



CABINET FOR HEALTH AND FAMILY SERVICES

Steven L. Beshear
Governor

Radiation Health Branch / Department for Public Health
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Audrey Tayse Haynes
Secretary

July 24, 2012

Christian Einberg, Acting Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

Dear Mr. Einberg:

Enclosed is a copy of the proposed revisions to the Kentucky Radiological Health Kentucky Administrative Regulations, Title 902, Chapter 100 Radiology published in their final form on June 3, 2011, November 16, 2011 and December 7, 2011. The proposed revisions to these final regulations are attached and correspond to the following amendments to equivalent NRC's regulations.

<u>Revision Date</u>	<u>Title</u>	<u>State Part</u>
• 6/3/11	Definitions for 902 KAR Chapter 100.	902 KAR 100:010
• 6/3/11	Specific licenses to manufacture, assemble, repair, or distribute products	902 KAR 100:058
• 6/3/11	Transportation of radioactive material	902 KAR 100:070
• 6/3/11	Use of radionuclides in the health arts	902 KAR 100:072
• 11/16/11	Standards for protection against radiation	902 KAR 100:019
• 11/16/11	Decommissioning and financial surety	902 KAR 100:042
• 11/16/11	Industrial radiography	902 KAR 100:100
• 12/7/11	Wire line service operations	902 KAR 100:142

Revisions to the attached regulations are based on a letter dated February 29, 2012 from Pamela J. Henderson, Acting Deputy Director, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs. The letter and attached "Compatibility Comments On Kentucky Final Regulations" were used as a basis for these attached regulation revisions.

The following RATS-IDs correspond to the regulation changes above:

- RATS ID # 1995-3
- RATS ID # 1998-5
- RATS ID # 1998-6
- RATS ID # 1999-3
- RATS ID # 2000-1
- RATS ID # 2000-2
- RATS ID # 2002-1
- RATS ID # 2003-1
- RATS ID # 2004-1
- RATS ID # 2005-1
- RATS ID # 2005-2
- RATS ID # 2006-1

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

If you have any questions, please feel free to contact me at 502-564-3700 ext. 3701 or Curt Pendergrass of my staff at 502-564-3700 ext. 4140 or curt.pendergrass@ky.gov .

Sincerely,



Matthew W. McKinley
Program Manager,
Kentucky Radiation Health Branch

Enclosures:

As stated

Cc: Kathleen Schneider
Sr. Project Manager
State Regulation Review Coordinator USNRC
Division of Materials Safety and State Agreements (MSSA)
Agreements State Program Branch (ASPB)
kathleen.schneider@nrc.gov
301-415-2320

February 29, 2012

Matthew McKinley, Administrator
Radiation Health Program
Cabinet for Health and Family Services
275 East Main Street, HS1C-A
Frankfort, KY 40621-0001

Dear Mr. McKinley:

We have reviewed the final revision to the Commonwealth of Kentucky regulations Title 902 Chapter 100 Radiology, received by our office on January 19, 2012. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 32, 34, 35, 36, 39, 40, 61, 70, 71 and the requirements of the 12 amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Curt Pendergrass on February 29, 2012.

As a result of our review, we have 14 comments that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. We have determined that if these regulations are revised, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

We request that when you revise your regulations to address our comments, a copy of the "as published" regulations be provided to us for review. As requested in FSME Procedure SA-201, "Review of State Regulatory Requirements," please highlight the location of any changes made by Kentucky, in response to our comments, and provide a copy to Division of Materials Safety and State Agreements, FSME. The SRS Data Sheet summarizes our knowledge of the status of other Kentucky regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the FSME website: <http://nrc-stp.ornl.gov/rulemaking.html>.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Kathleen Schneider, State Regulation Review Coordinator at (301) 415-2320 (email: kathleen.schneider@nrc.gov) or Monica Orendi at 610-337-5214 (email: monica.orendi@nrc.gov).

Sincerely,

/RA/

Pamela J. Henderson, Acting Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures:
As stated

[Concurrence Page]

Enclosures: As stated

Distribution:

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OFFICE	RI		ASPB		OGC		ASPB:BC		MSSA:DD	
NAME	MOrendi		KSchneider		BJones		DWhite		PHenderson	
DATE	02/03/12		02/09/12		02/27/12		02/28/12		02/29/12	

ML120390169

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Package ML120390127

COMPATIBILITY COMMENTS ON *KENTUCKY* FINAL REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	100:019 Section 3	20.1201	1998-5 2002-1	A	<p>Occupational Dose Limits for Adults</p> <p>Kentucky needs to change 100:019 Section 3 (1)(a)1. to read "Total effective dose equivalent being equal to five (5) rem (0.05 SV); and."</p> <p>Kentucky needs to make the above change in order to meet the Compatibility Category A designation assigned to 10 CFR 20.1201.</p>
2	100:142 Section 5	39.33	1998-5	C	<p>Radiation Detection Instruments</p> <p>Kentucky omits paragraph 10 CFR 39.33(b) from 100:142 Section (5).</p> <p>Kentucky is less restrictive with regards to its retention for calibration records. NRC requires that these records be maintained for a period of three years after the calibration date, while Kentucky only requires them to be maintained for a period of two years.</p> <p>Kentucky needs to adopt the essential objectives of 10 CFR 39.33(b) and changes their retention time for calibration records to three years in order to meet the Compatibility Category C designation assigned to 10 CFR 39.33.</p>
3	100:142 Section 1	39.15	2000-1	C	<p>Agreement With Well Owner or Operator</p> <p>In 100:142 Section 1 (1), Kentucky allows written agreements between the licensee and the drilling contractor. 10 CFR 39.15 does not allow the licensee to enter into an agreement with the drilling contractor which make Kentucky's regulation less restrictive than NRC's regulation.</p> <p>Kentucky has two wrong references in</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>100:142 Section 1. In Section 1. (1)(d), Kentucky references Section 14 of this administrative regulation. This points to the wrong Section and Kentucky should reference Section 24 of this administrative regulation. In Section 1. (1)(f), Kentucky references Section 23 of this administrative regulation. This also points to the wrong section and Kentucky should reference Section 27 of this administrative regulation.</p> <p>Kentucky needs to make the above changes in order to meet the Compatibility Category C designation assigned to 10 CFR 39.15.</p>
4	100:142 Section 19	39.53	2000-1	C	<p>Energy Compensation Source</p> <p>Kentucky lists a wrong reference to 10 CFR 39.77 in 100:142 Section 19 (3). Kentucky mistakenly references Section 25 as the equivalent to 10 CFR 39.77, however this should be corrected to read Section 27 (...subject to the requirements of Sections 1, 6, 7, and 27).</p> <p>Kentucky needs to make the above change in order to meet the Compatibility Category C designation assigned to 10 CFR 39.53.</p>
5	100:100 Section 16	34.83	2000-2	C	<p>Records of Personnel Monitoring Procedures</p> <p>Kentucky references the wrong section in 100:100 Section 19 (7)(a)3. Kentucky should state "... shall be included in the records maintained in accordance with paragraph (b) of this subsection and subsection 10(b) of this section."</p> <p>Kentucky needs to make the above change in order to meet the Compatibility Category C designation assigned to 10 CFR 34.83.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
6	100:042 Section 11 and 15	30.35/ 10 CFR 30 Appendix B	2003-1	H&S/B	<p>Financial Assurance and Recordkeeping for Decommissioning</p> <p>Kentucky has an error in 100:042 Section 16, its equivalent to 10 CFR 30 Appendix B. Kentucky lists the quantity for Strontium-90 as 0.12 microcuries when it should be listed as 0.10 microcuries.</p> <p>Kentucky needs to make the above change in order to meet the Compatibility Category H&S designation assigned to 10 CFR 30.35 and the Compatibility Category B designation assigned to 10 CFR 30 Appendix B.</p>
7	100:010 Section 1	71.4	2004-1	[B]	<p>Definition: Deuterium</p> <p>Kentucky omits the definition for deuterium from 100:010.</p> <p>Kentucky needs to add deuterium to 100:010 in order to meet the Compatibility Category [B] designation assigned to 10 CFR 71.4 Definition: Deuterium.</p>
8	100:010 Section 1 (116)	71.4	2004-1	[B]	<p>Definition: Fissile Material</p> <p>Kentucky has a wrong reference cited in 902 KAR 100:010 Section 1 (116)(c). Instead of 10 CFR 70.15, Kentucky should reference 10 CFR 71.15.</p> <p>Kentucky needs to make the above change in order to meet the Compatibility Category [B] designation assigned to 10 CFR 71.4 Definition: Fissile Material.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
9	100:010 Section 1	71.4	2004-1	[B]	<p>Definition: Graphite</p> <p>Kentucky omits a definition for Graphite from 100:010.</p> <p>Kentucky needs to add the definition for graphite to 100:010 in order to meet the Compatibility Category [B] designation assigned to 10 CFR 71.4 Definition: Graphite.</p>
10	100:010 Section 1 (165)	71.4	2004-1	[B]	<p>Definition: Low Specific Activity (LSA)</p> <p>Kentucky has a wrong reference cited in 100:010 Section 1 (165). Instead of 10 CFR 70.15, Kentucky should reference 10 CFR 71.15.</p> <p>Kentucky needs to make the above change in order to meet the Compatibility Category [B] designation assigned to 10 CFR 71.4 Definition: Low Specific Activity (LSA).</p>
11	100:070 Section 3	71.14(b)	2004-1	NRC	<p>Exemption for Low Level Materials</p> <p>Kentucky includes this section in 100:070 Section 3. Since this is a Compatibility Category NRC regulation, Kentucky needs to remove 100:070 Section 3(2) from its regulations.</p> <p>Kentucky needs to make the above change in order to meet the Compatibility Category NRC designation assigned to 10 CFR 71.14(b).</p>
12	100:070 Section 15	71.22	2004-1	[B]	<p>General License: Fissile Material</p> <p>Kentucky does not have the complete equation for "CSI=" in 100:070 Section 15. Kentucky needs to correct the equation to read:</p> $CSI = 10 \left[\frac{\text{grams of } ^{235}\text{U}}{X} + \frac{\text{grams of } ^{233}\text{U}}{Y} + \frac{\text{grams of Pu}}{Z} \right]$

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>Kentucky lists the wrong tables in 100:070 Section 15(5)(c). 100:070 15(5)(c) should read "The values of X, Y, and Z used in the CSI equation must be taken from 10 CFR Tables 71-1 or 71-2, as appropriate."</p> <p>Kentucky has an incorrect reference in 100:070 Section 15(5)(d). 100:070 Section 15(5)(d) should read "If 10 CFR Table 71-2 is used to obtain..."</p> <p>Kentucky has an incorrect reference in 100:070 Section 15(5)(e). 100:070 Section 15(5)(e) should read "10 CFR Table 71-1 values for..."</p> <p>Kentucky needs to make the above changes to 100:070 Section 15 in order to meet the Compatibility Category [B] designation assigned to 10 CFR 71.22.</p>
13	100:072 Section 64	35.50	2005-2 2006-1	B	<p>Training for Radiation Safety Officer</p> <p>Kentucky omits a citation in 100:072 Section 64 (4). Section 64 (4) should read "... completed the requirements in subsections (5) and in (1)(a)(1) and (2) or (1)(b)(1) and 2 or (2)(a) or (3)(a) or (3)(b)...."</p> <p>Kentucky needs to make the above change to 100:072 Section 64 (4) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.50.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
14	100:058 Section 9	32.72	2006-1	B	<p>Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Byproduct Material for Medical Use Under Part 35.</p> <p>Kentucky omits a reference in 100:058 Section 9(2). This section should read "A licensee described by subsection (1)(b)(3) or (4) of this section may:."</p> <p>Kentucky needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72.</p>

STATE REGULATION STATUS

State: Kentucky

Tracking Ticket Number: 12-3

[12 amendment(s) reviewed is identified by a ★
at the beginning of the equivalent NRC requirement.]

