION OF SURVEY INSTRUMENTS</u></p> <p><u>7-030.01</u> A licensee must ensure that the survey instruments used to show compliance with 180 NAC 7 and 180 NAC 4 have been calibrated before first use, annually and following any repair that affects the calibration.</p> <p><u>7-030.02</u> To satisfy the requirements of 180 NAC 7-030.01, the licensee must:</p> <ol style="list-style-type: none"> <li>1. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with a radiation source;</li> <li>2. Have each radiation survey instrument calibrated: <ol style="list-style-type: none"> <li>a. At energies appropriate for use and at annual intervals or after servicing instrument except for battery changes;</li> <li>b. For linear scale instruments at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range and each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and 10 mSv (2 and 1,000 mrem) per hour; and</li> <li>c. For dose rate instruments, so that an accuracy within plus or minus 20% of the true radiation dose rate can be demonstrated at each point checked. <ol style="list-style-type: none"> <li>3. Conspicuously note on the instrument the date of calibration.</li> </ol> </li> </ol> </li> </ol> <p><u>7-030.03</u> The licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20%.</p> <p><u>7-030.04</u> A licensee must check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not</p>

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						required to keep records of these checks. 7-030.05 A licensee must maintain a record of each survey instrument calibration in accordance with 180 NAC 7-092.
§35.63	Determination of dosages of unsealed byproduct material for medical use		H&S, except paragraph (e) is D.	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S because it assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure proper determination of prescribed dosages by proper measurement and/or calculation prior to human use.  The H&S two or fewer failure test scenario: If a licensee does not measure a dosage, and a preparation error occurs, a medical event could occur.	7-031 (NRC & SSR) NO	7-031 DETERMINATION OF DOSAGES OF RADIOACTIVE MATERIAL FOR MEDICAL USE 7-031.01 A licensee must determine and record the activity of each dosage prior to medical use. 7-031.02 For unit dosages not requiring a written directive, this determination must be made by either direct measurement of radioactivity or by a decay calculation, based on the measurements made by a manufacturer or preparer licensed pursuant to 180 NAC 3 or equivalent provision of the U.S. Nuclear Regulatory Commission or Agreement State. 7-031.03 For unit dosages requiring a written directive this determination must be made by direct measurement of radioactivity in accordance with 180 NAC 7-029. 7-031.04 For other than unit dosages not requiring a written directive, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 180 NAC 3 or equivalent provision of the U.S. Nuclear Regulatory Commission or Agreement State. 7-031.05 For other than unit dosages requiring a written directive this must be made by direct measurement of radioactivity in accordance with 180 NAC 7-029. 7-031.06 A licensee may not use a dosage if the dosage differs from the prescribed dosage by more than 20%. 7-031.07 A licensee must retain a record of the dosage determination required by 180 NAC 7 in accordance with 180 NAC 7-093.
§35.65	Authorization for calibration,		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-032	7-032

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	transmission and reference sources					
§35.67	Requirements for possession of sealed sources and brachytherapy sources		H&S, except paragraphs (d) & (f) are D.	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure. The essential objective of this requirement is to assure the safe handling, periodic leak testing, and inventory of sealed sources. The H&S two or fewer failure test scenario: if the licensee does not follow the manufacturers' instructions, including testing for leakage, and a source is damaged or misplaced, public and worker exposures in excess of limits and a medical event could occur.	7-033 (NRC) NO	<p><u>7-033 REQUIREMENTS FOR POSSESSION OF SEALED SOURCES AND BRACHYTHERAPY SOURCES</u></p> <p><u>7-033.01</u> A licensee in possession of any sealed source or brachytherapy source must follow the radiation safety and handling instructions supplied by the manufacturer, or equivalent instructions approved by the Department.</p> <p><u>7-033.02</u> A licensee in possession of a sealed source must:</p> <ol style="list-style-type: none"> <li>1. Test the source for leakage in accordance with 180 NAC 1-011; and</li> <li>2. Test the source for leakage at intervals not to exceed six months or at intervals approved by the Department, another Agreement State, or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.</li> </ol> <p><u>7-033.03</u> If the leak test reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination, the licensee must:</p> <ol style="list-style-type: none"> <li>1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of 180 NAC 1-011.06 and 180 NAC 4; and</li> <li>2. File a report within five days of the leak test in accordance with 180 NAC 7-118.</li> </ol> <p><u>7-033.04</u> A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotatic radiosurgery sources, must conduct a semi-annual physical inventory of all such sources. The licensee must retain each inventory record in accordance with 180 NAC 7-094</p>
§35.69	Labeling of vials and syringes		H&S	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker	7-034 * 7-035 (NRC & SSR) NO	<p><u>7-034 LABELS:</u> Each syringe and vial that contains a <b>unsealed</b> radioactive <b>material</b> must be labeled to identify the radioactive drug. <b>Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.</b></p> <p><u>7-035 VIAL SHIELDS AND SYRINGE SHIELD</u></p> <p><u>7-035.01</u> A licensee must require each individual</p>

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				<p>overexposure. The essential objective of this requirement is to make sure that licensees develop, implement and maintain written procedures for labeling syringes, syringe shields, and vial shields that contain radiopharmaceuticals.</p> <p>The H&amp;S two or fewer failure test scenario: If the syringe, syringe shield, or vial shield is not labeled, then the wrong radiopharmaceutical could be administered, and a medical event could occur. If syringe and vial shields are not used, then a worker could be overexposed.</p>		<p>preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.</p> <p><u>7-035.02</u> A licensee must keep syringes that contain radioactive material to be administered in a radiation shield.</p> <p><u>7-035.03</u> A licensee must require each individual who prepares or administers radioactive drugs to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.</p>
§35.70	Surveys of ambient radiation exposure rate		H&S, except paragraphs (b) and (c) are D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure. The essential objective of this requirement is to assure that daily radiation surveys are performed in areas where therapeutic radiopharmaceuticals are used.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not conduct surveys for ambient radiation exposure rates, and an unplanned release of radioactive material occurs, contamination could go undetected and cause public and worker exposure in excess of the radiation protection limits in Part 20.</p>	7-036 (NRC) NO	<u>7-036.01</u> Except as provided in 180 NAC 7-036.02 a licensee must survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered.
§35.75	Release of individuals containing unsealed byproduct material or		C, except paragraphs (c)	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(a) and (f), this requirement was designated a Category C. This provision assists in establishing a minimum level of safety for the medical use of agreement materials on a nationwide basis by reducing the likelihood of</p>	7-037 (NRC) NO	<u>7-037.01</u> A licensee may authorize the release from its control of any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). <sup>4</sup>

<sup>4</sup>U.S. Nuclear Regulatory Commission's – [NUREG-1556, vol. 9 "Consolidated Guidance About Materials Licenses: Program-specific Guidance About Medical Licenses,"](#) describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

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	implants containing byproduct material		and (d) are D.	public overexposures in multiple jurisdictions. The essential objective of this requirement is to assure that 0.5 rem TEDE is not exceeded by any individual, and that instructions are provided so that a breast-feeding infant/child does not receive an exposure exceeding 0.1 rem TEDE.		<p><u>7-037.02</u> For patients administered radioactive material for which a written directive is required, a licensee must provide the released individual, or individual's parent or guardian with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:</p> <ol style="list-style-type: none"> <li>1. Guidance on the interruption or discontinuation of breast-feeding and</li> <li>2. Information on the potential consequences, if any, of failure to follow the guidance.</li> </ol>
§35.80	Provision of mobile medical service		<p>H&amp;S (a)(2), (a)(3) &amp; (b) for those States which authorize this activity</p> <p>D for other States</p>	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&amp;S those Agreement States which authorize this service. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a public exposure. The essential objective of this requirement is to make sure that instruments are possessed, used, calibrated and checked as described in §35.60 and §35.61, that properly operating survey instruments are used and that radiation surveys are performed in areas where therapeutic radiopharmaceuticals are used.</p> <p>The H&amp;S two or fewer failure test scenario: Paragraphs (a)(2) and (a)(3) require that the requirements in §35.60 and §35.61 be applied to mobile services and that survey instruments are operating properly. If a mobile service licensee does not measure dosages with a proper operating instrumentation, then the prescribed dose could be exceeded, causing a medical event and the radiation protection limits in Part 20 for workers and the public could be exceeded. Paragraph (a)(4) requires that the mobile service survey all areas of use to assure compliance with Part 20 before</p>	<p>7-038 (NRC &amp; SSR) NO</p>	<p><u>7-038 MOBILE MEDICINE SERVICE TECHNICAL REQUIREMENTS:</u> A licensee providing mobile nuclear medicine service must:</p> <p><u>7-038.01</u> Transport to each address of use only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;</p> <p><u>7-038.02</u> Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;</p> <p><u>7-038.03</u> Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;</p> <p><u>7-038.04</u> Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each address of use or on each day of use, whichever is more frequent. At a minimum, the check for proper function must include a constancy check;</p> <p><u>7-038.05</u> Check survey instruments for consistent response with a dedicated check source before use at each client's address;</p> <p><u>7-038.06</u> Prior to leaving a client's address of use, perform area surveys and survey for removable contamination in all areas of use, to ensure</p>

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				leaving the client's address of use. If an exit survey is not conducted and byproduct material is left at the client's address of use, radiation protection limits in Part 20 for workers and the public could be exceeded.		compliance with the requirements in 180 NAC 4- <u>7-038.07</u> Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Department for compliance with airborne release standards; and, <u>7-038.08</u> Retain a record of each survey required by 180 NAC 7-038.05 in accordance with 180 NAC 7-097.
§35.92	Decay-in-storage		H&S - for those States which authorize this activity, except paragraph (b) is D.  D - for other States	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) are designated as H&S for those Agreement States which authorize this activity. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a public overexposure. The essential objective of this requirement is to allow decay in storage for byproduct materials with less than 120 day half-life and to assure that surveys will be performed on the material before disposal.  The H&S two or fewer failure test scenario: If byproduct material is allowed to decay-in-storage and is improperly surveyed, it may be disposed of as normal trash. Byproduct material could then be released into the public domain and overexpose workers and members of the public.	7-040	<u>7-040 DECAY-IN-STORAGE</u> : See 180 NAC 4-039.03 for decay-in-storage requirements. 4-039.03_A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee: 1. Holds radioactive material for decay a minimum of ten half-lives; 2. Monitors radioactive material at the container surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding; 3. Removes or obliterates all radiation labels; except for materials that will be handled as biomedical waste after released; and 4. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.
§35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required		H&S	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this provision was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that radiopharmaceuticals are obtained from a licensed vendor or authorized preparer.  The H&S two or fewer failure test scenario: If a licensee does not obtain radiopharmaceuticals from a licensed manufacturer or authorized preparer, a	7-041 (NRC) NO	<u>7-041 USE OF UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION, AND EXCRETION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED</u> : A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for diagnostic use involving measurements of uptake, dilution, or excretion that is: <u>7-041.01</u> Obtained from a manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent regulations of the U.S. Nuclear Regulatory Commission or Agreement State; or <u>7-041.02</u> Prepared by:

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				preparation error could occur, and a medical event could occur.		<ol style="list-style-type: none"> <li>1. An authorized nuclear pharmacist;</li> <li>2. Physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047 or 7-051 and 7-047.03, item 1.b.(7); or</li> <li>3. An individual under the supervision, as specified in 180 NAC 7-018, of the authorized nuclear pharmacist in 180 NAC 7-041.02, item 1 or the physician who is authorized user in 180 NAC 7-041.02, item 2; or  <u>7-041.03</u> Obtained from and prepared by an A U.S. Nuclear Regulatory Commission 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 FDA; or  <u>7-041.04</u> Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.</li> </ol>
§35.190	Training for uptake, dilution and excretion studies		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-043 (NRC) NO	<u>7-043 TRAINING FOR UPTAKE, DILUTION, AND EXCRETION STUDIES:</u> Except as provided in 180 NAC 7-026, the licensee must require an authorized user of unsealed radioactive material for the uses authorized in 180 NAC 7-041 to be a physician who: <u>7-043.01</u> Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 180 NAC 7-043.04. (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board must require all candidates for certification to: <ol style="list-style-type: none"> <li>3. 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 180 NAC 7-043.03, item 1.and 2 and 7-043.04; and</li> <li>4. Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in radiation safety,</li> </ol>

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						<p>radionuclide handling, and quality control; or <u>7-043.02</u> Is an authorized user under 180 NAC 7-047 or 7-051 or equivalent U.S. Nuclear Regulatory or Agreement State requirements; or <u>7-043.03</u> 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 must include:</p> <ol style="list-style-type: none"> <li>1. Classroom and laboratory training in the following areas: <ol style="list-style-type: none"> <li>a. Radiation physics and instrumentation;</li> <li>b. Radiation protection;</li> <li>c. Mathematics pertaining to the use and measurement of radioactivity;</li> <li>d. Chemistry of byproduct material for medical use; and</li> <li>e. Radiation biology; and</li> </ol> </li> <li>2. Work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-043, 7-047 or 7-051 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving: <ol style="list-style-type: none"> <li>a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;</li> <li>b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters</li> <li>c. Calculating, measuring, and safely preparing patient or human research subject dosages;</li> <li>d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;</li> <li>e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and</li> <li>f. Administering dosages of radioactive drugs</li> </ol> </li> </ol>
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						to patients or human research subjects; and 3. Meet the requirements of 180 NAC 7-043.04. <u>7-043.04</u> Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-043, 7-047, or 7-051, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirement in 180 NAC 7-043.01, item 1 or 7-043.03, item 1 and 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 180 NAC 7-041.
§35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required		H&S	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this section was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that radiopharmaceuticals are obtained from a licensed vendor or authorized preparer.  The H&S two or fewer failure test scenario: If a licensee does not obtain radiopharmaceuticals from a licensed manufacturer or authorized preparer, and a preparation error occurs, a patient could receive a radiation exposure and a medical event could occur.	7-044 (NRC) NO	<u>7-044 USE OF UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED:</u> A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 180 NAC 7-019 that is: <u>7-044.01</u> Obtained from a manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent U.S. Nuclear Regulatory Commission or Agreement State ; or <u>7-044.02</u> Prepared by: 1. An authorized nuclear pharmacist; 2. A physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047, or 7-051 and 7-047.03, item 1.b.(7), or 3. An individual under the supervision, as specified in 180 NAC 7-018; of, the authorized nuclear pharmacist in paragraph 180 NAC 7-044.02, item 1 or the physician who is an authorized user in paragraph 180 NAC 7-044.02, item 2; <u>7-044.03</u> Obtained from and prepared by an U.S. Nuclear Regulatory Commission 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 FDA.; or <del>a(1)—Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;</del>

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						<p><del>(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;</del></p> <p><del>(3) Calculating, measuring, and safely preparing patient or human research subject dosages;</del></p> <p><del>(4) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;</del></p> <p><del>(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;</del></p> <p><del>(6) Administering dosages of radioactive drugs to patients or human research subjects; and</del></p> <p><del>(7) 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</del></p> <p><del>ccordance with a Radioactive Drug Research Committee approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or</del></p> <p><del>7-044.04</del> Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.</p>
§35.204	Permissible molybdenum-99 concentration		H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that 5.55kBq is not exceeded.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not perform a Mo-99 measurement and the 5.55kBq limit is exceeded, and this contaminant is administered, a medical event could occur.</p>	7-045 (SSR) NO	<p><b>7-045 RADIONUCLIDE CONTAMINANTS</b></p> <p><u>7-045.01</u> A licensee must not administer to humans a radioactive drug containing:</p> <ol style="list-style-type: none"> <li>1. More than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 µCi of molybdenum-99 per mCi of technetium-99m).</li> <li>2. More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi of strontium-82 per mCi of rubidium-82 chloride injection).</li> <li>3. More than 0.02 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.02 µCi of strontium-85 per mCi of rubidium-82 chloride injection).</li> </ol> <p><u>7-045.02</u> To demonstrate compliance with 180 NAC 7-045, the licensee preparing radioactive drugs from</p>

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						<p>radionuclide generators must:</p> <ol style="list-style-type: none"> <li>1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;</li> <li>2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.</li> </ol> <p><u>7-045.03</u> A licensee who must measure radionuclide concentration must retain a record of each measurement in accordance with 180 NAC 7-099.</p> <p><u>7-045.04</u> A licensee must report immediately to the Department each occurrence of molybdenum-99 concentration exceeding the limits specified in 180 NAC 7-045.01.</p>
§35.290	Training for imaging and localization studies		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-047 (NRC) NO	<p><u>7-047 TRAINING FOR IMAGING AND LOCALIZATION STUDIES:</u> Except as provided in 180 NAC 7-026, the licensee must require an authorized user of unsealed radioactive material for the uses authorized in 180 NAC 7-044 to be a physician who:</p> <p><u>7-047.01</u> Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) and who meets to requirement in 180 NAC 7-047.04. (The names of board certification which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:</p> <p><u>5-4.</u> 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 180 NAC 7-047.03; and</p> <p><u>6-5.</u> Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or</p> <p><u>7-047.02</u> Is an authorized user in 180 NAC 7-051 and meets the requirements in 180 NAC 7-047.03, item 1.b.(7) or equivalent U.S. Nuclear Regulatory</p>

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						<p>Commission or Agreement State requirements; or 7-047.03 <u>The physician:</u></p> <p>1. 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 must include at a minimum:</p> <p>a. Classroom and laboratory training in the following areas:</p> <p>(1) Radiation physics and instrumentation;</p> <p>(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;</p> <p>(3) Mathematics pertaining to the use and measurement of radioactivity;</p> <p>(4) Chemistry of radioactive material for medical use;</p> <p>(5) Radiation biology; and</p> <p>b. Work experience, under the supervision of an authorized user, who meets the requirements in 180 NAC 7-047 or 7-47.03, item 1.b.(7) and 180 NAC 7-051 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving;</p> <p>2. Meets the requirement of 180 NAC 7-047.04.</p> <p><u>7-047.04</u> Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-047, or 7-051 and 7-047.03, item 1.b.(7) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-047.01, item 1 or 180 NAC 7-047.03, item 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 180 NAC 7-041 and 7-044 .</p>
§35.300	Use of unsealed		H&S	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated	7-048 (NRC) NO	<u>7-048 USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED:</u> A licensee may use any unsealed

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	byproduct material for which a written directive is required			<p>a H&amp;S for those Agreement States which authorize this activity. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that radiopharmaceuticals are obtained from a licensed vendor or authorized preparer.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not obtain radiopharmaceuticals from a licensed manufacturer or authorized preparer, a preparation error or medical event could occur.</p>		<p>radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:</p> <p><u>7-048.01</u> Obtained from a manufacturer or preparer licensed in 180 NAC 3; or</p> <p><u>7-048.02</u> Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047 or 7-051, or an individual under the supervision of either as specified in 180 NAC 7-018; or</p> <p><u>7-048.03</u> Obtained from and prepared by the Department, U.S. Nuclear Regulatory Commission or Agreement State licensee in accordance with a Radioactive Drug Research Committee's approval protocol or an Investigational New Drug (IND) protocol accepted by FDA for use in research; or</p> <p><u>7-048.04</u> Prepared by the licensee for use in research in accordance with an approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.</p>
§35.310	Safety instruction		H&S, except paragraph (b) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of exposure to members of the public. The essential objective of this requirement is to assure that personnel caring for patients receive initial and annual radiation safety instruction.</p> <p>The H&amp;S two or fewer failure test scenario: If the personnel caring for patients are not properly instructed, then personnel could be overexposed and persons visiting the patient could be overexposed. In addition, contaminated material could be released into the public domain, and a public overexposure could occur.</p>	7-049 .01 (SSR) NO	<p><u>7-049 SAFETY INSTRUCTION AND SAFETY PRECAUTIONS</u></p> <p><u>7-049.01</u> In addition to the requirements of 180 NAC 10-003,</p> <p>1. A licensee must provide radiation safety instruction to all personnel caring for patients or human research subjects that have received therapy with radioactive drug, and cannot be released in accordance with 180 NAC 7-037. The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:</p> <p>a. Patient or human research subject control;</p> <p>b. Visitor control to include the following:</p> <p>(1) Routine visitation to hospitalized individuals in accordance with 180 NAC 4-013.01, item 1; and</p> <p>(2) Visitation authorized in accordance with 180 NAC 4-013.03.</p> <p>c. Contamination control;</p> <p>d. Waste control; and</p> <p>e. Notification of the Radiation Safety Officer or his/her designee and the authorized user if the patient or the human research subject has a medical</p>