Date: February 29, 2012

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (★ Superceded by 1997-5)	01/10/1994	Final	No Comments 03/15/1996	Kentucky has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 (★ Superceded by 1997-5)	none	Not Required	Not Required	Kentucky has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-3	Standards for Protection Against Radiation Part 20 56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183;	01/01/1994	Final	No Comments 04/17/1998	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final	No Comments 03/15/1996	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (★ Superceded by 2002-2)	01/27/1995	Final	No Comments 03/15/1996	Kentucky has not yet adopted Final Regulations equivalent to RATS ID: 2002-2.
1992-2	Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30, 35 57 FR 45566	none	Not Required	Not Required	Kentucky has adopted Final Regulations equivalent to RATS ID: 1997-5.
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628	10/25/1996	Final	No Comments 03/15/1996	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Not Applicable ¹	Not Applicable	Kentucky does not have any licensees subject to these regulations. (See SECY-95-112)
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable ¹	Not Applicable	Kentucky does not have any licensees subject to these regulations. (See SECY-95-112)
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Not Required	Not Required	These regulations are not required to be adopted for purposes of Compatibility.
1994-2	Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220	07/01/1997	Not Applicable	Not Applicable	Kentucky does not have authority to regulate this material under its Agreement.
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997	Final	No Comments 04/17/1998	
1995-1	Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use Parts 30, 32, 35 59 FR 61767; 59 FR 65243; 60 FR 322	01/01/1998	Final	No Comments 04/17/1998	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final	No Comments 04/17/1998	
*1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final ML120190307	No Comments 02/29/2012 ML120390127	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superseded by 1997-5)	06/30/1998	Final	No Comments 03/15/1996	Kentucky has adopted Final Regulations equivalent to RATS ID: 1997-5.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final	No Comments 04/17/1998	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Proposed	No Comments 06/21/2000	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 (Superseded by 2002-2 and 2005-2)	10/20/1998			Kentucky has not yet adopted Final Regulations equivalent to RATS IDs: 2002-2 and 2005-2.
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 (Superseded by 2004-1)	04/01/1999	Final	Comments 06/21/2000	Kentucky has not yet adopted Final Regulations equivalent to RATS ID: 2004-1.
1996-2	One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40, 70 61 FR 1109	02/15/1999	Not Required	Not Required	These regulations are not required to be adopted for purposes of Compatibility.
1996-3	Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61, 70 61 FR 24669	06/17/1999	Final	No Comments 06/21/2000	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final	No Comments 04/17/1998	
1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662	02/27/2000	Final ML010780156	No Comments 03/30/2001 ML010890409	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final	No Comments 04/17/1998	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superseded by 2004-1)	02/10/2000	Not Required	Not Required	These regulations are not required to be adopted for purposes of Compatibility. (See STP-97-078)
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, 150 62 FR 28947	06/27/2000	Final ML010780156	Comments 03/30/2001 ML010890409	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final	No Comments 06/21/2000	
1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	Final	No Comments 04/17/1998	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773	02/12/2001	Final	No Comments 06/21/2000	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535	07/01/2001	Not Required	Not Required	These regulations are not required to be adopted for purposes of Compatibility.
1998-3	License Term for Medical Use Licenses Part 35 63 FR 31604 (Superseded by 2002-2)	07/10/2001	Not Required	Not Required	These regulations are not required to be adopted for purposes of Compatibility. (See STP-98-074)

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final ML010780156	No Comments 03/30/2001 ML010890409	
*1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 32, 35, 36, 39 63 FR 39477; 63 FR 45393	10/26/2001	Final ML120190307	Comments 02/29/2012 ML120390127	
*1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML120190307	No Comments 02/29/2012 ML120390127	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	Kentucky does not have authority to regulate this material under its Agreement.
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 64 FR 42269	10/04/2002	Not Required	Not Required	These regulations are not required to be adopted for purposes of Compatibility.
*1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	Final ML120190307	No Comments 02/29/2012 ML120390127	
*2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML120190307	Comments 02/29/2012 ML120390127	
*2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML120190307	Comments 02/29/2012 ML120390127	Part 36 regulation changes were not adopted by Kentucky because they do not have any licensees. See RATS ID: 1993-2.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31, 32 65 FR 79162	02/16/2004	License Condition for 32.52 (a) & (b) only (nothing else reviewed) ML040550046	Comments 03/16/2004 ML040770705	
*2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML120190307	Comments 02/29/2012 ML120390127	
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Proposed ML042720262	Comments 10/28/2004 ML043030121	
*2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML120190307	Comments 02/29/2012 ML120390127	
*2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML120190307	Comments 02/29/2012 ML120390127	
*2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Final ML120190307	No Comments 02/29/2012 ML120390127	
*2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Final ML120190307	Comments 02/29/2012 ML120390127	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML053180137	No Comments 11/15/2005 ML053190005	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
*2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Final ML120190307	Comments 02/29/2012 ML120390127	
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Not Applicable	Not Applicable	Kentucky responded on 03/02/2007 to FSME 06-110 stating that they currently have no licensees applicable to this rule ¹ . ML070610044
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	License Condition ML083180064	No Comments 12/17/2008 ML083220486	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010			
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, 150 72 FR 58473	12/17/2010			
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010			
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901	06/05/2008	License Condition ML080990413	No Comments 05/02/2008 ML081220993	
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012			
2011-1	Decommissioning Planning Parts 20, 30, 40, 70 76 FR 35512	12/17/2015			
2011-2	Licenses, Certifications, and Approvals for Materials Licensees Parts 30, 36, 39, 40, 70, and 150 76 FR 56951	11/14/2014			
2012-1	Change of Compatibility of 10 CFR 31.5 and 31.6 (See RATS ID: 2001-1 for Rule text) 77 FR 3640	01/25/2015			

¹ IMPEP Team: verify that Kentucky does not have any licensees subject to these regulations during each review.

1 **CABINET FOR HEALTH AND FAMILY SERVICES**

2 **Department of Public Health**

3 **Division of Public Health Protection and Safety**

4 **(Amendment)**

5 **902 KAR 100:010. Definitions for 902 KAR Chapter 100.**

6 RELATES TO: KRS 211.840, 211.842-211.852, 211.990(4), 10 C.F.R. 20.1003-
7 20.1005, NCRP Report 141, 42 U.S.C. 2011 et seq.

8 STATUTORY AUTHORITY: KRS 194A.050, 211.090(3), 211.844, 10 C.F.R.
9 20.1003-20.1005

10 NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 authorizes the
11 Cabinet for Health and Family Services to provide by administrative regulation for the
12 registration and licensing of the possession or use of sources of ionizing or electronic
13 product radiation and the handling and disposal of radioactive waste. The Nuclear
14 Regulatory Commission (NRC) approves or denies Kentucky's program for regulating
15 radioactive materials after the effective date of administrative regulations within 902
16 KAR Chapter 100. The federal guidance manual, Compatibility Categories and Health
17 and Safety Identification for NRC Regulations and Other Program Elements - SA - 200,
18 issued June 5, 2009, provides parameters states shall follow in order for approval. The
19 parameters include the provision that definitions shall be identical to NRC definitions.
20 This administrative regulation establishes definitions for 902 KAR Chapter 100.

21 Section 1. Definitions. (1) "A₁" and "A₂":

(a) "A₁" means the maximum activity of special form radioactive material permitted in a Type A package;

(b) "A₂" means the maximum activity of radioactive material, other than special form radioactive material, LSA, and SCO material, permitted in a Type A package;

(c) These values are listed in 10 C.F.R. 71, Appendix A, or may be derived under the procedure prescribed in 10 C.F.R. 71 Appendix A.

(2) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

(3) "Accelerator" means a machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one (1) MeV, such as the cyclotron, synchrotron, synchrocyclotron, betatron, linear accelerator, and Van de Graaff electrostatic generator.

(4) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(5) "Act" means the "Kentucky Radiation Control Act of 1978", as established in KRS 211.840.

(6) "Activity" means the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

(7) "Address of use" means the building or buildings that are identified on the license and where radioactive material may be received, used or stored.

(8) "Adult" means an individual eighteen (18) or more years of age.

(9) "Agreement state" means a state with which the United States Nuclear Regulatory

Commission or the United States Atomic Energy Commission has entered into an effective agreement under subsection 274 b. of the Atomic Energy Act of 1954, 42 U.S.C. 200 et seq., as amended (73 Stat. 689).

(10) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(11) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material, composed wholly or partly of radioactive material, exists in concentrations:

(a) In excess of the derived air concentrations specified in 10 C.F.R. 20 Appendix B; or

(b) That an individual present in the area without respiratory protective equipment may exceed an intake of six-tenths (0.6) percent of the annual limit on intake or twelve (12) DAC hours.

(12) "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM , where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM . The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

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

(14) "Alert" means the notice given when an event may occur, is in progress, or has occurred that may lead to a release of radioactive material, but the release is not

1 expected to require a response by an off-site response organization in order to protect
2 persons offsite.

3 (15) "Aluminum equivalent" means the thickness of type 1100 aluminum, which is
4 composed of at least ninety-nine (99.0) percent aluminum, 0.12 percent copper,
5 affording the same attenuation, under specified conditions, as the material for which it is
6 substituted.

7 (16) "Analytical x-ray system" means a system which utilizes x-rays for the
8 examination of the structure of materials, such as x-ray diffraction and spectrographic
9 equipment.

10 (17) "Annual limit on intake" or "ALI" means the derived limit for the amount of
11 radioactive material taken into the body of an adult worker by inhalation or ingestion in a
12 year. ALI is the smaller value of annual intake of a given radionuclide by the reference
13 man that would result in:

14 (a) A committed effective dose equivalent of five (5) rems, or 0.05 Sv; or

15 (b) A committed dose equivalent of fifty (50) rems, or five-tenths (0.5) Sv, to an
16 individual organ or tissue. ALI values for intake by ingestion and by inhalation of
17 selected radionuclides are established in 10 C.F.R. 20 Appendix B.

18 (18) "Area of use" means a portion of a physical structure that has been set aside for
19 the purpose of receiving, using or storing radioactive material.

20 (19) "As low as reasonably achievable" or "ALARA" means making every reasonable
21 effort to maintain exposures to radiation as far below the dose limits established in 902
22 KAR 100:019 as practical, consistent with the purpose for which the licensed activity is
23 undertaken. ALARA shall take into account the state of technology, the economics of

1 improvement in relation to benefits to the public health and safety, and other societal
2 and socioeconomic considerations, in relation to the utilization of nuclear energy and
3 radioactive materials in the public interest.

4 (20) "Assigned protection factor" or "APF" means the expected workplace level of
5 respirator protection that would be provided by a properly functioning respirator or a
6 class of respirators to properly fitted and trained users. Operationally, the inhaled
7 concentration may be estimated by dividing the ambient airborne concentration by the
8 APF.

9 (21) "Atmosphere-supplying respirator" means a respirator that supplies the
10 respirator user with breathing air from a source independent of the ambient atmosphere,
11 and includes supplied-air respirators (SARs) and self-contained breathing apparatus
12 (SCBA) units.

13 (22) "Attenuation" means the reduction of exposure rate upon passage of radiation
14 through matter.