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						emergency or dies. 2. A licensee must retain a record of individuals receiving instruction required by 180 NAC 7-101.
§35.315	Safety precautions		H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&amp;S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of worker and public exposure. The essential objective of this requirement is to limit unnecessary patient contact with members of the public, and to assure that proper notifications are made if the patient dies.</p> <p>The H&amp;S two or fewer failure test scenario: If the safety precautions are not taken, then hospital personnel could be overexposed and persons visiting the patient could be overexposed. Contaminated material could also be released into the public domain, and public overexposures could occur. In addition, if the proper persons are not notified if a patient dies or, if a medical emergency occurs, other personnel could be overexposed.</p>	7-049.02 (SSR) NO	<p><u>7-049.02 Safety Precautions</u></p> <p>1. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 180 NAC 7-037, a licensee must:</p> <p>a. Quarter the patient or the human research subject either in:</p> <p>(1) A private room with a private sanitary facility; or</p> <p>(2) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who also cannot be released under 180 NAC 7-037;</p> <p>b. Visibly post the patient's or the human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and</p> <p>c. Either:</p> <p>(1) Monitor material and items removed from the patient's or the human 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</p> <p>(2) Handle such material and items as radioactive waste.</p> <p>2. The Radiation Safety Officer, or his/her designee, and the authorized user must be notified immediately if the hospitalization patient dies or has a medical emergency. The licensee must also notify the Department in accordance with 180 NAC 7-119 if it is possible that any individual could receive exposures in excess of 180 NAC 4-013 as a result of the deceased's body.</p> <p>3. Measure the thyroid burden of each individual</p>

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						who helped prepare or administer a liquid dosage of iodine-131 or in all cases where the patient's vomits or the capsule is compromised. The measurement must be done within three days after administering the dosage, and retain for the period required by 180 NAC 4-051.01 a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.
§35.390	Training for use of unsealed byproduct material for which a written directive is required		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-052 (NRC) NO	<p><u>7-051 TRAINING FOR USE OF UNSEALED RADIOACTIVE MATERIAL</u> Except as provided in 180 NAC 7-026, the licensee must require an authorized user of unsealed radioactive material for the uses authorized under 180 NAC 7-048 to be a physician who:</p> <p><u>7-051.01</u> Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) who meets the requirements in 180 NAC 7-051.02, item 1.b.(6) and 7-051.03. (Specialty Boards whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) To be recognized, a specialty board must require all candidates for certification to:</p> <p>2. Successfully complete a <b>minimum of three years of</b> residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 180 NAC 7-051.02, item 1.a. through 7-051.02, item 1.b.(5). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and</p> <p>3. Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of</p>

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						<p>unsealed radioactive material for which a written directive is required; or</p> <p><u>7-051.02. The physician:</u></p> <p>1. 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 must include:</p> <p>a. Classroom and laboratory training in the following areas:</p> <ol style="list-style-type: none"> <li>(1) Radiation physics and instrumentation;</li> <li>(2) Radiation protection;</li> <li>(3) Mathematics pertaining to the use and measurement of radioactivity;</li> <li>(4) Chemistry of radioactive material for medical use; and</li> <li>(5) Radiation biology; and</li> </ol> <p>b. Work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-051, or equivalent U.S. Nuclear Regulatory or Agreement State requirements. A supervising authorized user, who meets the requirements in 180 NAC 7-051.02, must also have experience in administering dosages in the same dosage category or categories (that is, 180 NAC 7-051.02, item 1., b.(6)) as the individual requesting authorized user status. The work experience must involve:</p> <ol style="list-style-type: none"> <li>(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;</li> <li>(2) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;</li> <li>(3) Calculating, measuring, and safely preparing patient or human research subject dosages;</li> <li>(4) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;</li> <li>(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;</li> </ol>
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						<p>(6) 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:  Oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131, for which a written directive is required;  Oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131<sup>5</sup>;  Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or  Parenteral administration of any betha emitter, or a photon-emitting radionuclide with a photon energy less than 150 kev, for which a written directive is required; and/or</p> <p>2. Meets the requirements of 180 NAC 7-051.03.  <u>7-051.03</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-051.01, item 1 and 7-051.02, item 1.b.(6) or 7-051.02, item 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-051, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirement in 180 NAC 7-051.02 must have experience in administering dosages in the same dosage category or categories (that is, 180 NAC 7-051.02, item 1.b.(6)) as the individual requesting authorized user status.</p>
§35.392	Training for the oral administratio		B	o be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple	7-053 (NRC) NO	<u>7-052 TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 IN QUANTITIES LESS THAN OR EQUAL TO 1.22</u>

<sup>5</sup>Experience with at least 3 cases in 180 NAC 7-051.02, item 1.b. (6) (b) also satisfies the requirement in 180 NAC 7-051.02, item 1.b.(6)(a).

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	n of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)			jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.		<p><u>GIGABECQUERELS (33 MILLICURIES) FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED:</u>  Except as provided in 180 NAC 7-026, the licensee must require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 GBq (33 mCi), for which a directive is required, to be a physician who:</p> <p><u>7-052.01</u> Is certified by a medical specialty board whose certification process includes all of the requirements in 180 NAC 7-052.03, item 1. and 2. and whose certification has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission who meets the requirements of 180 NAC 7-052.04. (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) or</p> <p><u>7-052.02</u> Is an authorized user under 180 NAC 7-051.01, 7-051.02 for uses listed in 180 NAC 7-051.02, item 1.b.(6)(a) or (b), 180 NAC 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or</p> <p><u>7-052.03</u> The physician:</p> <ol style="list-style-type: none"> <li>1. Has successfully completed 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 must include: <ol style="list-style-type: none"> <li>a. Radiation physics and instrumentation;</li> <li>b. Radiation protection;</li> <li>c. Mathematics pertaining to the use and measurement of radioactivity;</li> <li>d. Chemistry of radioactive material for medical use; and</li> <li>e. Radiation biology; and</li> </ol> </li> <li>2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-051.01, 7-051.02, 7-052, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(a) or (b). The work experience</li> </ol>

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						<p>must involve:</p> <ul style="list-style-type: none"> <li>a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;</li> <li>b. Performing quality control procedures on instruments used to determine the activity of dosages and performing check for proper operation of survey meters;</li> <li>c. Calculating, measuring, and safely preparing patient or human research subject dosages;</li> <li>d. Using administrative controls to prevent a misadministration involving the use of radioactive material;</li> <li>e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and</li> <li>f. Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131; and</li> </ul> <p>3. Meets the requirements of 180 NAC 7-052.04.</p> <p><u>7-052.04</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-052.03, item 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-051, 7-052, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(a) or (b).</p>
§35.394	Training for the oral administration of sodium iodide I-131 requiring a written		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other	7-054 (NO	<p><u>7-054 TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE</u></p> <p>Except as provided in 180 NAC 7-026, the licensee must require an authorized user for the parenteral administration requiring a written directive, to be a physician who:</p>

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	directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)			individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.		<p><u>7-054.01</u> Is an authorized user under 180 NAC 7-051 for uses listed in 7-051.02, item 1.b. (6)(c) or (d), or equivalent Agreement State requirements; or</p> <p><u>7-054.02</u> Is an authorized user under 180 NAC 7-063 or 7-084, or equivalent Agreement State requirements and who meets the requirements in 180 NAC 7-054.04; or</p> <p><u>7-054.03</u> Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State under 180 NAC 7-063 or 7-084; and who meets the requirements in 180 NAC 7-054.04.</p> <p><u>7-054.04</u> The physician:</p> <ol style="list-style-type: none"> <li>1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, 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. The training must include: <ol style="list-style-type: none"> <li>(1) Radiation physics and instrumentation;</li> <li>(2) Radiation protection;</li> <li>(3) Mathematics pertaining to the use and measurement of radioactivity;</li> <li>(4) Chemistry of radioactive material for medical use; and</li> </ol> </li> <li>(1) Radiation biology; and</li> <li>2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-051 or 7-054, or equivalent U.S. Nuclear Regulatory Commission 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 in 180 NAC 7-051, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(c) and/or (d). The work experience must involve: <ol style="list-style-type: none"> <li>a. Ordering, receiving, and unpacking radioactive materials safely, and performing the</li> </ol> </li> </ol>
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						<p>related radiation surveys;</p> <p>b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;</p> <p>c. Calculating, measuring, and safely preparing patient or human research subject dosages;</p> <p>d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;</p> <p>e. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and</p> <p>f. 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</p> <p>3. Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-054.02 or 7-054.03, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-051, or 7-054, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 180 NAC 7-051, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(c) and/or (d).</p>
§35.400	Use of sealed sources for manual brachytherap		[C]	This section is a bracketed Category C, because it is already required by 10 CFR § 30.32 (g) and § 32.74. Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(f), 10 CFR § 30.32 (g) was designated a Category C. This section requires the use of	7-055 (SSR) NO	<p><u>7-055 USE OF SOURCES FOR MANUAL BRACHYTHERAPY:</u> A licensee must use only brachytherapy sources for therapeutic medical uses:</p> <p><u>7-055.01</u> As approved in the Sealed Source and Device Registry; or</p> <p><u>7-055.02</u> For research in accordance with an active</p>

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	y			sealed sources in the SS&D Registry by all specific licensees. In addition, 10 CFR § 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," is designated a Category B. This designation was based upon Handbook 5.9 Part II, "Categorization Criteria," Section (B), paragraph (b), requirements for approval of products that are distributed nationwide. If an Agreement State has adopted 10 CFR § 30.32 (g) and 10 CFR § 32.74, it is not necessary to adopt this section since the requirements are covered by these provisions.		Investigational Device Exemption (IDE) application that has been accepted by the FDA, provided the requirements of 180 NAC 7-021.01 are met.
§35.404	Surveys after source implant and removal		H&S, except paragraph (c) is D.	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event, and overexposures in excess of Part 20 limits. The essential objective of this requirement is to assure that patient and area surveys are performed immediately after removal of sources from the patient or human research subject.  The H&S two or fewer failure test scenario: If a licensee does not perform a patient radiation survey after implanting sources, sources could be misplaced and the public and workers could be exposed to radiation in excess of basic radiation protection limits in Part 20 and a medical event could occur.	7-056 (NRC) NO	<u>7-056 SURVEYS AFTER SOURCE IMPLANT AND REMOVAL</u> <u>7-056.01</u> Immediately after implanting sources in a patient or a human research subject, the licensee must make a survey to locate and account for all sources that have not been implanted. <u>7-056.02</u> Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee must make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. <u>7-056.03</u> A licensee must retain a record of the surveys in accordance with 180 NAC 7-102.