15 (23) "Attenuation block" means a block or stack, having dimensions twenty (20)
16 centimeters by twenty (20) centimeters by three and eight-tenths (3.8) centimeters, of
17 type 1100 aluminum alloy or other materials having equivalent attenuation.

18 (24) "Authorized medical physicist" means an individual who:

19 (a) Meets the requirements in 902 KAR 100:072, Sections (63) and 65(1); or

20 (b) Is identified as an authorized medical physicist or teletherapy physicist on:

21 1. A specific medical use licensee issued by the cabinet, U.S. Nuclear Regulatory
22 Commission, or an agreement state;

23 2. A medical use permit issued by a U.S. Nuclear Regulatory Commission master

1 material licensee;

2 3. A permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or an
3 agreement state broad scope medical use licensee; or

4 4. A permit issued by the U.S. Nuclear Regulatory Commission master material
5 license broad scope medical use permittee.

6 (25) "Authorized nuclear pharmacist" means a pharmacist who:

7 (a) Meets the requirements in 902 KAR 100:072, Sections 63 and 66(1);

8 (b) Is identified as an authorized nuclear pharmacist on a:

9 1. Specific license issued by the cabinet, state, or U.S. Nuclear Regulatory
10 Commission that authorizes the medical use or the practice of nuclear pharmacy;

11 2. Permit issued by a U.S. Nuclear Regulatory Commission master material licensee
12 that authorizes medical use or the practice of nuclear pharmacy;

13 3. Permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or agreement
14 state broad scope medical use licensee that authorizes medical use or the practice of
15 nuclear pharmacy; or

16 4. Permit issued by a U.S. Nuclear Regulatory Commission master material license
17 broad scope medical use permittee that authorizes medical use or the practice of
18 nuclear pharmacy;

19 (c) Is identified as an authorized nuclear pharmacist by a commercial nuclear
20 pharmacy that has been authorized to identify authorized nuclear pharmacists; or

21 (d) Is designated as an authorized nuclear pharmacist under 902 KAR 100:058,
22 Section 9(2)(c).

23 (26) "Authorized user" means a physician, dentist, or podiatrist who:

1 (a) Meets the requirements in 902 KAR 100:072, Sections 63 and 68(1), 69(1), 71(1),
2 72(1), 74(1), 76(1), and 77(1); or

3 (b) Is identified as an authorized user on:

4 1. The cabinet's, U.S. Nuclear Regulatory Commission's, or an agreement state's
5 license that authorizes the medical use of radioactive material;

6 2. A permit issued by a U.S. Nuclear Regulatory Commission master material
7 licensee that is authorized to permit the medical use of radioactive material;

8 3. A permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or
9 agreement state licensee of broad scope that is authorized to permit the medical use of
10 radioactive material; or

11 4. A permit issued by a U.S. Nuclear Regulatory Commission master material license
12 broad scope permittee that is authorized to permit the medical use of radioactive
13 material.

14 (27) "Automatic exposure control" means a device that automatically controls one (1)
15 or more technique factors in order to obtain, at a preselected location, a required
16 quantity of radiation.

17 (28) "Background radiation" means radiation not under the control of the licensee,
18 including:

19 (a) From cosmic sources;

20 (b) Naturally occurring radioactive materials;

21 (c) Radon that is not a decay product of source or special nuclear material; and

22 (d) Global fallout as it exists in the environment from the testing of nuclear explosive
23 devices or from past nuclear accidents. Background radiation shall not include radiation

1 from radioactive materials regulated by the Cabinet for Health and Family Services.

2 (29) "Beam axis" means the axis of rotation of the beam limiting device.

3 (30) "Beam limiting device" or "collimator" means a device that provides a means to
4 restrict the dimensions of the x-ray field.

5 (31) "Beam monitoring system" means a system designed to detect and measure the
6 radiation present in the useful beam.

7 (32) "Beam scattering foil" means a thin piece of material (usually metallic) placed in
8 the beam to scatter a beam of electrons in order to provide a more uniform electron
9 distribution in the useful beam.

10 (33) "Becquerel" means a unit, in the International System of Units (SI), of
11 measurement of radioactivity equal to one (1) transformation per second.

12 (34) "Bioassay" or "radiobioassay" means the determination of kinds, quantities or
13 concentrations, and, in some cases, the locations of radioactive material in the human
14 body, by direct measurement (in vivo counting) or by analysis and evaluation of
15 materials excreted or removed from the human body.

16 (35) "Brachytherapy" means a method of radiation therapy in which an encapsulated
17 source or group of sources is utilized to deliver radiation at a distance to a few
18 centimeters, by surface, intracavitary, or interstitial application.

19 (36) "Broker" or "waste broker" means a person who takes possession of low-level
20 waste solely for the purposes of consolidation and shipment.

21 (37) "By-product material" means:

22 (a) Radioactive material, except special nuclear material, yielded in or made
23 radioactive by exposure to the radiation incident to the process of producing or utilizing

special nuclear material; or

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations shall not constitute by-product material within this definition.

(38) "Cabinet" means Cabinet for Health Services, or its duly authorized representatives.

(39) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in 902 KAR 100:019, Section 11.

(40) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed or used in a permanent enclosure in which the enclosure is intended to contain at least that portion of the material being irradiated, not to include x-ray systems used by licensed practitioners of the healing arts. The enclosure:

(a) May be the architectural structure or may be independent of the architectural structure;

(b) Shall provide attenuation of the radiation to meet the requirements of 902 KAR 100:105; and

(c) Shall exclude personnel from its interior during the generation of x-radiation.

(41) "Calendar quarter" means between twelve (12) and fourteen (14) consecutive weeks.

(a) The first calendar quarter of each year shall begin in January and subsequent

1 calendar quarters shall be arranged so that no day is included in more than one (1)
2 calendar quarter and no day in a one (1) year period is omitted from inclusion within a
3 calendar quarter.

4 (b) A licensee or registrant shall not change the method observed of determining
5 calendar quarters, except at the beginning of a calendar year.

6 (42) "Calibration" means the determination of:

7 (a) The response or reading of an instrument relative to a series of known radiation
8 values over the range of the instrument; or

9 (b) The strength of a source of radiation relative to a standard.

10 (43) "Carrier" is defined by KRS 174.405(1).

11 (44) "Cephalometric device" means a device intended for the radiographic
12 visualization and measurement of the dimensions of the human head.

13 (45) "Certificate holder" means a person who has been issued a certificate of
14 compliance or other package approval by the U.S. Nuclear Regulatory Commission.

15 (46) "Certificate of Compliance" or "CoC" means the certificate issued by the U.S.
16 Nuclear Regulatory Commission under 10 C.F.R. Part 71, which approves the design of
17 a package for the transportation of radioactive material.

18 (47) "Certified cabinet x-ray system" means an x-ray system that has been certified
19 pursuant to ~~under~~ 21 C.F.R. 1010.2 as being manufactured and assembled according
20 to the provisions of 21 C.F.R. 1020.40.

21 (48) "Certified component" means a component of an x-ray system subject to 21
22 C.F.R. Subchapter J.

23 (49) "Certified system" means an x-ray system that has one (1) or more certified

1 component.

2 (50) "C.F.R." means Code of Federal Regulations.

3 (51) "Changeable filters" means a filter, exclusive of inherent filtration, which can be
4 removed from the useful beam through an electronic, mechanical, or
5 physical process.

6 (52) "Chemical description" means a description of the principal chemical
7 characteristics of a low-level radioactive waste.

8 (53) "Class" or "lung class" or "inhalation class" means a classification scheme for
9 inhaled material according to its rate of clearance from the pulmonary region of the lung.
10 Materials shall be classified as D, W, or Y, which applies to a range of clearance half-
11 times:

12 (a) For Class D (Days) of less than ten (10) days;

13 (b) For Class W (Weeks) from ten (10) to 100 days; and

14 (c) For Class Y (Years) of greater than 100 days.

15 (54) "Close reflection by water" means immediate contact by water of sufficient
16 thickness for maximum reflection of neutrons.

17 (55) "Collective dose" means the sum of the individual doses received in a given
18 period of time by a specified population from exposure to a specified source of radiation.

19 (56) "Collimator" means a device used to limit the size, shape, and direction of the
20 primary radiation beam.

21 (57) "Commission" means the U.S. Nuclear Regulatory Commission or its duly
22 authorized representatives.

23 (58) "Committed dose equivalent ($H_{T,50}$)" means the dose equivalent to organs or

tissues of reference (T) that will be received from an intake of radioactive material by an individual during the fifty (50) year period following the intake.

(59) "Committed effective dose equivalent ($H_{E,50}$)" means the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \sum W_T H_{T,50}$).

(60) "Computer-readable medium" means the cabinet's computer can transfer the information from the medium into its memory.

(61) "Computed tomography" or "CT" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

(62) "Consignee" means the designated receiver of the shipment of low-level radioactive waste.

(63) "Consignment" means each shipment of a package or groups of packages or load of radioactive material officered by a shipper for transport.

(64) "Constraint" or "dose constraint" means a value above which specified licensee actions are required.

(65) "Contact therapy system" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five (5) centimeters of the surface being treated.

(66) "Containment system" means the assembly of components of the package intended to retain the radioactive material during transport.

(67) "Controlled area" means an area, outside of a restricted area but inside the site boundary, to which access can be limited by the licensee or registrant for a stated

1 reason.

2 (68) "Cooling curve" means the graphical relationship between heat units stored and
3 cooling time.

4 (69) "Conveyance" means:

5 (a) For transport by public highway or rail, a transport vehicle or large freight
6 container;

7 (b) For transport by water, a vessel or a hold, compartment, or defined deck area of a
8 vessel including a transport vehicle on board the vessel; or

9 (c) Transportation by an aircraft.

10 (70) "Critical group" means the group of individuals reasonably expected to receive
11 the greatest exposure to residual radioactivity for any applicable set of circumstances.

12 (71) "Criticality Safety Index" or "CSI", means the dimensionless number, rounded up
13 to the next tenth, assigned to and placed on the label of a fissile material package, to
14 designate the degree of control of accumulation of packages containing fissile material
15 during transportation. Determination of the criticality safety index is described in 10
16 C.F.R. 71.22, 71.23, and 71.59.

17 (72) "Curie" means a quantity of radioactivity.

18 (a) One (1) curie (Ci) is that quantity of radioactive material that decays at the rate of
19 3.7×10^{10} disintegrations per second (dps).

20 (b) Commonly used submultiples of the curie are the millicurie and the microcurie.

21 1. One (1) millicurie (mCi) = 0.001 curie = 3.7×10^7 dps.

22 2. One (1) microcurie (uCi) = 0.000001 curie = 3.7×10^4 dps.

23 (73) "Dead man switch" means a switch so constructed that a circuit closing contact

1 can be maintained only by continuous pressure on the switch by the operator.

2 (74) "Declared pregnant woman" means a woman who has voluntarily informed her
3 employer, in writing, of her pregnancy and the estimated date of conception. The
4 declaration remains in effect until the declared pregnant woman withdraws the
5 declaration in writing or is not longer pregnant.

6 (75) "Decommission" means the:

7 (a) Safe removal from service of a facility or site;

8 (b) Termination of license; and

9 (c) Reduction of residual radioactivity to a level permitting release of the property:

10 1. For unrestricted use; or

11 2. Under restricted conditions.

12 (76) "Decontamination facility" means a facility operating under the cabinet, U.S.
13 Nuclear Regulatory Commission, or an agreement state license whose principal
14 purpose is decontamination of equipment or materials to accomplish recycle, reuse, or
15 other waste management objectives, and is not considered to be a consignee for LLW
16 shipments.