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§35.406	Brachytherapy sources accountability		H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a lost source, medical event, public and worker overexposure. The essential objective of this requirement is to assure the accountability of sources after use.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not maintain source accountability a</p>	7-057 (NRC) NO	<p><u>7-057 BRACHYTHERAPY SOURCES INVENTORY</u>  <u>7-057.01</u> A licensee must maintain accountability at all times for all brachytherapy sources in storage or use.  <u>7-057.02</u> Promptly after removing sources from a patient or a human research subject, a licensee must return brachytherapy sources to a secure storage area.  <u>7-057.03</u> A licensee must maintain a record of the brachytherapy source accountability in accordance with 180 NAC 7-103.</p>
§35.410	Safety instruction		H&S, except paragraph (b) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of exposure to members of the public. The essential objective of this requirement is to assure that personnel caring for a patient receive proper radiation safety instruction.</p> <p>The H&amp;S two or fewer failure test scenario: If the personnel caring for patients are not properly instructed, then the personnel could be overexposed and persons visiting the patient could be overexposed.</p>	7-058 (NRC) NO	<p><u>7-058 SAFETY INSTRUCTION:</u> In addition to the requirements of 180 NAC 10-003,  <u>7-058.01</u> The licensee must provide radiation safety instruction, initially and at least annually, to personnel caring for a patient or human research subjects that are undergoing implant therapy and can not be released under 180 NAC 7-037. The instruction must be commensurated with the duties of the personnel and will include the following:</p> <ol style="list-style-type: none"> <li>1. Size and appearance of the brachytherapy sources;</li> <li>2. Safe handling and shielding instructions;</li> <li>3. Patient or human research subject control;</li> <li>4. Visitor control, including both: <ol style="list-style-type: none"> <li>a. Routine visitation of hospitalized individual in accordance with 180 NAC 4-013.01 and</li> <li>b. Visitation authorized in accordance with 180 NAC 4-013.01; and</li> </ol> </li> <li>5. Notification of the Radiation Safety Officer or his/her designee, and authorized user if the patient or the human research subject dies or has a medical emergency. The licensee will also notify the Department in accordance with 180 NAC 7-119 if it is possible that any individual could receive exposures in excess of 5 mSv (500 mrem) as a result of the deceased's body.</li> </ol> <p><u>7-058.02</u> A licensee must retain a record of individuals receiving instruction required by 180 NAC 7-101.</p>

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§35.415	Safety precautions		H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of worker and public exposure. The essential objective of these requirements is to limit patient contact with members of the public, to assure the availability of emergency response equipment and to assure that proper notifications are made if the patient dies.</p> <p>The H&amp;S two or fewer failure test scenario: If the safety precautions are not taken, then hospital personnel could be overexposed and persons visiting the patient could be overexposed. In addition, if the proper persons are not notified if a patient dies or, if a medical emergency occurs, other hospital personnel could be overexposed and material could be released into the public domain, and public overexposures could occur.</p>	7-059 (SSR) NO	<p><u>7-059 SAFETY PRECAUTIONS FOR PATIENTS OR HUMAN RESEARCH SUBJECTS RECEIVING BRACHYTHERAPY</u></p> <p><u>7-059.01</u> For each patient or human research subject that is receiving brachytherapy that cannot be released pursuant to 180 NAC 7-037 a licensee must:</p> <ol style="list-style-type: none"> <li>1. Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy;</li> <li>2. Visibly post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign; and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.</li> </ol> <p><u>7-059.02</u> A licensee must have radiological emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:</p> <ol style="list-style-type: none"> <li>4. Dislodged from the patient; and</li> <li>5. Lodged within the patient following removal of the source applicators.</li> </ol> <p><u>7-059.03</u> The Radiation Safety Officer, or his/her designee, and authorized user must be notified immediately if the hospitalized patient or human research subject has a medical emergency or dies.</p>
§35.432	Calibration measurements of brachytherapy sources		H&S, except paragraph (d) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that full calibration measurements on sources are performed before the first use of the source or source/applicator configuration.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not perform full calibration measurements of brachytherapy sources, a</p>	7-060 (SSR) NO	<p><u>7-060 CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES</u></p> <p><u>7-060.01</u> Prior to the first medical use of a brachytherapy source on or after [the effective date of these regulations], a licensee must have performed the following:</p> <ol style="list-style-type: none"> <li>1. Determine the source output or activity using a dosimetry system that meets the requirements of 180 NAC 7-072.01;</li> <li>2. Determine source positioning accuracy within applicators; and</li> <li>3. Use published protocols currently accepted by nationally recognized bodies to meet the requirements of 180 NAC 7-060.01, item 1. and 2.</li> </ol> <p><u>7-060.02</u> A licensee may use measurements provided by the source manufacturer or by a</p>

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				medical event could occur.		<p>calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with 180 NAC 7-060.01.</p> <p><u>7-060.03</u> A licensee must mathematically correct the outputs or activities determined in 180 NAC 7-060.01 for physical decay at intervals consistent with one percent physical decay.</p> <p><u>7-060.04</u> An authorized medical physicist must perform or review the calculation measurements made pursuant to 180 NAC 7-060.01, 7-060.02, or 7-060.03.</p> <p><u>7-060.05</u> Only an authorized medical physicist must calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with 180 NAC 7-060.01, 7-060.02, or 7-060.03.</p> <p><u>7-060.06</u> A licensee must retain a record of each calibration in accordance with 180 NAC 7-104.</p> <p><u>7-060.07</u> A licensee must retain a record of decay calculations required by 180 NAC 7-060.5 in accordance with 180 NAC 7-105.</p>
§35.433	Decay of strontium-90 sources for ophthalmic treatments		H&S-(a), except paragraph (b) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the source is properly decayed to identify the correct source strength.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not properly decay the source and it's strength is not accurately determined, a medical event could occur.</p>	NA	
§35.457	Therapy-related computer systems		H&S	Based upon Handbook 5.9 Part paragraphs (a) and (b) was designated II, "Categorization Criteria," Section E, this provision was designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement	7-061 (NRC) NO	<u>7-061 THERAPY-RELATED COMPUTER SYSTEMS</u> : The licensee must 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

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				<p>materials by reducing the likelihood a medical event. The essential objective of this requirement is to assure that therapy related computer systems are functioning properly and testing is done in accordance with national protocols.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not verify that computerized treatment planning systems are operating properly, and a medical event occurs.</p>		<p>testing must include, as applicable, verification of:  <u>7-061.01</u> The source-specific input parameters required by the dose calculation algorithm;  <u>7-061.02</u> The accuracy of dose, dwell time, and treatment time calculations at representative points;  <u>7-061.03</u> The accuracy of isodose plots and graphic displays; and  <u>7-061.04</u> The accuracy of the software used to determine sealed source positions from radiographic images.</p>
§35.490	Training for use of manual brachytherapy sources		B	<p>To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.</p>	7-063 NO	<p><u>7-063 TRAINING FOR USE OF MANUAL BRACHYTHERAPY SOURCES:</u> Except as provided in 180 NAC 7-026, the licensee must require an authorized user of a manual brachytherapy source for the uses authorized under 180 NAC 7-055 to be a physician who:  <u>7-063.01</u> Is certified by a medical specialty board whose certification has been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC), and who meets to requirements of 180 NAC 7-063.03. (The names of board certifications which have been recognized an Agreement State or the U.S. Nuclear Regulatory Commission will be posed on the NRC's web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:  1. 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 or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and  2. Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use manual brachytherapy; or  <u>7-063.02</u> The physician:  1. Has completed a structured educational program in basic radionuclide handling techniques</p>

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						<p>applicable to the use of manual brachytherapy sources that includes:</p> <ol style="list-style-type: none"> <li>a. 200 hours of classroom and laboratory training in the following areas: <ol style="list-style-type: none"> <li>1. Radiation physics and instrumentation;</li> <li>2. Radiation protection;</li> <li>3. Mathematics pertaining to the use and measurement of radioactivity; and</li> <li>4. Radiation biology; and</li> </ol> </li> <li>b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements at a medical institution, involving: <ol style="list-style-type: none"> <li>1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;</li> <li>2. Checking survey meters for proper operation;</li> <li>3. Preparing, implanting, and removing brachytherapy sources;</li> <li>4. Maintaining running inventories of material on hand;</li> <li>5. Using administrative controls to prevent a misadministration involving the use of radioactive material;</li> <li>6. Using emergency procedures to control radioactive material; and</li> </ol> </li> </ol> <p>2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 180 NAC 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements, as a part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or 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 180 NAC 7-063.02, item 1.b.; and</p> <p>6. Meet the requirements of 180 NAC 7-063.03. <u>7-063.03</u> Has obtained written attestation, signed by</p>
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						a preceptor authorized user who meets the requirements in 180 NAC 7-063, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-063.01, item 1 or 7-063.02, item 2 and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under 180 NAC 7-055.
§35.491	Training for ophthalmic use of strontium-90		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-064 (NRC) NO	<p><u>7-064 TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90:</u> Except as provided in 180 NAC 7-026, the licensee must require the authorized user of strontium-90 for ophthalmic uses authorized under 180 NAC 7-055 to be a physician who:</p> <p><u>7-064.01</u> Is an authorized user under 180 NAC 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements; or</p> <p><u>7-064.02</u> The physician:</p> <ol style="list-style-type: none"> <li>1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include: <ol style="list-style-type: none"> <li>a. Radiation physics and instrumentation;</li> <li>b. Radiation protection;</li> <li>c. Mathematics pertaining to the use and measurement of radioactivity; and</li> <li>d. Radiation biology; and</li> </ol> </li> <li>2. 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 must involve: <ol style="list-style-type: none"> <li>a. Examination of each individual to be treated;</li> <li>b. Calculation of the dose to be administered;</li> <li>c. Administration of the dose; and</li> <li>d. Follow up and review of each individual's case history; and</li> </ol> </li> <li>3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-063 or 7-064 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual</li> </ol>

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						has satisfactorily completed the requirements in 180 NAC 7-064.01 and 7-064.02 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.
§35.500	Use of sealed sources for diagnosis		[C]	This section is a bracketed Category C, because it is already required by 10 CFR § 30.32 (g) and § 32.74. Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(f), 10 CFR § 30.32 (g) was designated a Category C. This section requires the use of sealed sources in the SS&D Registry by all specific licensees. In addition, 10 CFR § 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," is designated a Category B. This designation was based upon Handbook 5.9 Part II, "Categorization Criteria," Section (B), paragraph (b), requirements for approval of products that are distributed nationwide. If an Agreement State has adopted 10 CFR § 30.32 (g) and 10 CFR § 32.74, it is not necessary to adopt this section since the requirements are covered by these provisions.	7-065 (SSR) NO	<u>7-065 USE OF SEALED SOURCES FOR DIAGNOSIS:</u> A licensee must use only sealed sources for diagnostic medical uses: <u>7-065.01</u> Approved in the U.S. Nuclear Regulatory Commission's Sealed Source and Device Registry; and <u>7-065.02</u> Handled in accordance with the manufacturer's radiation safety instructions.
§35.590	Training for use of sealed sources for diagnosis		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-066 (NRC) NO	<u>7-066 TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS:</u> Except as provided in 180 NAC 7-026, the licensee must require the authorized user of a diagnostic sealed source for use in a device authorized under 180 NAC 7-065 to be a physician, <b>dentist or podiatrist</b> who: <u>7-066.01</u> Is certified by a specialty board whose certification includes all of the requirements in 180 NAC 7-066.02 and 7-066.03 whose certification has been recognized by, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC). (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's web page.); or <u>7-066.02</u> The physician, <b>dentist or podiatrist</b> : 1. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the