17 (77) "Dedicated check source" means a radioactive source that is used to assure the
18 constant operation of a radiation detection or measurement device over several months
19 or years. The source may also be used for other purposes.

20 (78) "Deep-dose equivalent (H_d)" which applies to external whole-body exposure,
21 means the dose equivalent at a tissue depth of one (1) centimeter (cm) (1000 mg/cm^2).

22 (79) "Demand respirator" means an atmosphere-supplying respirator that admits
23 breathing air to the facepiece only when a negative pressure is created inside the

facepiece by inhalation.

(80) "Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one (1) ALI.

(a) "Light work" produces an inhalation rate of one and two-tenths (1.2) cubic meters (1.2m³) of air per hour.

(b) DAC values are given in 10 C.F.R., 20 Appendix B.

(81) "Derived air concentration-hour" or "DAC-hour" means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one (1) ALI, equivalent to a committed effective dose equivalent of five (5) rems (0.05 Sv).

(82) "Deuterium" means deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

(83)~~(82)~~ "Diagnostic clinical procedure manual" means the collection of written procedures, methods, instructions, and precautions by which the licensee performs diagnostic clinical procedures, where each diagnostic clinical procedure:

(a) Has been approved by the authorized user; and

(b) Includes the radiopharmaceutical name, dosage, and route of administration.

(84)~~(83)~~ "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

(85)~~(84)~~ "Diagnostic-type protective tube housing" means an x-ray tube housing so constructed that the leakage radiation measured at a distance of one (1) meter from

1 the source cannot exceed 100 milliroentgens in one (1) hour if the tube is operated at its
2 maximum continuous rated current for the maximum tube potential.

3 (86)~~[(85)]~~ "Diagnostic x-ray system" means an x-ray system designed for irradiation
4 of a part of the human body for the purpose of diagnosis or visualization.

5 (87)~~[(86)]~~ "Direct scatter radiation" means that scattered radiation that has been
6 deviated in direction only by materials irradiated by the useful beam. (See also
7 "scattered radiation").

8 (88)~~[(87)]~~ "Disposable container" means a container principally used to confine low-
9 level radioactive waste during disposal operations at a land disposal facility. (See also
10 "high integrity container".) For some shipments, the disposal container may be transport
11 package.

12 (89)~~[(88)]~~ "Disposable respirator" means a respirator for which maintenance is not
13 intended and that is designed to be discarded after excessive breathing resistance,
14 sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for
15 use. Disposal respirator may include, but not limit to a disposable half-mask respirator
16 or a disposable escape-only self-contained breathing apparatus (SCBA).

17 (90)~~[(89)]~~ "Disposal" means the disposition of waste as authorized by 902 KAR
18 100:021.

19 (91)~~[(90)]~~ "Distinguishable from background" means that the detectable concentration
20 of a radionuclide is statistically different from the background concentrations of that
21 radionuclide in the vicinity of the site or, in the case of structures, in similar materials
22 using adequate measurements technology, survey, and statistical techniques.

23 (92)~~[(91)]~~ "Dose" or "radiation dose" means:

- 1 (a) Absorbed dose;
- 2 (b) Dose equivalent;
- 3 (c) Effective dose equivalent;
- 4 (d) Committed dose equivalent;
- 5 (e) Committed effective dose equivalent; or
- 6 (f) Total effective dose equivalent.

7 (93)~~[(92)]~~ "Dose commitment" means the total radiation dose to a part of the body
8 that results from retention in the body of radioactive material. Estimation assumes the
9 period of exposure to retained material to be less than fifty (50) years.

10 (94)~~[(93)]~~ "Dose equivalent (H_T)" means the product of the absorbed dose in tissue,
11 the quality factor, and other necessary modifying factors at the location of interest. The
12 units of dose equivalent are the rem and sievert (Sv).

13 (95)~~[(94)]~~ Dose monitor unit (DMU)" means a unit response from the beam
14 monitoring system from which the absorbed dose can be calculated.

15 (96)~~[(95)]~~ "Dosimetry processor" means an individual or an organization that
16 processes and evaluates individual monitoring equipment in order to determine the
17 radiation dose delivered to the equipment.

18 (97)~~[(96)]~~ "DOT " means the U.S. Department of Transportation.

19 (98)~~[(97)]~~ "Effective dose equivalent (H_E)" means the sum of the products of the dose
20 equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each
21 of the body organs or tissues that are irradiated ($H_E = W_TH_T$).

22 (99)~~[(98)]~~ "Embryo or fetus" means the developing human organism from conception
23 until the time of birth.

1 ~~(100)~~~~(99)~~ "Energy compensation source or "ECS" means a small sealed source,
2 with an activity not exceeding 100 microcuries (3.7 MBq), used within a logging tool, or
3 other tool components, to provide a reference standard to maintain the tool's calibration
4 when in use.

5 ~~(101)~~~~(100)~~ "Entrance or access point" means a location through which an individual
6 may gain access to a radiation area or radioactive material, including an entry or exit
7 portal of sufficient size to permit human entry, irrespective of its intended use.

8 ~~(102)~~~~(101)~~ "Entrance exposure rate" means the roentgens per unit time at the point
9 the center of the useful beam enters the patient.

10 ~~(103)~~~~(102)~~ "Environmental Protection Agency "EPA" Identification number" means
11 the number received by a transporter following application to the EPA as required by 40
12 C.F.R. Part 263.

13 ~~(104)~~~~(103)~~ "Exclusive use" means the sole use of a conveyance by a single
14 consignor in which initial, intermediate, and final loading and unloading are carried out
15 under the direction of the consignor or consignee.

16 (a) Consignor and carrier shall each ensure that loading and unloading is performed
17 by personnel having radiological training and resources appropriate for safe handling of
18 the consignment.

19 (b) Consignor shall include with the shipping paper information provided to the
20 carrier, specific written instructions for maintenance of exclusive use shipment controls.

21 ~~(105)~~~~(104)~~ "Exposure" means being exposed to ionizing radiation or to radioactive
22 material.

23 ~~(106)~~~~(105)~~ "Exposure rate" means the exposure per unit of time.

(107)[(106)] "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

(108)[(107)] "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

(109)[(108)] "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

(110)[(109)] "Eye dose equivalent". See "lens dose equivalent".

(111)[(110)] "Facility" means a location at which one (1) or more devices or sources are installed or located within one (1) building, vehicle, or under one (1) roof, under the same administrative control.

(112)[(111)] "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(113)[(112)] "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

(114)[(113)] "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.

(115)[(114)] "Filter" means the material in the useful beam which usually absorbs preferentially the less penetrating radiations.

(a) "Inherent filtration" means the filter permanently in the useful beam. It includes the window of the x-ray tube and the permanent tube enclosure.

(b) "Added filter" means the filter added to the inherent filtration.

(c) "Total filter" means the sum of the inherent and added filters.

1 (116)~~[(415)]~~ "Filtering facepiece (dust mask)" means a negative pressure particulate
2 respirator with a filter as an integral part of the facepiece or with the entire facepiece
3 composed of the filtering medium, not equipped with elastomeric sealing surfaces and
4 adjustable straps.

5 (117)~~[(416)]~~(a) "Fissile material" means the:

6 1. Radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or
7 any combination of these radionuclides; and

8 2. Fissile nuclides themselves, not material containing fissile nuclides.

9 (b) Fissile material does not include unirradiated natural and depleted uranium; and
10 natural or depleted uranium that has been irradiated in thermal reactors only;

11 (c) Fissile material also excludes certain controls as provided in 10 C.F.R.
12 71.15~~[70.15]~~.

13 (118)~~[(417)]~~ "Fissile material package" means a fissile material packaging together
14 with its fissile material contents.

15 (119)~~[(418)]~~ "Fit factor" means a quantitative estimate of the fit of a particular
16 respirator to a specific individual, and typically estimates the ratio of the concentration of
17 a substance in ambient air to its concentration inside the respirator while worn.

18 (120)~~[(419)]~~ "Fit test" means the use of a protocol to qualitatively or quantitatively
19 evaluate the fit of a respirator on an individual.

20 (121)~~[(420)]~~ "Fluoroscopic imaging assembly" means a component that comprises a
21 reception system in which x-ray photons produce a fluoroscopic image. It includes
22 equipment housings, electrical interlocks if present, the primary protective barrier, and

1 structural material providing linkage between the image receptor and the diagnostic
2 source assembly.

3 (122)~~[(124)]~~ "Focal spot" means the area projected on the anode of the x-ray tube by
4 the electrons accelerated from the cathode and from which the useful beam originates.

5 (123)~~[(122)]~~ "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear
6 Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel
7 reprocessing plants, uranium enrichment plants, or critical mass experimental facilities
8 where AEC or NRC licenses have been terminated.

9 (124)~~[(123)]~~ "Gantry" means that part of a radiation producing machine supporting
10 and allowing movements of the radiation head about a center of rotation.

11 (125)~~[(124)]~~ "General purpose radiographic x-ray system" means a radiographic x-ray
12 system which, by design, is not limited to radiographic examination of specific
13 anatomical regions.

14 (126)~~[(125)]~~ "Generally applicable environmental radiation standards" means
15 standards issued by the Environmental Protection Agency (EPA) under the authority of
16 42 U.S.C. sec. 2011 et seq., that impose limits on radiation exposures or levels, or
17 concentrations or quantities of radioactive material, in the general environment outside
18 the boundaries of locations under the control of persons possessing or using radioactive
19 material.

20 (127)~~[(126)]~~ "Generator" or means a licensee operating under the cabinet, U.S.
21 Nuclear Regulatory Commission or an agreement state who:

22 (a) Is a waste generator as defined in this administrative regulation; or

(b) Is the licensee to whom waste can be attributed within the context of the Low Level Radioactive Waste Policy Amendments Act of 1985, such as, waste generated as a result of decontamination or recycle activities.

~~(128)[(127)]~~ "Gonad shield" means a protective barrier for the testes or ovaries.

(129) "Graphite" means graphite with a boron equivalent content less than five (5) parts per million and density greater than one and five-tenths (1.5) grams per cubic centimeter.

~~(130)[(128)]~~ "Gray" or "Gy" means the SI unit of absorbed dose. One (1) gray equals an absorbed dose of one (1) Joule/kilogram (100 rads).

~~(131)[(129)]~~ "Half-value layer" or "HVL" means the thickness of specified material which attenuates the beam of radiation to one-half (1/2) of its original air kerma rate, exposure rate or absorbed dose rate. This excludes the contribution of scattered radiation, other than that which might be present initially in the beam concerned.

~~(132)[(130)]~~ "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications if these tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe these x-ray tests for the purpose of diagnosis or treatment.

~~(133)[(131)]~~ "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds.

~~(134)[(132)]~~ "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

~~(135)[(133)]~~ "High integrity container or "HIC" means a container commonly designated to meet the structural stability requirements of 10 C.F.R. 61.56, and to meet

1 the U.S. Department of Transportation requirements for a Type A package.

2 (136)~~[(134)]~~ "High radiation area" means an area, accessible to individuals, in which
3 radiation levels from radiation sources external to the body may result in an individual
4 receiving a dose equivalent in excess of one-tenth (0.1) rem (1m Sv) in one (1) hour at
5 thirty (30) centimeters from the radiation source or thirty (30) centimeters from a surface
6 that the radiation penetrates.

7 (137)~~[(135)]~~ "Hood" means a respiratory inlet covering that completely covers the
8 head and neck and may also cover portions of the shoulders and torso.

9 (138)~~[(136)]~~ "Human use" means the internal or external administration of radiation or
10 radioactive materials to human beings.

11 (139)~~[(137)]~~ "Image intensifier" means a device that converts instantaneously, by
12 means of photoemissive surfaces and electronic circuitry, an x-ray pattern into a light
13 pattern of greater intensity than would have been produced by the original x-ray pattern.

14 (140)~~[(138)]~~ "Image receptor" means a device that transforms incident radiation into a
15 visual image or into another form which can be made into a visual image by
16 further transformations.

17 (141)~~[(139)]~~ "Image receptor support" means, for mammographic systems, that part
18 of the system designed to support the image receptor in a horizontal plane during a
19 mammographic examination.

20 (142)~~[(140)]~~ "Individual" means a human being.

21 (143)~~[(141)]~~ "Individual monitoring" means the assessment of:

22 (a) Dose equivalent by the use of an individual monitoring device;

23 (b) Committed effective dose equivalent by:

- 1 1. Bioassay; or
- 2 2. Determination of the time-weighted air concentrations to which an individual has
- 3 been exposed; or
- 4 (c) Dose equivalent by the use of survey data.
- 5 (144)~~[(142)]~~ "Individual monitoring device" or "individual monitoring equipment"
- 6 means a device designed to be worn by a single individual for the assessment of dose
- 7 equivalent, such as film badges, thermoluminescence dosimeters (TLDs), pocket
- 8 ionization chambers, or personal ("lapel") air sampling devices.
- 9 (145)~~[(143)]~~ "Industrial radiography" means the examination of the macroscopic
- 10 structure of materials by nondestructive methods utilizing sources of radiation.
- 11 (146)~~[(144)]~~ "Injection tool" means a device used for controlled subsurface injection
- 12 of radioactive tracer material.
- 13 (147)~~[(145)]~~ "Interlock" means a device preventing the start or continued operation of
- 14 equipment unless certain predetermined conditions prevail.
- 15 (148)~~[(146)]~~ "Internal dose" means that portion of the dose equivalent received
- 16 from radioactive material taken into the body.
- 17 (149)~~[(147)]~~ "Irradiation" means the exposure of matter to ionizing radiation.
- 18 (150)~~[(148)]~~ "Kilovolt (kV) {kilo electron volt}" means the energy equal to that acquired
- 19 by a particle with one (1) electron charge in passing through a potential difference of
- 20 1,000 volts in a vacuum. {Note: current convention is to use kV for photons and keV for
- 21 electrons.}
- 22 (151)~~[(149)]~~ "Kilovolt peak" or "kVp" means the crest value in kilovolts of the potential
- 23 difference of a pulsating potential generator. If only one-half (1/2) of the wave is used,

the value refers to the useful half of the wave.

(152)~~[(150)]~~ "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(153)~~[(151)]~~ "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly, except for the useful beam.

(154)~~[(152)]~~ "Leakage technique factor" means, with respect to different tube housing assemblies:

(a) For capacitor energy storage equipment: the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential, with a charge per exposure of ten (10) milliamperere seconds (mAs) or the minimum obtainable from the unit, whichever is larger.

(b) For field emission equipment rated for pulsed operation: the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.

(c) For all other equipment: the maximum rated continuous tube current for the maximum rated peak tube potential.

(155)~~[(153)]~~ "Lens dose equivalent" or "LDE" means the external exposure of the lens of the eye, and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).

(156)~~[(154)]~~ "License" means a license issued by the cabinet under 902 KAR Chapter 100.

(157)~~[(155)]~~ "Licensed material" means radioactive material, source material, or special nuclear material received, possessed, used, or transferred, under a general or

specific license issued by the cabinet, U.S. Nuclear Regulatory Commission or an agreement state.

(158)~~(156)~~ "Light field" means the area illuminated by light, simulating the radiation field.

(159)~~(157)~~ "Limits" or "dose limits" means the permissible upper bounds of radiation doses.

(160)~~(158)~~ "Lixiscope" means a portable light-intensified imaging device using a sealed source.

(161)~~(159)~~ "Logging assistant" means an individual who, under the personal supervision of a logging supervisor:

(a) Handles sealed sources or tracers that are not in logging tools or shipping containers; or

(b) Uses survey instruments in well-logging activities.

(162)~~(160)~~ "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.

(163)~~(161)~~ "Logging tool" means a device used subsurface to perform well-logging.

(164)~~(162)~~ "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

(165)~~(163)~~ "Lost or missing licensed material" means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

(166)~~(164)~~ "Low-level radioactive waste" means radioactive waste not classified as:

(a) High-level radioactive waste;

1 (b) Transuranic waste;

2 (c) Spent nuclear fuel; or

3 (d) By-product material as defined in Section 11e(2) of the Atomic Energy Act of
4 1954, 42 U.S.C. 2014.

5 ~~(167)~~~~[(165)]~~ "Low specific activity" or "LSA" means radioactive material with limited
6 specific activity, which is nonfissile or is excepted pursuant to~~[under]~~ 10 C.F.R.
7 71.15~~[70.15]~~ and that satisfies the descriptions and limits established in paragraphs (a),
8 (b), and (c) of this subsection. Shielding materials surrounding the LSA material shall
9 not be considered in determining the estimated average specific activity of the package
10 contents. LSA material shall be in one (1) of three (3) groups:

11 (a) LSA-I:

12 1. Uranium and thorium ores, uranium or thorium concentrates of these ores, and
13 other ores containing naturally occurring radioactive nuclides that are
14 not intended to be processed for the use of these radionuclides;

15 2. Solid unirradiated natural or depleted uranium or natural thorium or their solid or
16 liquid compounds or mixtures;

17 3. Radioactive material for which the A_2 value is unlimited; or

18 4. Other radioactive material in which the activity is distributed throughout and the
19 estimated average specific activity does not exceed thirty (30) times the value for
20 exempt material activity concentration determined in 10 C.F.R. 71 Appendix A.

21 (b) LSA-II:

22 1. Water with tritium concentration up to 20.0 curies/liter (0.8 TBq/liter); or

23 2. Material in which the radioactive material is distributed throughout, and the

average specific activity does not exceed 10^{-4} A₂/gram for solids and gases, and 10^{-5} A₂/gram for liquids.

(c) LSA-III: Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 C.F.R. 71.77 in which:

1. The radioactive material is distributed throughout a solid or a collection of solid objects;

2. Is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.);

3. 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 seven (7) days, would not exceed 0.1 A₂; and the average specific activity of the solid does not exceed 2×10^{-3} A₂/gram; and

4. The average specific activity of the solid does not exceed 2×10^{-3} A₂/gram.

(168)~~[(166)]~~ "Low toxicity alpha emitter" 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 ten (10) days.

(169)~~[(167)]~~ "mA" means milliamperere.

(170)~~[(168)]~~ "Management" means the chief executive officer or that individual's designee.

(171)~~[(169)]~~ "mAs" means milliamperere second.

(172)~~[(170)]~~ "Maximum normal operating pressure" means the maximum gauge

1 pressure that would develop in the containment system in a period of one (1) year under
2 the heat condition specified in 10 C.F.R. Part 71.71(c)(1), in the absence of venting,
3 external cooling by an ancillary system, or operational controls during transport.

4 (173)~~[(174)]~~ "Medical institution" means an organization in which several medical
5 disciplines are practiced.

6 (174)~~[(172)]~~ "Medical use" means the intentional internal or external administration of
7 radioactive material, or the radiation therefrom, to patients or human research subjects
8 under the supervision of an authorized user.

9 (175)~~[(173)]~~ "Member of the public" means an individual except when the individual is
10 receiving an occupational dose.

11 (176)~~[(174)]~~ "Microscopic analytical x-ray equipment" means a device which utilizes
12 x-rays for examining the microscopic structure of materials. This includes x-ray
13 diffraction and spectrographic equipment.

14 (177)~~[(175)]~~ "Mineral logging" means logging performed for the purpose of mineral
15 exploration other than oil or gas.

16 (178)~~[(176)]~~ "Minor" means an individual less than eighteen (18) years of age.

17 (179)~~[(177)]~~ "Misadministration" means the administration of:

18 (a) A radiopharmaceutical dosage greater than thirty (30) microcuries of sodium
19 iodide I-125 or I-131:

20 1. Involving the wrong patient or human research subject or the wrong
21 radiopharmaceutical; or

22 2. If both the administered dosage differs from the prescribed dosage by more than
23 twenty (20) percent of the prescribed dosage and the difference between the

administered dosage and prescribe dosage exceeds thirty (30) microcuries.

(b) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

1. Involving the wrong patient, human research subject, radiopharmaceutical, or route of administration; or

2. If the administered dosage differs from the prescribed dosage by more than twenty (20) percent of the prescribed dosage.

(c) A gamma stereotactic radiosurgery radiation dose:

1. Involving the wrong patient, human research subject, or treatment site; or

2. If the calculated total administered dose differs from the total prescribed dose by more than ten (10) percent.

(d) A teletherapy radiation dose:

1. Involving the wrong patient, human research subject, mode of treatment, or treatment site;

2. If the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten (10) percent;

3. If the calculated weekly administered dose is thirty (30) percent greater than the weekly prescribed dose; or

4. If the calculated total administered dose differs from the total prescribed dose by more than twenty (20) percent.

(e) A brachytherapy radiation dose:

1. Involving the wrong patient, human research subject, radioisotope, or treatment site except for permanent implant seeds that were implanted in the correct site but

1 migrated outside the treatment site;

2 2. Involving a sealed source that is leaking;

3 3. If, for a temporary implant, one (1) or more sealed sources are not removed upon
4 completion of the procedure; or

5 4. If the calculated administered dose differs from the prescribed dose by more than
6 twenty (20) percent.

7 (f) A diagnostic radiopharmaceutical dosage, other than quantities greater than thirty
8 (30) microcuries of sodium iodide I-125 or I-131:

9 1. Involving the wrong patient, human research subject, radiopharmaceutical, or route
10 of administration, or if the administered dosage differs from the prescribed dosage; and

11 2. If the dose to the patient or human research subject exceeds five (5) rems effective
12 dose equivalent or fifty (50) rems dose equivalent to an individual organ.

13 (180)~~[(178)]~~ "Mobile nuclear medicine service" means the transportation and medical
14 use of radioactive material.

15 (181)~~[(179)]~~ "Monitor unit (MU)" (See "Dose monitor unit").

16 (182)~~[(180)]~~ "Monitoring" or "radiation monitoring" or "radiation protection monitoring"
17 means the measurement of radiation levels, concentrations, surface area
18 concentrations or quantities of radioactive material and the use of the results of these
19 measurements to evaluate potential exposures and doses.

20 (183)~~[(184)]~~ "Moving beam radiation therapy" means radiation therapy with any
21 planned displacement of radiation field or patient relative to each other, or with any
22 planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity
23 modulation and rotational therapy.

1 (184)~~[(182)]~~ "Natural thorium" means thorium with the naturally occurring distribution
2 of thorium isotopes; that is, 100 weight percent thorium-232.

3 (185)~~[(183)]~~ "Negative pressure respirator (tight fitting)" means a respirator in which
4 the air pressure inside the facepiece is negative during inhalation with respect to the
5 ambient air pressure outside the respirator.

6 (186)~~[(184)]~~ "Nominal treatment distance" means:

7 (a) For electron irradiation, the distance from the scattering foil, virtual source, or exit
8 window of the electron beam to the entrance surface of the irradiated object along
9 the central axis of the useful beam.

10 (b) For x-ray irradiation, the virtual source or target to isocenter distance along the
11 central axis of the useful beam. For non-isocentric equipment, this distance shall be that
12 specified by the manufacturer.

13 (187)~~[(185)]~~ "Nonstochastic effect" or "deterministic effect" means a health effect, the
14 severity of which varies with the dose and for which a threshold is believed to exist.