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						device. The training must include: <ul style="list-style-type: none"> <li>a. Radiation physics and instrumentation;</li> <li>b. Radiation protection;</li> <li>c. Mathematics pertaining to the use and measurement of radioactivity; and</li> <li>d. Radiation biology; and</li> </ul> <u>7-066.03</u> Has completed training in the use of the device for the uses requested.
§35.600	Use of a sealed sources in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit		[C]	This section is a bracketed Category C, because it is already required by 10 CFR § 30.32 (g) and § 32.74. Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(f), 10 CFR § 30.32 (g) was designated a Category C. This section requires the use of sealed sources in the SS&D Registry by all specific licensees. In addition, 10 CFR § 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," is designated a Category B. This designation was based upon Handbook 5.9 Part II, "Categorization Criteria," Section (B), paragraph (b), requirements for approval of products that are distributed nationwide. If an Agreement State has adopted 10 CFR § 30.32 (g) and 10 CFR § 32.74, it is not necessary to adopt this section since the requirements are covered by these provisions.	7-067 (NRC) NO	<u>7-067 USE OF A SEALED SOURCE IN A REMOTE AFTERLOADER UNITS, TELE THERAPY UNITS.</u> A licensee must use sealed sources in photon emitting remote afterloader units, or gamma stereotactic radiosurgery units for therapeutic medical uses: <u>7-067.01</u> As approved in the U.S. Nuclear Regulatory Commission Sealed Source and Device Registry; or <u>7-067.02</u> For research in accordance with an active Investigational Device Exemption (IDE) application that has been accepted by the FDA provided the requirements of 180 NAC 7-021.01 are met.
§35.604	Surveys of patients and human research subjects treated with a remote afterloader unit		H&S, except paragraph (b) is D.	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials on a nationwide basis by reducing the likelihood of a lost source, medical event, and public/worker overexposure. The essential objective of this requirement is to assure that a survey is conducted on the patient and the device after source(s) removal from the patient or human research subject.  The H&S two or fewer failure test scenario: If a licensee does not perform a patient radiation	7-068 (NRC) NO	<u>7-068 SURVEYS OF PATIENTS AND HUMAN RESEARCH SUBJECTS TREATED WITH A REMOTE AFTERLOADER UNIT</u> <u>7-068.01</u> Before releasing a patient or a human research subject from licensee control, a licensee must make 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 source(s) has been removed from the patient or human research subject and returned to the shielded position. <u>7-068.02</u> A licensee must retain a record of surveys in accordance with 180 NAC 7-102.

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				survey after implanting sources, sources could be misplaced and the public and workers could be exposed to radiation in excess of radiation protection limits in Parts 20 and 35 and a medical event could occur.		
§35.605	Installation, maintenance, adjustment and repair		H&S, except paragraph (d) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and public and worker overexposure. The essential objective of these requirements is to assure that installation, maintenance, and adjustments are performed by a person specifically licensed by the Commission or an Agreement State.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not use a person who is specifically licensed to install and service devices and an equipment failure occurs, the person servicing the device could become overexposed. In addition, the public and workers could receive exposures in excess of the radiation protection limits in Part 20, if the device is not serviced properly.</p>	7-069 (NRC) NO	<p><u>7-069 INSTALLATION, MAINTENANCE, ADJUSTMENT, AND REPAIR</u></p> <p><u>7-069.01</u> Only a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State may install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).</p> <p><u>7-069.02</u> Except for low dose-rate remote afterloader units, only a person specifically licensed by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State may install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.</p> <p><u>7-069.03</u> For a low dose-rate remote afterloader unit, only a person specifically licensed by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or an authorized medical physicist may install, replace, relocate, or remove a sealed source(s) contained in the unit.</p> <p><u>7-069.04</u> A licensee must retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 180 NAC 7-106.</p>
§35.610	Safety procedures and instructions for remote afterloader		H&S, except paragraphs (f) &	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&S. These provisions assist in establishing a minimum level of safety for agreement materials by reducing the likelihood of a medical event and public and worker overexposure.	7-070 (NRC) NO	<p><u>7-070 SAFETY PROCEDURES AND INSTRUCTIONS FOR REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS</u></p> <p><u>7-070.01</u> A licensee must:</p> <ol style="list-style-type: none"> <li>Secure the unit, the console, the console keys, and the treatment room when not in use or</li> </ol>

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	units, teletherapy units, and gamma stereotactic radiosurgery units		(g) are D.	<p>The essential objective of these requirements is to assure the establishment and use of safety procedures and instructions for remote afterloaders, teletherapy units and gamma stereotactic radiosurgery units.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not develop and implement safety procedures and instructions, and radioactive material is mishandled, workers and the public could receive radiation exposures in excess of the radiation protection limits in Part 20 and a medical event could occur.</p>		<p>unattended;</p> <p>2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);</p> <p>3. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and</p> <p>4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the 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. These procedures must include:</p> <p>a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;</p> <p>b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and</p> <p>c. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.</p> <p><u>7-070.02</u> A copy of the procedures required by 180 NAC 7-070.01, item 4 must be physically located at the unit console.</p> <p><u>7-070.03</u> A licensee must post instructions at the unit console to inform the operator of:</p> <p>1. The location of the procedures required by 180 NAC 7-70.01, item 4; and</p> <p>2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.</p> <p><u>7-070.04</u> A licensee must provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:</p> <p>1. The procedures identified in 180 NAC 7-070.01, item 4; and</p> <p>2. The operating procedures for the unit.</p> <p><u>7-070.05</u> A licensee must ensure that operators, authorized medical physicists, and authorized users</p>

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						participate in drills of the emergency procedures, initially and at least annually. <u>7-070.06</u> A licensee must retain a record of individuals receiving instruction required by 180 NAC 7-070.04, in accordance with 180 NAC 7-101.
§35.615	Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units		H&S	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event, worker and public exposure. The essential objective of these requirements is to assure that controls are implemented, to require the physical presence of the authorized user and/or authorized medical physicist during the use of the device, and to assure the accessibility of emergency equipment.  The H&S two or fewer failure test scenario: If a licensee does not control access to therapy equipment and treatment rooms, and an equipment failure occurs, the public and workers could receive exposures in excess of the radiation protection limits in Part 20 and a medical event could occur.	7-071 (SSR) NO	<u>7-071 SAFETY PRECAUTIONS FOR REMOTE AFTERLOADER UNITS, TELE THERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS</u> <u>7-071.01</u> A licensee must control access to the treatment room by a door at each entrance. <u>7-071.02</u> A licensee must equip each entrance to the treatment room with an electrical interlock system that will: 1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed; 2. Cause the source(s) to be shielded promptly when an entrance door is opened; and 3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console. <u>7-071.03</u> A licensee must require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. <u>7-071.04</u> Except for low-dose remote afterloader units, a licensee will 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. <u>7-071.05</u> For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source. <u>7-071.06</u> In addition to the requirements specified in 180 NAC 7-071.01 through 7-071.05, a licensee must: 1. For low dose-rate, medium dose-rate and

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	Dosimetry		H&S,	Based upon Handbook 5.9 Part II, "Categorization	7-072 (NRC)	<p>pulsed dose-rate remote afterloader units, require:</p> <p>a. 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 to be physically present during the initiation of all patient treatments involving the unit; and</p> <p>b. 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 source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.</p> <p>2. For high dose-rate remote afterloader units, require:</p> <p>a. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and</p> <p>b. 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, to be physically present during continuation of all patient treatments involving the unit.</p> <p>3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.</p> <p>4. Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency and immediately if the patient dies.</p> <p><u>7-071.07</u> A licensee must have applicable radiological emergency response equipment available near each treatment room to respond to a source that inadvertently:</p> <p>1. Remains in the unshielded position; or</p> <p>2. Lodges within the patient following completion of the treatment.</p> <p><u>7-072 DOSIMETRY EQUIPMENT</u></p>

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§35.630	equipment		except paragraph (c) is D.	<p>Criteria," Section E, paragraphs (a) and (b) were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure the use of a dosimetry system that has been calibrated in accordance with national standards.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not calibrate and check dosimetry equipment in accordance with industry standards, and an equipment failure occurs, the public and workers could be exposed to radiation in excess of radiation limits in Part 20 and a medical event could occur.</p>	NO	<p><u>7-072.01</u> Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee must have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following conditions must be met.</p> <p>1. The system must have been calibrated using a system or source traceable to the National Institute of Science 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 must have been performed within the previous two years and after any servicing that may have affected system calibration; or</p> <p>2. The system must have been calibrated within the previous four years. Within 18 to 30 months after that calibration, the system must 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 must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. 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 units, the licensee must use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.</p> <p><u>7-072.02</u> The licensee must have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 180 NAC 7-072.01. This comparison must 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 requirement in 180 NAC 7-072.01.</p> <p><u>7-072.03</u> The licensee must retain a record of each calibration, intercomparison, and comparison in accordance with 180 NAC 7-107.</p>

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§35.632	Full calibration measurements on teletherapy units		H&S, except paragraph (g) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated H&amp;S. These provisions assist in establishing a minimum level of safety basis by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not perform full calibration measurements on teletherapy units in accordance with industry standards, and an equipment failure occurs, the public and workers could be exposed to radiation in excess of the radiation protection limits in Part 20 and a medical event could occur.</p>	7-073 (NRC) NO	<p><u>7-073 FULL CALIBRATION MEASUREMENTS ON TELETHERAPY UNITS</u></p> <p><u>7-073.01</u> A licensee authorized to use a teletherapy unit for medical use must perform full calibration measurements on each teletherapy unit:</p> <ol style="list-style-type: none"> <li>1. Before the first medical use of the unit; and</li> <li>2. Before medical use under the following conditions: <ol style="list-style-type: none"> <li>a. Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;</li> <li>b. Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and</li> <li>c. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and</li> </ol> </li> <li>3. At intervals not exceeding one year.</li> </ol> <p><u>7-073.02</u> To satisfy the requirement of 180 NAC 7-073.01, full calibration measurements must include determination of:</p> <ol style="list-style-type: none"> <li>1. The output within +/-3% for the range of field sizes and for the distance or range of distances used for medical use;</li> </ol> <p>The coincidence of the radiation field and the field indicated by the light beam localizing device;  The uniformity of the radiation field and its dependence on the orientation of the useful beam;</p> <ol style="list-style-type: none"> <li>4. Timer accuracy, and linearity over the range of use;</li> <li>5. "On-off" error; and</li> <li>6. The accuracy of all distance measuring and localization devices in medical use.</li> </ol> <p><u>7-073.03</u> A licensee must use the dosimetry system described in 180 NAC 7-072.01 to measure the output for one set of exposure conditions. The remaining radiation measurements required by 7-073.02, item 1. may then be made using a dosimetry system that indicates relative dose rates.</p> <p><u>7-073.04</u> A licensee must make full calibration measurements required by 180 NAC 7-073.01 in</p>

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						<p>accordance with published protocols accepted by nationally recognized bodies.</p> <p><u>7-073.05</u> A licensee must mathematically correct the outputs determined in 180 NAC 7-073.02, item 1, for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1% decay for all other nuclides.</p> <p><u>7-073.06</u> Full calibration measurements required by 180 NAC 7-073.01 and physical decay corrections required by 180 NAC 7-073.05 must be performed by a authorized medical physicist.</p> <p><u>7-073.07</u> A licensee must maintain a record of each calibration in accordance with 180 NAC 7-108.</p>
§35.633	Full calibration measurements on remote afterloader units		H&S, except paragraph (i) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not perform full calibration measurements on remote afterloaders in accordance with industry standards, and an equipment failure occurs, the public and workers could be exposed to radiation in excess of the radiation protection limits in Part 20 and a medical event could occur.</p>	7-074 (SSR & NRC) NO	<p><u>7-074 FULL CALIBRATION MEASUREMENTS ON REMOTE AFTERLOADER UNITS</u></p> <p><u>7-074.01</u> A licensee authorized to use a remote afterloader unit for medical use must perform full calibration measurements on each unit:</p> <ol style="list-style-type: none"> <li>1. Before the first medical use of the unit;</li> <li>2. Before medical use under the following conditions: <ol style="list-style-type: none"> <li>a. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and</li> <li>b. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and</li> </ol> </li> <li>3. At intervals not exceeding one calendar quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and</li> <li>4. At intervals not exceeding one year for low dose-rate remote afterloader units.</li> </ol> <p><u>7-074.02</u> To satisfy the requirement of 7-074.01, full calibration measurements must include, as applicable, determination of:</p> <ol style="list-style-type: none"> <li>1. The output within ± 5%;</li> <li>2. Source positioning accuracy to within ±1 millimeter;</li> <li>3. Source retraction with backup battery upon power failure;</li> </ol>

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						<p>4. Length of the source transfer tubes;</p> <p>5. Timer accuracy and linearity over the typical range of use;</p> <p>6. Length of the applicators; and</p> <p>7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.</p> <p><u>7-074.03</u> In addition to the requirements for full calibration for low dose-rate remote afterloader units in 180 NAC 7-074.02, a licensee must perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one calendar quarter.</p> <p><u>7-074.04</u> A licensee must use the dosimetry system described in 180 NAC 7-072.01 to measure the output.</p> <p><u>7-074.05</u> A licensee must make full calibration measurements required by 180 NAC 7-074.01 in accordance with published protocols accepted by nationally recognized bodies.</p> <p><u>7-074.06</u> For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 180 NAC 7-074.01 through 7-074.05.</p> <p><u>7-074.07</u> A licensee must mathematically correct the outputs determined in 180 NAC 7-074.02, item 1 for physical decay at intervals consistent with one percent physical decay.</p> <p><u>7-074.08</u> Full calibration measurements required by 180 NAC 7-074.01 and physical decay corrections required by 180 NAC 7-074.07 must be performed by the authorized medical physicist.</p> <p><u>7-074.09</u> A licensee must retain a record of each calibration in accordance with 180 NAC 7-108.</p>
§35.635	Full calibration measurements on gamma stereotactic radiosurgery units		H&S, except paragraph (g) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&amp;S two or fewer failure test scenario: If a</p>	7-075 (SSR) NO	<p><u>7-075 FULL CALIBRATION MEASUREMENTS ON GAMMA STEREOTACTIC RADIOSURGERY UNITS</u></p> <p><u>7-075.01</u> A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform full calibration measurements on each unit:</p> <ol style="list-style-type: none"> <li>1. Before the first medical use of the unit;</li> <li>2. Before medical use under the following conditions: <ol style="list-style-type: none"> <li>a. Whenever spot-check measurements indicate that the output differs by +/- 5% from the</li> </ol> </li> </ol>

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				<p>licensee does not perform full calibration measurements on gamma stereotactic radiosurgery units in accordance with industry standards, and an equipment failure occurs, the public and workers could be exposed to radiation in excess of the radiation protection limits in Part 20 and a medical event could occur.</p>		<p>output obtained at the last full calibration corrected mathematically for radioactive decay;</p> <p>b. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and</p> <p>c. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and</p> <p>3. At intervals not exceeding 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.</p> <p><u>7-075.02</u> To satisfy the requirement of 180 NAC 7-075.01, full calibration measurements must include determination of:</p> <ol style="list-style-type: none"> <li>1. The output within <math>\pm 3\%</math>;</li> <li>2. Relative helmet factors; (to verify that the helmet material provides the required shielding to the patient);</li> <li>3. Isocenter coincidence; (to confirm the centering accuracy of the radiation beam relative to the alignment helmet openings);</li> <li>4. Timer accuracy and linearity over the range of use;</li> <li>5. On-off error;</li> <li>6. Trunnion centricity; (to determine the rotational center of the source relative to the alignment helmet openings);</li> <li>7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;</li> <li>8. Helmet microswitches; (to determine if the switches terminate the radiation beam when);</li> <li>9. Emergency timing circuits; and</li> <li>10. Stereotactic frames and localizing devices (trunnions).</li> </ol> <p><u>7-075.03</u> A licensee must use the dosimetry system described in 180 NAC 7-072.01 to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 180 NAC 7-075.02, item 1 may be made using a dosimetry system that indicates relative dose rates.</p> <p><u>7-075.04</u> A licensee must make full calibration</p>
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						<p>measurements required by 180 NAC 7-075.01 in accordance with published protocols accepted by nationally recognized bodies.</p> <p><u>7-075.05</u> A licensee must mathematically correct the outputs determined in 180 NAC 7-075.02, item 1 at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1% physical decay for all other radionuclides.</p> <p><u>7-075.06</u> Full calibration measurements required by 180 NAC 7-075.01 and physical decay corrections required by 180 NAC 7-075.05 must be performed by the authorized medical physicist.</p> <p><u>7-075.07</u> A licensee must retain a record of each calibration in accordance with 180 NAC 7-108.</p>
§35.642	Periodic spot-checks for teletherapy units		H&S, except paragraph (f) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (e) were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement material by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not perform periodic spot checks of teletherapy units, and an equipment failure occurs, the public and workers could receive exposures in excess of radiation protection limits in Part 20 and a medical event could occur.</p>	7-076 (NRC) NO	<p><u>7-076 PERIODIC SPOT-CHECKS FOR TELETHERAPY UNITS</u></p> <p><u>7-076.01</u> A licensee authorized to use teletherapy units for medical use must perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:</p> <ol style="list-style-type: none"> <li>1. Timer accuracy, and timer linearity over the range of use;</li> <li>2. On-off error;</li> <li>3. The coincidence of the radiation field and the field indicated by the light beam localizing device;</li> <li>4. The accuracy of all distance measuring and localization devices used for medical use;</li> <li>5. The output for one typical set of operating conditions measured with the dosimetry system described in 180 NAC 7-072.02; and</li> <li>6. The difference between the measurement made in 180 NAC 7-076.01, item 5 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).</li> </ol> <p><u>7-076.02</u> A licensee must perform measurements required by 180 NAC 7-076.01 in accordance with written procedures established by the authorized medical physicist. The authorized medical physicist need not actually perform the spot-check measurements.</p>

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						<p><u>7-076.03</u> A licensee must have the authorized medical physicist review and sign the results of each spot-check within 15 days. The authorized medical physicist must notify the licensee within 10 days in writing of the results of each spot-check.</p> <p><u>7-076.04</u> A licensee authorized to use a teletherapy unit for medical use must perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:</p> <ol style="list-style-type: none"> <li>1. Electrical interlocks at each teletherapy room entrance;</li> <li>2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);</li> <li>3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;</li> <li>4. Viewing and intercom systems;</li> <li>5. Treatment room doors from inside and outside the treatment room; and</li> <li>6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.</li> </ol> <p><u>7-076.05</u> If the results of the checks required in 180 NAC 7-076.02 and 7-076.04 indicate the malfunction of any system, a licensee must 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.</p> <p><u>7-076.06</u> A licensee must retain a record of each spot-check required by 180 NAC 7-076.01 and 7-076.04 and in accordance with 180 NAC 7-109.</p>
§35.643	Periodic spot-checks for remote afterloader units		H&S, except paragraph (f) is D.	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (e) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the medical device is performing properly.	7-077 (SSR) NO	<p><u>7-077 PERIODIC SPOT-CHECKS FOR REMOTE AFTERLOADER UNITS</u></p> <p><u>7-077.01</u> A licensee authorized to use a remote afterloader unit for medical use must perform spot-checks of each remote afterloader facility and on each unit:</p> <ol style="list-style-type: none"> <li>1. At the beginning of each day of use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit;</li> </ol>