15 (188)~~[(186)]~~ "Normal form radioactive material" means radioactive material that has
16 not been demonstrated to qualify as "special form radioactive material."

17 (189)~~[(187)]~~ "NRC" means the U.S. Nuclear Regulatory Commission or its duly
18 authorized representatives.

19 (190)~~[(188)]~~(a) "NRC Forms 540, 540A, 541, 541A, 542, and 542A" means official
20 NRC forms as referenced in 902 KAR 100:021.

21 (b) Licensees need not use originals of these forms as long as any substitute forms
22 are equivalent to the original documentation in respect to content, clarity, size, and
23 location of information.

(c) Upon agreement between the shipper and consignee, NRC Forms 541, 541A, 542, and 542A may be completed, transmitted, and stored in electronic media.

(d) The electronic media shall have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

(191)~~(189)~~ "Occupational dose" means dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose shall not include dose received:

(a) From background radiation;

(b) As a medical patient;

(c) From voluntary participation in a medical research program;

(d) As a member of the public; or

(e) From exposure to individuals administered radioactive material and released in accordance with 902 KAR 100:072, Section 27.

(192)~~(190)~~ "Operating procedures" means detailed written instructions, such as:

(a) Normal operation of equipment and movable shielding;

(b) Closing of interlock circuits;

(c) Manipulation of controls;

(d) Radiation monitoring procedures for personnel and areas;

(e) Testing of interlocks; and

(f) Recordkeeping requirements. ~~["Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.]~~

1 ~~(193)[(194)]~~ "Output" means the exposure rate, dose rate, or a quantity related in a
2 known manner to these rates from a teletherapy unit for a specified set of exposure
3 conditions. [~~"Operating procedures" means detailed written instructions, such as:~~

- 4 ~~(a) Normal operation of equipment and movable shielding;~~
5 ~~(b) Closing of interlock circuits;~~
6 ~~(c) Manipulation of controls;~~
7 ~~(d) Radiation monitoring procedures for personnel and areas;~~
8 ~~(e) Testing of interlocks; and~~
9 ~~(f) Recordkeeping requirements.]~~

10 ~~(194)[(192)]~~ "Package" means the packaging together with its radioactive contents as
11 presented for transport:

12 (a) Fissile material package or Type AF package, Type BF package, Type B(U)F
13 package, or Type B(M)F package are all fissile material packaging types together with
14 its fissile material complete.

15 (b) Type A package means a Type A packaging together with its radioactive
16 contents. A Type A package is defined and shall comply with the DOT regulations in 49
17 C.F.R. Part 173.

18 (c) Type B package means a Type B packaging together with its radioactive contents.

19 (i) On approval, a Type B package design is designated by the U.S. Nuclear
20 Regulatory Commission as B(U) unless the package has a maximum normal operating
21 pressure of more than 100 pounds/in² (700 kPa) gauge or a pressure relief device that
22 would allow the release of radioactive material to the environment under the tests
23 specified in 10 C.F.R. Part 71.73 (hypothetical accident conditions), in which case it will

1 receive a designation B(M).

2 (ii) B(U) refers to the need for unilateral approval of international shipments.

3 (iii) B(M) refers to the need for multilateral approval of international shipments.

4 (iv) There is no distinction made in how packages with these designations may be
5 used in domestic transportation.

6 (v) To determine their distinction for international transportation, refer to U.S.
7 Department of Transportation Regulations in 49 C.F.R. Part 173.

8 (vi) A Type B package approved before September 6, 1983, was designated only as
9 Type B. Limitations on its use are specified in 902 KAR 100:070, Section 7.

10 (195)~~[(193)]~~ "Packaging" means the assembly of components necessary to
11 ensure compliance with the requirements of 902 KAR 100:070.

12 (a) It may consist of one (1) or more receptacles, absorbent materials, spacing
13 structures, thermal insulation, radiation shielding, and devices for cooling or absorbing
14 mechanical shocks.

15 (b) The vehicle, tie-down system, and auxiliary equipment may be designated as part
16 of the packaging.

17 (196)~~[(194)]~~ "Patient" means an individual subjected to healing arts examination,
18 diagnosis, or treatment.

19 (197)~~[(195)]~~ "Peak tube potential" means the maximum value of the potential
20 difference across the x-ray tube during an exposure.

21 (198)~~[(196)]~~ "Periodic quality assurance check" means a procedure which is
22 performed to ensure that a previous calibration continues to be valid.

23 (199)~~[(197)]~~ "Permanent radiographic installation" means an installation or structure

designed or intended for radiography and in which radiography is regularly performed.

(200)~~[(198)]~~ "Person" is defined by ~~[at]~~ KRS 216B.015(16).

(201)~~[(199)]~~ "Personal supervision" means guidance and instruction by the supervisor who is physically present at the job site and watching the performance of the operation in proximity so that contact can be maintained and immediate assistance given as required.

(202)~~[(200)]~~ "Personnel monitoring equipment" means a device designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual.

(203)~~[(204)]~~ "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

(204)~~[(202)]~~ "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is activated. See "automatic exposure control".

(205)~~[(203)]~~ "Physical description" means the items called for on NRC Form 541 to describe low-level radioactive waste.

(206)~~[(204)]~~ "Physician" is defined by KRS 311.720(9).

(207)~~[(205)]~~ "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

(208)~~[(206)]~~ "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin)

1 distance. It may or may not incorporate or serve as a beam-limiting device.

2 (209)~~(207)~~ "Positive pressure respirator" means a respirator in which the pressure
3 inside the respirator inlet covering exceeds the ambient air pressure outside the
4 respirator.

5 (210)~~(208)~~ "Powered air-purifying respirator" or "PAPR" means an air-purifying
6 respirator that uses a blower to force the ambient air through air-purifying elements to
7 the inlet covering.

8 (211)~~(209)~~ "Preceptor" means an individual who provides, directs, or verifies the
9 training and experience required for an individual to become an authorized user, an
10 authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety
11 Officer.

12 (212)~~(210)~~ "Pressure demand respirator" means a positive pressure atmosphere-
13 supplying respirator that admits breathing air to the facepiece when the positive
14 pressure is reduced inside the facepiece by inhalation.

15 (213)~~(214)~~ "Preregistrant" means a person who is preregistered with the cabinet for
16 the intent of obtaining a radiation producing machine registerable under 902 KAR
17 100:110.

18 (214)~~(212)~~ "Preregistration" means preregistration with the cabinet as specified in
19 902 KAR 100:110.

20 (215)~~(213)~~ "Prescribed dosage" means the quantity of radiopharmaceutical activity
21 as documented:

22 (a) In a written directive;

23 (b) In the diagnostic clinical procedures manual; or

(c) In an appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

(216)~~(214)~~ "Prescribed dose" means:

(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive; or

(c) For brachytherapy, the total source strength and exposure time or the total dose, as documented in the written directive.

(217)~~(215)~~ "Primary dose monitoring system" means a system that:

(a) Monitors the useful beam during irradiation; and

(b) Terminates irradiation if a preselected number of dose monitor units have been acquired.

(218)~~(216)~~ "Principal activities" means activities authorized by the license that are essential to achieving the purpose for which the license was issued or amended.

"Principal activities" do not include:

(a) Storage during which licensed material is not accessed for use or disposal; and

(b) Activities incidental to decontamination or decommissioning.

(219)~~(217)~~ "Protective apron" means an apron made of radiation absorbing materials of at least 0.25 mm lead equivalency; that is, if the HVL of the apron is not less than 0.25 mm lead at normal operating voltages.

(220)~~(218)~~ "Protective barrier" means a barrier of radiation absorbing material used to reduce radiation exposure.

(a) "Primary protective barrier" means a barrier sufficient to attenuate the useful beam to the required degree.

(b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

(221)~~(219)~~ "Protective glove" means a glove made of radiation absorbing materials of at least 0.25 mm lead equivalency; that is, if the HVL of the glove is not less than 0.25 mm lead at normal operating voltages.

(222)~~(220)~~ "Public dose" means the dose received by a member of the public from sources of radiation from licensed or registered operations. It shall not include radiation received:

(a) As an occupational dose;

(b) From background radiation;

(c) As a medical patient;

(d) From voluntary participation in a medical research program; or

(e) From exposure to an individual administered radioactive material and released in accordance with 902 KAR 100:072, Section 27.

(223)~~(221)~~ "Qualified expert" means an individual who has been recognized by the cabinet to possess the knowledge and training to:

(a) Measure ionizing radiation;

(b) Evaluate safety techniques; and

(c) Advise regarding radiation protection needs.

(224)~~(222)~~ "Qualitative fit test or "QFT" means a pass or fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

1 (225)~~(223)~~ "Quality factor" or "Q" means the modifying factor used to derive dose
2 equivalent from absorbed dose.

3 (a) Quality factors and absorbed dose equivalencies:

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent ^a
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments, and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

4 ^aAbsorbed dose in rad equal to one (1) rem or the absorbed dose in gray equal to
5 one (1) sievert.

(b) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in paragraph (a) of this subsection, one (1) rem (0.01 sievert) of neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result from a total fluence of twenty-five (25) million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from paragraph (c) of this subsection to convert a measured tissue dose in rads to dose equivalent in rems.

(c) Mean quality factors, Q, and fluency per unit dose equivalent for monoenergetic neutrons:

	Neutron Energy (MeV)	Quality Factor ^a (Q)	Fluency per Unit Dose Equivalent ^b (neutrons cm ⁻² rem ⁻¹)
(thermal)	2.5×10^{-8}	2	980×10^6
	1×10^{-7}	2	980×10^6
	1×10^{-6}	2	810×10^6
	1×10^{-5}	2	810×10^6

	1×10^{-4}	2	840×10^6
	1×10^{-3}	2	980×10^6
	1×10^{-2}	2.5	1010×10^6
	1×10^{-1}	7.5	170×10^6
	5×10^{-1}	11	39×10^6
	1	11	27×10^6
	2.5	9	29×10^6
	5	8	23×10^6
	7	7	24×10^6
	10	6.5	24×10^6
	14	7.5	17×10^6
	20	8	16×10^6
	40	7	14×10^6
	60	5.5	16×10^6
	1×10^2	4	20×10^6
	2×10^2	3.5	19×10^6
	3×10^2	3.5	16×10^6
	4×10^2	3.5	14×10^6

1 ^a Value of quality factor (Q) at the point at which the dose equivalent is maximum in a
2 thirty (30)-cm diameter cylinder tissue-equivalent phantom.

3 ^b Monoenergetic neutrons incident normally on a thirty (30)-cm diameter cylinder
4 tissue-equivalent phantom.

1 ~~(226)~~~~(224)~~ "Quantitative fit test "QNFT" means an assessment of the adequacy of
2 respirator fit by numerically measuring the amount of leakage into the respirator.

3 ~~(227)~~~~(225)~~ "Quarter" is defined by KRS 341.080(1)(b).

4 ~~(228)~~~~(226)~~ "Rad" means the special unit of absorbed dose. One (1) rad equals an
5 absorbed dose of 0.01 joule per kilogram (0.01 gray) or 100 ergs per gram.

6 ~~(229)~~~~(227)~~ "Radiation" means ionizing radiation.

7 (a) It includes the following:

- 8 1. Gamma rays;
- 9 2. X-rays;
- 10 3. Alpha particles;
- 11 4. Beta particles;
- 12 5. High speed electrons;
- 13 6. Neutrons;
- 14 7. High-speed protons; and
- 15 8. Other atomic particles capable of producing ions.