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				<p>The H&amp;S two or fewer failure test scenario: If a licensee does not perform periodic spot checks of high dose-rate and pulsed dose-rate remote afterloaders, and an equipment failure occurs, the public and workers could receive exposures in excess of radiation protection limits in Part 20 and a medical event could occur.</p>		<p>2. Prior to each patient treatment with a low dose-rate remote afterloader unit; and  3. After each source installation.  <u>7-077.02</u> The licensee must have the authorized medical physicist establish written procedures for performing the spot-checks required in 180 NAC 7-077.01. The authorized medical physicist need not actually perform the spot-check measurements.  <u>7-077.03</u> A licensee must have the authorized medical physicist review and sign the results of each spot-check within 15 days. The authorized medical physicist must notify the licensee within 10 days in writing of the results of each spot-check.  <u>7-077.04</u> To satisfy the requirements of 180 NAC 7-077.01, spot-checks must, at a minimum, assure proper operation of:  1. Electrical interlocks at each remote afterloader unit room entrance;  2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;  3. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;  4. Radiological emergency response equipment;  5. Radiation monitors used to indicate the source position;  6. Timer accuracy;  7. Clock (date and time) in the unit's computer; and  8. Decayed source(s) activity in the unit's computer.  <u>7-077.05</u> If the results of the checks required in 180 NAC 7-077.04 indicate the malfunction of any system, a licensee must 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.  <u>7-077.06</u> A licensee must retain a record of each check required by 180 NAC 7-077.04 in accordance with 180 NAC 7-110.</p>
	Periodic		H&S,	Based upon Handbook 5.9 Part II, "Categorization	7-078 (SSR)	<u>7-078 PERIODIC SPOT-CHECKS FOR GAMMA</u>

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§35.645	spot-checks for gamma stereotactic radiosurgery units		except paragraph (g) is D.	<p>Criteria," Section E, paragraphs (a) through (f) were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event by checking instrument performance between maintenance and full calibrations. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not perform periodic spot checks of gamma stereotactic radiosurgery units, and an equipment failure occurs, then the public and workers could receive exposures in excess of radiation protection limits in Part 20 and a medical event could occur.</p>	NO	<p><u>STEREOTACTIC RADIOSURGERY UNITS</u>  <u>7-078.01</u> A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:</p> <ol style="list-style-type: none"> <li>1. Monthly;</li> <li>2. Before the first use of the unit on a given day; and</li> <li>3. After each source installation.</li> </ol> <p><u>7-078.02</u> The licensee must have the authorized medical physicist:</p> <ol style="list-style-type: none"> <li>1. Establish written procedures for performing the spot-checks required in 180 NAC 7-078.01; and</li> <li>2. Review and sign the results of each spot-check required by 180 NAC 7-078.01 within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist must notify the licensee within 10 days in writing of the results of the spot check.</li> </ol> <p><u>7-078.03</u> To satisfy the requirements of 180 NAC 7-078.01, item 1, spot-checks must, at a minimum:</p> <ol style="list-style-type: none"> <li>1. Assure proper operation of: <ol style="list-style-type: none"> <li>a. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;</li> <li>b. Helmet microswitches;</li> <li>c. Emergency timing circuits; and</li> <li>d. Stereotactic frames and localizing devices (trunnions).</li> </ol> </li> <li>2. Determine: <ol style="list-style-type: none"> <li>a. The output for one typical set of operating conditions measured with the dosimetry system described in 180 NAC 7-072.02;</li> <li>b. The difference between the measurement made in 180 NAC 7-078.03, item b. and the anticipated output, expressed as a percentage of the anticipated output, (that is, the value obtained at last full calibration corrected mathematically for physical decay);</li> <li>c. Source output against computer calculation;</li> <li>d. Timer accuracy and linearity over the range of use;</li> <li>e. On-off error; and</li> <li>f. Trunnion centricity.</li> </ol> </li> </ol>

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						<p><u>7-078.04</u> To satisfy the requirements of 180 NAC 7-078.01, item 2 and 3, spot-checks must assure proper operation of:</p> <ol style="list-style-type: none"> <li>1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;</li> <li>2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;</li> <li>3. Viewing and intercom systems;</li> <li>4. Timer termination;</li> <li>5. Radiation monitors used to indicate room exposures; and</li> <li>6. Emergency off buttons.</li> </ol> <p><u>7-078.05</u> A licensee must arrange for the repair of any system identified in 180 NAC 7-078.03 that is not operating properly.</p> <p><u>7-078.06</u> If the results of the checks required in 180 NAC 7-078.04 indicate the malfunction of any system, a licensee must 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.</p> <p><u>7-078.07</u> A licensee must retain a record of each check required by 180 NAC 7-078.03 and 7-078.04 and in accordance with 180 NAC 7-111.</p>
§35.647	Additional technical requirements for mobile remote afterloader units		H&S - paragraphs (a) through (d) for those States which authorize this activity, except (e) is	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&amp;S those Agreement States which authorize this service. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a public exposure. The essential objective of this requirement is to assure that the appropriate radiation surveys are performed and that the proper administrative controls are utilized.</p> <p>The H&amp;S two or fewer failure test scenario: If these requirements are not adopted, a mobile remote afterloader licensee would not be required to check survey instruments and verify sources after use, then sources could be misplaced and the public and workers could be exposed to radiation in</p>	7-079 (SSR) NO	<p><u>7-079 ADDITIONAL TECHNICAL REQUIREMENTS FOR MOBILE REMOTE AFTERLOADER UNITS</u></p> <p><u>7-079.01</u> A licensee providing mobile remote afterloader service must:</p> <ol style="list-style-type: none"> <li>1. Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and</li> <li>2. Account for all sources before departure from a client's address of use.</li> </ol> <p><u>7-079.02</u> In addition to the periodic spot-checks required by 180 NAC 7-077 a licensee authorized to use mobile afterloaders for medical use will perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:</p> <ol style="list-style-type: none"> <li>1. Electrical interlocks on treatment area access points;</li> </ol>

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			D. D - for other States	excess of radiation protection limits in Part 20 and a medical event could occur.		<p>2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;</p> <p>3. Viewing and intercom systems;</p> <p>4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;</p> <p>5. Radiation monitors used to indicate room exposures;</p> <p>6. Source positioning (accuracy); and</p> <p>7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.</p> <p><u>7-079.03</u> In addition to the requirements for checks 180 NAC 7-079.02, a licensee must ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.</p> <p><u>7-079.04</u> If the results of the checks required in 180 NAC 7-079.02 indicate the malfunction of any system, a licensee must 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.</p> <p><u>7-079.05</u> A licensee must retain a record of each check required by 180 NAC 7-079.02 in accordance with 180 NAC 7-112.</p>
§35.652	Radiation surveys		H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&amp;S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of public and worker overexposures. The essential objective of this requirement is to assure that exposure to the source(s) in the shielded position does not exceed the levels stated in the SS&amp;D registry.</p> <p>The H&amp;S two or fewer failure test scenario: If a licensee does not perform these radiation surveys, and the radiation safety of the device is compromised, then the public and workers could receive exposures in excess of radiation protection limits in Part 20.</p>	7-080 (NRC) NO	<p><u>7-080 RADIATION SURVEYS</u></p> <p><u>7-080.01</u> In addition to the survey requirement in 180 NAC 4-021, a person licensed to possess or a use remote afterloader, teletherapy or gamma stereotactic radiosurgery unit must perform surveys of the device and ensure the results of the surveys from the surface of the main source safe, with the sources in the shielded position, do not exceed the maximum and average radiation levels listed in the sealed source and device registry.</p> <p><u>7-080.02</u> The licensee must make the survey required by 180 NAC 7-080.01 upon installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).</p>

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						<u>7-080.03</u> A licensee must retain a record of the radiation surveys required by 180 NAC 7-080.01 in accordance with 180 NAC 7-113.
§35.655	Five-year inspection for teletherapy and gamma stereotactic radiosurgery units		H&S, except paragraph (c) is D.	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood a medical event, and public and worker exposure. The essential objective of this requirement is to assure that the inspection and servicing of teletherapy and gamma stereotactic radiosurgery units during source replacements or at intervals not to exceed 5 years and this inspection and servicing is performed by a person specifically licensed by the Commission or an Agreement State.  The H&S two or fewer failure test scenario: If a licensee does not have their teletherapy and gamma stereotactic radiosurgery units inspected and serviced at 5-year intervals and an equipment failure occurs, the public and workers could receive radiation exposures in excess of radiation protection limits in Part 20 and a medical event could occur.	7-081 (NRC) NO	<u>7-081 FIVE-YEAR INSPECTION FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS</u> <u>7-081.01</u> A licensee must have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism. <u>7-081.02</u> This inspection and servicing must only be performed by persons specifically licensed to do so by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State. <u>7-081.03</u> A licensee must maintain a record of the inspection and servicing in accordance with 180 NAC 7-114.
§35.657	Therapy-related computer systems		H&S	Based upon Handbook 5.9 Part paragraphs (a) and (b) was designated II, "Categorization Criteria," Section E, this provision was designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood a medical event. The essential objective of this requirement is to assure that therapy related computer systems are functioning properly and testing is done in accordance with national protocols.  The H&S two or fewer failure test scenario: If a licensee does not verify that computerized treatment planning systems are operating properly,	7-082 (NRC) NO	<u>7-082 THERAPY-RELATED COMPUTER SYSTEMS:</u> The licensee must perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of: <u>7-082.01</u> The source-specific input parameters required by the dose calculation algorithm; <u>7-082.02</u> The accuracy of dose, dwell time, and treatment time calculations at representative points; <u>7-082.03</u> The accuracy of isodose plots and graphic displays; <u>7-082.04</u> The accuracy of the software used to determine radioactive source positions from radiographic images; and

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				and a medical event occurs.		<u>7-082.05</u> The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.
§35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units		B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.	7-084 (NRC) NO	<p><u>7-084 TRAINING FOR USE OF REMOTE AFTERLOADER UNITS, TELE THERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS</u>; Except as provided in 180 NAC 7-026, the licensee must require an authorized user of a sealed source for a use authorized under 180 NAC 7-067 to be a physician who:</p> <p><u>7-084.01</u> Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) and who meets the requirements of 180 NAC 7-084.03 and 7-084.04. (The names of board certifications which have been recognized the Department, an Agreement State or the U.S. Nuclear Regulatory Commission will be posed on the NRC's web page.) To be recognized, a specialty board must require all candidates for certification to:</p> <p>2. 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 or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and</p> <p>3. Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, high and low dose-rate brachytherapy, and external beam therapy; or</p> <p><u>7-084.02</u> The physician:</p> <p>1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:</p> <p>a. 200 hours of classroom and laboratory training in the following areas:</p> <p>(1) Radiation physics and instrumentation;</p>

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						<p>(2) Radiation protection;</p> <p>(3) Mathematics pertaining to the use and measurement of radioactivity; and</p> <p>(4) Radiation biology; and</p> <p>b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-084.01, 7-084.02 or equivalent U.S. Nuclear Regulatory or Agreement State requirements at a medical institution, involving:</p> <p>(1) Reviewing full calibration measurements and periodic spot-checks;</p> <p>(2) Preparing treatment plans and calculating treatment doses and times;</p> <p>(3) Using administrative controls to prevent a misadministration involving the use of radioactive material;</p> <p>(4) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;</p> <p>(5) Checking and using survey meters; and</p> <p>(6) Selecting the proper dose and how it is to be administered; and</p> <p>2. Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 180 NAC 7-084, or equivalent Agreement State or U.S. Nuclear Regulatory Commission 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 or 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 180 NAC 7-084.02, item 1.b.; and</p> <p>3. Meets the requirements of 180 NAC 7-084.03 and 7-084.04.</p> <p><u>7-084.03</u> Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-084.01, item 1 or 7-084.02, item 1 and 2, and 7-084.04 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</p>
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						user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-084 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and <u>7-084.04</u> Has received training in device operation, safety procedures, and clinical use of 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.
Subpart J - Retained for 2-year Transition Period	Training & Experience Requirements		No compatibility category changes	A two year "Transition Period" has been established starting on the effective date of the revised Part 35. The current Subpart J addressing training and experience requirements will be accepted along with the revised requirements.	NA	
§35.900	Radiation Safety Officer		D		NA	
§35.910	Training for uptake, dilution, and excretion studies		D		NA	
§35.920	Training for imaging and localization		D		NA	

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	studies					
§35.930	Training for Therapeutic use of unsealed byproduct material		D		NA	
§35.932	Training for treatment of hyperthyroidism		D		NA	
§35.934	Training for treatment of thyroid carcinoma		D		NA	
§35.940	Training for use of brachytherapy sources		D		NA	
§35.941	Training for ophthalmic use of strontium-90		D		NA	
§35.950	Training for use of sealed sources for diagnosis		D		NA	
§35.960	Training for use of therapeutic medical		D		NA	

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	devices					
§35.961	Training for authorized medical physicist		D		NA	
§35.980	Training for an authorized nuclear pharmacist		D		NA	
§35.981	Training for experienced nuclear pharmacist		D		NA	
§35.1000	Other medical uses of byproduct material or radiation from byproduct material		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-085	180 NAC 7-085
§35.2024	Records of authority and responsibilities for radiation protection programs		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-086	180 NAC 7-086
§35.2026	Records of radiation protection program		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-087	180 NAC 7-087

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	changes					
§35.2040	Records of written directives		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-088	180 NAC 7-088
§35.2041	Records for procedures for administrations requiring a written directive		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-089	180 NAC 7-089
§35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-091	180 NAC 7-091
§35.2061	Records of radiation survey instrument calibrations		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-092	180 NAC 7-092
§35.2063	Records of dosage of unsealed byproduct material for medical use		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-093	Draft 2006
§35.206	Records of leak test and		D	Does not meet any of the criteria of Category A, B,	7-094	180 NAC 7-094

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7	inventory of sealed sources and brachytherapy sources			C, or H&S.		
§35.2070	Records of surveys for ambient radiation exposure rate		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-095	180 NAC 7-095
§35.2075	Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-096	180 NAC 7-096
§35.2080	Records of mobile medical services		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-097	180 NAC 7-097
§35.2092	Records of decay-in-storage		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-098	180 NAC 7-098
§35.2204	Records of molybdenum-99 concentrations		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-099	180 NAC 7-099
					7-101	180 NAC 7-101

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§35.2310	Records of safety instruction		D	Does not meet any of the criteria of Category A, B, C, or H&S.		
§35.2404	Records of surveys after source implant and removal		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-102	180 NAC 7-101
§35.2406	Records of brachytherapy source accountability		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-103	180 NAC 7-102
§35.2432	Records of calibration measurements of brachytherapy sources		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-0104	180 NAC 7-104
§35.2433	Records of decay of strontium-90 sources for ophthalmic treatments		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-0105	180 NAC 7-105
§35.2605	Records of installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units, and gamma		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-106	180 NAC 7-106

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	stereotactic radiosurgery units					
§35.2610	Records of safety procedures		D	Does not meet any of the criteria of Category A, B, C, or H&S.		
§35.2630	Records of dosimetry equipment used for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-107	180 NAC 7-17
§35.2632	Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-108	180 NAC 7-108
§35.2642	Records of periodic spot-checks for teletherapy units		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-109	180 NAC 7-109
§35.264	Records of periodic		D	Does not meet any of the criteria of Category A, B,	7-110	180 NAC 7-110

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3	spot-checks for remote afterloader units			C, or H&S.		
§35.264 5	Records of periodic spot-checks for gamma stereotactic radiosurgery units		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-111	180 NAC 7-111
§35.264 7	Records of additional technical requirements for mobile remote afterloader units		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-112	180 NAC 7-112
§35.265 2	Records of surveys of therapeutic treatment units		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-0113	180 NAC 7-113
§35.265 5	Records of 5-year inspection of teletherapy and gamma stereotactic radiosurgery units		D	Does not meet any of the criteria of Category A, B, C, or H&S.	7-114	180 NAC 7-114
§35.304 5	Report and notification of a medical		C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(c), this requirement was designated a Category C because absent this provision there could be a potential	7-115 (SSR) NO	7-115 REPORT AND NOTIFICATION OF MISADMINISTRATION <u>7-115.01</u> Other than events that result from intervention by a patient or human research subject, a licensee must report any event in which the

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	event			preclusion of an effective review or evaluation by the Commission and Agreement State programs for agreement material with respect to protection of public health and safety. The essential objective of this requirement is to assure that medical events are reported to the radiation control program and in order to assess the effectiveness of the national program for control of Atomic Energy Act materials.		<p>administration of radioactive material or radiation from radioactive material results in:</p> <ol style="list-style-type: none"> <li>1. A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either <ol style="list-style-type: none"> <li>a. The total dose delivered differs from the prescribed dose by 20% or more; or</li> <li>b. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or</li> <li>c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.</li> </ol> </li> <li>2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following: <ol style="list-style-type: none"> <li>a. An administration of a wrong radioactive drug;</li> <li>b. An administration of a radioactive drug containing radioactive material by the wrong route of administration;</li> <li>c. An administration of a dose or dosage to the wrong individual or human research subject;</li> <li>d. An administration of a dose or dosage delivered by the wrong mode of treatment; or</li> <li>e. A leaking sealed source.</li> </ol> </li> <li>3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) 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).</li> </ol> <p><u>7-115.02</u> A licensee must 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, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.</p> <p><u>7-115.03</u> The licensee must notify the Department by telephone, no later than the next business day</p>
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						<p>after the discovery of a misadministration.</p> <p><u>7-115.04</u> The licensee must submit a written report to the Department within 15 days after discovery of the misadministration.</p> <ol style="list-style-type: none"> <li>1. The written report must include: <ol style="list-style-type: none"> <li>a. The licensee's name;</li> <li>b. The name of the prescribing physician;</li> <li>c. A brief description of the event;</li> <li>d. Why the event occurred;</li> <li>e. The effect, if any, on the individual(s) who received the administration;</li> <li>f. What actions, if any, have been taken or are planned to prevent recurrence; and</li> <li>g. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.</li> </ol> </li> <li>2. The report can not contain the individual's name or any other information that could lead to identification of the individual.</li> </ol> <p><u>7-115.05</u> The licensee must provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that s/he 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 must make the appropriate notifications as soon as possible thereafter. The licensee may 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 180 NAC 7-115.05, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee must 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 must provide such a written description if requested.</p>
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						<p><u>7-115.06</u> Aside from the notification requirement, nothing in 180 NAC 7-115 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.</p> <p><u>7-115.07</u> A licensee must retain a record of a misadministration in accordance with 180 NAC 7-089. A copy of the record required under 180 NAC 7-089 must be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.</p>
§35.304 7	Report and notification of a dose to an embryo/fetus or a nursing child		C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(c), this requirement was designated a Category C because absent this provision there could be a potential preclusion of an effective review or evaluation by the Commission and Agreement State programs for agreement material with respect to protection of public health and safety. The essential objective of this requirement is to assure that doses to the embryo/fetus or nursing child are reported to the radiation control program.	7-117 (SSR) NO	<p><u>7-117 REPORT AND NOTIFICATION OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD</u></p> <p><u>7-117.01</u> A licensee must report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) 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.</p> <p><u>7-117.02</u> A licensee must report any dose to a nursing child that was not specifically approved, in advance, by the authorized user; that is a result of an administration of radioactive material to a breast-feeding individual that:</p> <ol style="list-style-type: none"> <li>1. Is greater than 5 mSv (500 mrem) total effective dose equivalent; or</li> <li>2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.</li> </ol> <p><u>7-117.03</u> The licensee must notify by telephone the Department no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 180 NAC 7-117.01 or 7-117.02.</p> <p><u>7-117.04</u> The licensee must submit a written report to the Department within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 180 NAC 7-117.01 or 7-117.02.</p> <ol style="list-style-type: none"> <li>1. The written report must include: <ol style="list-style-type: none"> <li>a. The licensee's name;</li> <li>b. The name of the prescribing physician;</li> </ol> </li> </ol>

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						<p>c. A brief description of the event;</p> <p>d. Why the event occurred;</p> <p>e. The effect, if any, on the embryo/fetus or the nursing child;</p> <p>f. What actions, if any, have been taken or are planned to prevent recurrence; and</p> <p>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.</p> <p>2. The report can not contain the individual's or child's name or any other information that could lead to identification of the individual or child.</p> <p><u>7-117.05</u> The licensee must provide notification of the event to 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 180 NAC 7-117.01 and 7-117.02, unless the referring physician personally informs the licensee either that s/he 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 must 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 180 NAC 7-117.05, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee must 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 must provide such a written description if requested.</p> <p><u>7-117.06</u> A licensee must retain a record of a dose to an embryo/fetus or a nursing child in accordance with 180 NAC 7-090. A copy of the record required under 180 NAC 7-090 must be provided to the referring</p>
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						physician, if other than the licensee, within 15 days after the discovery of the event.
§35.306 7	Report of a leaking source		C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(c), this requirement was designated a Category C because absent this provision there could be a potential preclusion of an effective review or evaluation by the Commission and Agreement State programs for agreement material with respect to protection of public health and safety. The essential objective of this requirement is to assure that leaking sources are reported to the radiation control program.	7-118 (SSR) NO	<u>7-118 REPORTS OF LEAKING SOURCES</u> A licensee must file a report within 5 days if a leak test required by 180 NAC 7-033 reveals the presence of 185 Bq ( 0.005 µCi) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.
§35.400 1	Violations		D	Does not meet any of the criteria of Category A, B, C, or H&S.	NA	
§35.400 2	Criminal penalties		D	Does not meet any of the criteria of Category A, B, C, or H&S.	NA	

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