16 (b) It excludes nonionizing radiations, such as:

- 17 1. Sound;
- 18 2. Microwaves;
- 19 3. Radiowaves; or
- 20 4. Visible, infrared, or ultraviolet light.

21 (c) The following are specific forms of radiation:

- 22 1. "Leakage radiation" means radiation coming from within the tube or source
23 housing except the useful beam.

2. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction, and may have been modified by a decrease in energy.

3. "Useful radiation" or "primary beam" means radiation that passes through the window, aperture, cone, or other beam limiting device of the tube or source housing.

4. "Stray radiation" means the sum of leakage and scattered radiation.

(230)~~[(228)]~~ "Radiation area" means an area, accessible to individuals, in which there exists radiation at levels that an individual may receive in excess of five (5) millirems (0.05 mSv) in one (1) hour at thirty (30) centimeters from the radiation source or from a surface that the radiation penetrates.

(231)~~[(229)]~~ "Radiation detector" means a device which, in the presence of radiation, by either direct or indirect means, provides a signal or other indication suitable for use in measuring one (1) or more quantities of incident radiation.

(232)~~[(230)]~~ "Radiation head" means the structure from which the useful beam emerges.

(233)~~[(234)]~~ "Radiation machine" means a device capable of producing radiation, except a device that produces radiation only from radioactive material.

(234)~~[(232)]~~ "Radiation safety officer" means an individual who:

(a) Has the knowledge and responsibility to apply appropriate radiation protection administrative regulations; and

(b) For licenses issued under 902 KAR 100:072, meets the requirements in 902 KAR 100:072, Sections 63 and 64(1) and (3)(a).

1. A specific medical use licensee issued by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state; or

2. A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

(235)~~(233)~~ "Radiation therapy simulation system" means a fluoroscopic or radiographic x-ray system intended for:

(a) Localizing the volume to be exposed during radiation therapy; and

(b) Confirming the position and size of the therapeutic irradiation field.

(236)~~(234)~~ "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

(237)~~(235)~~ "Radioactive material" means a solid, liquid, or gas, which emits radiation spontaneously.

(238)~~(236)~~ "Radioactivity" means the disintegration of unstable atomic nuclei by the emission of radiation.

(239)~~(237)~~ "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

(240)~~(238)~~ "Radiographer" means an individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of administrative regulations and license conditions.

(241)~~(239)~~ "Radiographer's assistant" means an individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or survey instruments in industrial radiography.

(242)~~(240)~~ "Radiographer instructor" means a radiographer who has been

1 authorized by the cabinet to provide on-the-job training to radiographer trainees under
2 902 KAR 100:100, Section 14.

3 (243)~~[(241)]~~ "Radiographer trainee" means an individual who, under the personal
4 supervision of a radiographer instructor, uses sources of radiation, related handling
5 tools, or radiation survey instruments during the course of instruction.

6 (244)~~[(242)]~~ "Radiographic exposure device" means an instrument containing a
7 sealed source fastened or contained within, in which the sealed source or its shielding
8 may be moved, or otherwise changed, from a shielded to an unshielded position for
9 purposes of making a radiographic exposure.

10 (245)~~[(243)]~~ "Radiographic imaging system" means a system designed to record a
11 permanent or semipermanent image on an image receptor by the action of ionizing
12 radiation.

13 (246)~~[(244)]~~ "Radiographic personnel" means a:

14 (a) Radiographer;

15 (b) Radiographer instructor; or

16 (c) Radiographer trainee.

17 (247)~~[(245)]~~ "Rating" means the operating limits specified by the component
18 manufacturer.

19 (248)~~[(246)]~~ "Recordable event" means the administration of:

20 (a) A radiopharmaceutical or radiation without a written directive, if a written directive
21 is required;

22 (b) A radiopharmaceutical or radiation if a written directive is required without daily
23 recording of each administered radiopharmaceutical dosage or radiation dose in the

appropriate record;

(c) A radiopharmaceutical dosage greater than thirty (30) microcuries of sodium iodide I-125 or I-131 if:

1. The administered dosage differs from the prescribed dosage by more than twenty (20) percent; and

2. The difference between the administered dosage and prescribed dosage exceeds fifteen (15) microcuries;

(d) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, if the administered dosage differs from the prescribed dosage by more than twenty (20) percent;

(e) A teletherapy radiation dose, if the calculated weekly administered dose is fifteen (15) percent greater than the weekly prescribed dose; or

(f) A brachytherapy radiation dose, if the calculated administered dose differs from the prescribed dose by more than twenty (20) percent.

(249)~~(247)~~ "Recording" means producing a permanent form of an image resulting from x-ray photons.

(250)~~(248)~~ "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

(251)~~(249)~~ "Registrant" means a person who is registered with the cabinet and is legally obligated to register with the cabinet under 902 KAR 100:110.

(252)~~(250)~~ "Registration" means registration with the cabinet under 902 KAR

1 100:110.

2 (253)~~(254)~~ "Regulations of the U.S. Department of Transportation" means the
3 regulations in 49 C.F.R. Parts 100-189.

4 (254)~~(252)~~ "Rem" means a special unit of quantities expressed as dose equivalent.
5 The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the
6 quality factor (one (1) rem = 0.01 sievert).

7 (255)~~(253)~~ "Research and development" means:

8 (a) Theoretical analysis, exploration, or experimentation; or

9 (b) The extension of investigative findings and theories of a scientific or technical
10 nature into practical application for experimental and demonstration purposes, including
11 the experimental production and testing of models, devices, equipment, materials, and
12 processes. Research and development does not include the internal or external
13 administration of radiation or radioactive material to human beings.

14 (256)~~(254)~~ "Residential location" means an area where structures for human
15 habitation are located.

16 (257)~~(255)~~ "Residual radioactivity" means low-level radioactive waste resulting from
17 processing or decontamination activities that cannot be easily separated into distinct
18 batches attributable to specific waste generators. This waste is attributable to the
19 processor or decontamination facility, as applicable.

20 (258)~~(256)~~ "Respiratory protective device" means an apparatus used to reduce an
21 individual's intake of airborne radioactive materials.

22 (259)~~(257)~~ "Restricted area" means an area access to which is limited by the
23 licensee or registrant for purposes of protection of individuals against undue risks from

1 exposure to radiation and radioactive materials. A restricted area shall not include areas
2 used as residential quarters, although a separate room or rooms in a residential building
3 may be set apart as a restricted area.

4 ~~(260)~~~~[(258)]~~ "Roentgen" or "R" means the special unit of exposure. One (1) roentgen
5 (R) equals 2.58×10^{-4} coulombs per kilogram of air. See "Exposure".

6 ~~(261)~~~~[(259)]~~ "Sanitary sewerage" means a system of public sewers for carrying off
7 waste, water, and refuse, but excludes sewage treatment facilities, septic tanks, and
8 leach fields owned or operated by the licensee.

9 ~~(262)~~~~[(260)]~~ "Sealed source" means radioactive material that is permanently bonded
10 or fixed in a capsule or matrix designed to prevent leakage or escape of the radioactive
11 material.

12 ~~(263)~~~~[(264)]~~ "Secondary dose monitoring system" means a system which terminates
13 irradiation upon failure of the primary system.

14 ~~(264)~~~~[(262)]~~ "Self-contained breathing apparatus" or "SCBA" means an atmosphere-
15 supplying respirator for which the breathing air source is designed to be carried by the
16 user.

17 ~~(265)~~~~[(263)]~~ "Shallow-dose equivalent (H_S)", with respect to external exposure of the
18 skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue
19 depth of 0.007 centimeter (seven (7) mg/cm²).

20 ~~(266)~~~~[(264)]~~ "Shielded position" means the location within the radiographic exposure
21 device or storage container which, by manufacturer's design, is the proper location for
22 storage of the sealed source.

23 ~~(267)~~~~[(265)]~~ "Shielded-room radiography" means industrial radiography conducted in

1 a room shielded so that radiation levels at every location on the exterior meet the
2 limitations specified in 902 KAR 100:019, Section 10.

3 (268)~~[(266)]~~ "Shipper" means the licensed entity, the generator that offers low-level
4 radioactive waste for transportation, and may consign the waste to a licensed waste
5 collector, waste processor, or land disposal facility operator.

6 (269)~~[(267)]~~ "Shipping paper" means NRC Form 540, and if required, 540A, or their
7 equivalent, and includes the information required by the U.S. Department of
8 Transportation in 49 C.F.R. Part 172.

9 (270)~~[(268)]~~ "Shutter" means a device attached to the tube housing assembly which
10 can totally intercept the useful beam and which has a lead equivalency not less than
11 that of the tube housing assembly.

12 (271)~~[(269)]~~ "Sievert" means:

13 (a) The International System (SI) unit of quantities expressed as dose equivalent.
14 The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the
15 quality factor (1 Sv=100 rems).

16 (b) See the table in the definition of "quality factors" for the quality factors to convert
17 absorbed dose to dose equivalent.

18 (272)~~[(270)]~~ "Site area emergency" means the existence of situation where an event
19 may occur, is in progress, or has occurred that may:

20 (a) Lead to a significant release of radioactive material; and

21 (b) Require a response by an off-site response organization to protect persons off
22 site.

23 (273)~~[(271)]~~ "Site boundary" means that line beyond which the land or property is not

owned, leased, or otherwise controlled by the licensee.

(274)~~(272)~~ "Source" means the focal spot of the x-ray tube.

(275)~~(273)~~ "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

(276)~~(274)~~ "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source.

(277)~~(275)~~ "Source image receptor distance" or "SID" means the distance from the source to the center of the input surface of the image receptor.

(278)~~(276)~~ "Source material" means:

(a) Uranium or thorium, or a combination thereof, in a physical or chemical form; or

(b) Ores that contain by weight 0.05 percent or more of:

1. Uranium;

2. Thorium; or

3. A combination of uranium and thorium.

(c) Source material does not include special nuclear material.

(279)~~(277)~~ "Source of radiation" means a radioactive material or device, or equipment emitting or capable of producing radiation.

(280)~~(278)~~ "Special form radioactive material" means radioactive material that satisfies the following conditions:

(a) It is a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) The piece or capsule has at least one (1) dimension not less than five (5)

1 millimeters (0.197 inch); and

2 (c)1. It satisfies the test requirements specified by the NRC in 10 C.F.R. Part 71.75.

3 2. A special form encapsulation designed under the NRC requirements in 10 C.F.R.
4 71.4 in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to
5 be used.

6 3. A special form encapsulation designed in accordance with the NRC requirements
7 in 10 C.F.R. 71.4 in effect on March 31, 1996, and constructed before April 1, 1998 may
8 continue to be used.

9 4. Any other special form encapsulation shall meet the specifications of this definition.

10 ~~(281)~~~~[(279)]~~ "Special nuclear material" means:

11 (a) Plutonium, uranium 233, uranium enriched in the isotope U-233 or in the isotope
12 U-235, and other material which the Governor declares by order to be special nuclear
13 material after the United States Nuclear Regulatory Commission, or successor thereto,
14 has determined the material to be special nuclear material, but does not include source
15 material; or

16 (b) Material artificially enriched by one (1) of the foregoing, but does not include
17 source material.

18 ~~(282)~~~~[(280)]~~ "Special nuclear material in quantities not sufficient to form a critical
19 mass" means:

20 (a) Uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of
21 contained U-235;

22 (b) U-233 in quantities not exceeding 200 grams;

23 (c) Plutonium in quantities not exceeding 200 grams; or

(d) A combination of them as specified by the following formula:

1. For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material.

2. The sum of these ratios for the different kinds of special nuclear material in combination shall not exceed one (1).

3. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U- 235)}}{350} + \frac{50 \text{ (grams U- 233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

(283)~~[(284)]~~ "Special purpose x-ray system" means a radiographic x-ray system which, by design, is limited to radiographic examination of a specific anatomical region.

(284)~~[(282)]~~ "Specific activity" 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.

(285)~~[(283)]~~ "Spot check" means a procedure performed to assure that a previous calibration continues to be valid.

(286)~~[(284)]~~ "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

(287)~~[(285)]~~ "Spot-film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor.

1 It includes a device intended to hold a cassette over the input end of an image
2 intensifier for the purpose of making a radiograph.

3 (288)~~[(286)]~~ "SSD" means the distance between the source and the skin of the
4 patient.

5 (289)~~[(287)]~~ "Stationary beam radiation therapy" means radiation therapy without
6 displacement of one (1) or more mechanical axes relative to the patient during
7 irradiation.

8 (290)~~[(288)]~~ "Stochastic effect" means a health effect that occurs randomly and for
9 which the probability of the effect occurring, rather than its severity, is assumed to be a
10 linear function of dose plus threshold factors.

11 (291)~~[(289)]~~ "Storage" or "waste storage" means the holding of waste for treatment or
12 disposal for a period of twenty-four (24) hours or more.

13 (292)~~[(290)]~~ "Storage area" means:

14 (a) A location, facility, or vehicle used to store, transport, or secure a radiographic
15 exposure device, storage container, or sealed source if the source is not in use; and

16 (b) Which is locked or has a physical barrier to prevent accidental exposure,
17 tampering with, or unauthorized removal of the device, container, or source.

18 (293)~~[(291)]~~ "Storage container" means a device in which a sealed source is
19 transported or stored.

20 (294)~~[(292)]~~ "Stray radiation" means the sum of leakage and scattered radiation.

21 (295)~~[(293)]~~ "Subsurface tracer study" means the release of a substance tagged with
22 radioactive material for the purpose of tracing the movement or position of the tagged
23 substance in the well-bore or adjacent formation.

1 (296)[(294)] "Supplied-air respirator "SAR" "airline respirator" means an atmosphere-
2 supplying respirator for which the source of breathing air is not designated to be carried
3 by the user.

4 (297)[(295)] "Surface contaminated object" or "SCO" means a solid object that is not
5 classed as radioactive material, but which has radioactive material distributed on a
6 surface. SCO must be in one (1) of two (2) groups with surface activity not exceeding
7 the following limits:

8 (a) SCO-I: A solid object on which:

9 1. The nonfixed contamination on the accessible surface averaged over 300 cm² (or
10 the area of the surface if less than 300 cm²) does not exceed 10⁻⁴ microcurie/cm² (4
11 Bq/cm²) for beta and gamma and low toxicity alpha emitters, or 10⁻⁵ microcurie/cm² (0.4
12 Bq/cm²) for all other alpha emitters;

13 2. The fixed contamination on the accessible surface averaged over 300 cm² (or the
14 area of the surface if less than 300 cm²) does not exceed 1.0 microcurie/cm² (4x10⁴
15 Bq/cm²) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/cm²
16 (4x10³ Bq/cm²) for all other alpha emitters; and

17 3. The nonfixed contamination plus the fixed contamination on the inaccessible
18 surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does
19 not exceed 1 microcurie/cm² (4x10⁴ Bq/cm²) for beta and gamma and low toxicity alpha
20 emitters, for 0.1 microcurie/cm² (4x10³ Bq/cm²) for all other alpha emitters.

21 (b) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

22 1. The nonfixed contamination on the accessible surface averaged over 300cm² (or
23 the area of the surface if less than 300 cm²) does not exceed 10⁻² microcurie/cm² (400

Bq/cm²) for beta and gamma and low toxicity alpha emitters or 10⁻³ microcurie/cm² (40 Bq/cm²) for all other alpha emitters;

2. 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 20 microcuries/cm² (8x10⁵ Bq/cm²) for beta and gamma and low toxicity alpha emitters, or 2 microcuries/cm² (8x10⁴ Bq/cm²) for all other alpha emitters; and

3. 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 20 microcuries/cm² (8x10⁵ Bq/cm²) for beta and gamma and low toxicity alpha emitters, or 2 microcuries/cm² (8x10⁴ Bq/cm²) for all other alpha emitters.

(298)~~(296)~~ "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. If appropriate, the evaluation shall include at least:

- (a) A physical survey of the location of sources of radiation; and
- (b) Measurements or calculations of levels of radiation or concentrations or quantities of radioactive material present.

(299)~~(297)~~ "Target" means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

(300)~~(298)~~ "Technique factors" means the conditions of operation. They are specified as follows:

- (a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
- (b) For field emission equipment rated for pulsed operation, peak tube potential in kV

and number of x-ray pulses;

(c) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(d) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time if the scan time and exposure time are equivalent; and

(e) For other equipment, peak tube potential in kV and tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

(301)~~[(299)]~~ "Technically Enhanced Naturally Occurring Radioactive Material "TENORM" means N.O.R.M., which has been separated to various degrees from the original ore or other material, refining or implementing it.

(302)~~[(300)]~~ "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

(303)~~[(304)]~~ "Teletherapy physicist" means the individual identified as the teletherapy physicist on a cabinet license.

(304)~~[(302)]~~ "Temporary job site" means a location to which radioactive material has been dispatched to perform a job, operation, or study other than the location listed in a specific license or certificate of registration.

(305)~~[(303)]~~ "Tenth-value layer (TVL)" means the thickness of a specified material that attenuates X-radiation or gamma radiation to an extent that the air kerma rate,

1 exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured
2 without the material at the same point.

3 (306)~~[(304)]~~ "Termination of irradiation" means the stopping of irradiation in a fashion
4 that does not permit continuance of irradiation without the resetting of operating
5 conditions at the control panel.

6 (307)~~[(305)]~~ "Tests" means the process of verifying compliance with an applicable
7 regulation.

8 (308)~~[(306)]~~ "Therapeutic radiation machines" means x-ray or electron-producing
9 equipment designed and used for external beam radiation therapy.

10 (309)~~[(307)]~~ "Therapeutic-type protective tube housing" means:

11 (a) For x-ray therapy equipment not capable of operating at 500 kVp or above: an x-
12 ray tube housing so constructed that the leakage radiation at a distance of one (1)
13 meter from the target does not exceed one (1) roentgen in one (1) hour if the tube is
14 operated at its maximum rated tube potential. Small areas of reduced protection are
15 acceptable providing the average reading over a 100-square centimeter area at one (1)
16 meter distance from the target does not exceed the value established in this paragraph;
17 or

18 (b) For x-ray therapy equipment capable of operating at 500 kVp or above: an x-ray
19 tube housing so constructed that the leakage radiation at a distance of one (1) meter
20 from the target does not exceed one-tenth (0.1) percent of the useful beam exposure
21 rate at one (1) meter from the target, for its operating conditions. Small areas of reduced
22 protection are acceptable providing the average reading over a 100-square centimeter
23 area at one (1) meter distance from the target does not exceed the value established in

1 this paragraph.

2 (310)~~[(308)]~~ "Tight-fitting facepiece" means a respiratory inlet covering that forms a
3 complete seal with the face.

4 (311)~~[(309)]~~ "Tomogram" means the depiction of the x-ray attenuation properties of a
5 section through the body.

6 (312)~~[(310)]~~ "Total effective dose equivalent" or "TEDE" means the sum of the deep-
7 dose equivalent (for external exposures) and the committed effective dose equivalent
8 (for internal exposures).

9 (313)~~[(311)]~~ "Traceable to a national standard" means that a quantity or a
10 measurement has been compared to a national standard directly or indirectly through
11 one (1) or more intermediate steps and that comparisons have been documented.

12 (314)~~[(312)]~~ "Transport container" means a package that is designed to provide
13 radiation safety and security if sealed sources are transported and which meets the
14 requirements of the 49 C.F.R. 173, Subpart I.

15 (315)~~[(313)]~~ "Transport index" means:

16 (a) The dimensionless number that designates the degree of control to be exercised
17 by the carrier during transportation, rounded up to the next tenth required to be placed
18 on the label of a package.

19 (b) The transport index is determined by multiplying the maximum radiation level in
20 millisievert (mSv) per hour at one (1) meter (3.3 feet) from the external surface of the
21 package by 100 (equivalent to the maximum radiation level in millirem per hour at one
22 (1) meter (3.3 feet).

23 (316)~~[(314)]~~ "Treatment" or "waste treatment" means a method, technique, or

1 process, including storage for radioactive decay, designed to change the physical,
2 chemical, or biological characteristics or composition of a waste in order to render the
3 waste for transport, storage or disposal, amendable to recovery, convertible to another
4 usable material, or reduced in volume.

5 (317)~~[(315)]~~ "Tritium neutron generator target source" means a tritium source used
6 within a neutron generator tube to produce neutrons.

7 (318)~~[(316)]~~ "Tube" means an x-ray tube, unless otherwise specified.

8 (319)~~[(317)]~~ "Tube housing assembly" means the tube housing with tube installed. It
9 includes high-voltage or filament transformers and other appropriate elements if they
10 are contained within the tube housing.

11 (320)~~[(318)]~~ "Tube rating chart" means the set of curves which specify the rated limits
12 of operation of the tube in terms of the technique factors.

13 (321)~~[(319)]~~ "Type A quantity" means a quantity of radioactive material, the
14 aggregate radioactivity of which does not exceed A_1 for special form radioactive
15 material or A_2 for normal form radioactive material, where A_1 and A_2 are given in 10
16 C.F.R. 71 Appendix A, or may be determined by procedures described in 10 C.F.R. 71
17 Appendix A.

18 (322)~~[(320)]~~ "Type B packaging" means a packaging designed to retain the integrity
19 of containment and shielding required by U.S. Nuclear Regulatory Commission
20 regulations if subjected to the normal conditions of transport and hypothetical accident
21 test conditions established in 10 C.F.R. Part 71.

22 (323)~~[(321)]~~ "Type B quantity" means a quantity of radioactive material greater than a
23 Type A quantity.

1 ~~(324)~~~~(322)~~ "Uniform low-level radioactive waste manifest" or "uniform manifest"
2 means the combination of NRC Forms 540, 541, and if necessary, 542, or their
3 equivalents, and their respective continuation sheets as needed, or equivalent.

4 ~~(325)~~~~(323)~~ "Unirradiated uranium" means uranium containing not more than 2×10^3
5 Bq of plutonium per gram of uranium-235, not more than 9×10^6 Bq of fission products
6 per gram of uranium-235, and not more than 5×10^{-3} gram of uranium-236 per gram of
7 uranium-235.

8 ~~(326)~~~~(324)~~ "U.S. Department of Energy" means the Department of Energy
9 established by 42 U.S.C. 7101 et seq., to the extent that the department exercises
10 functions formerly vested in the U.S. Atomic Energy Commission, its chairman,
11 members, officers and components and transferred to the U.S. Energy Research and
12 Development Administration and to the Administrator thereof and retransferred to the
13 Secretary of Energy in 42 U.S.C. 7151, effective October 1, 1977.

14 ~~(327)~~~~(325)~~ "Unrefined and unprocessed ore" means ore in its natural form prior to
15 processing, such as grinding, roasting, beneficiating, or refining.

16 ~~(328)~~~~(326)~~ "Unrestricted area" means an area access to which is not controlled or
17 limited by the licensee or registrant for purposes of protection of individuals from
18 exposure to radiation and radioactive material.

19 ~~(329)~~~~(327)~~ "Uranium - natural, depleted, enriched" means:

20 (a) "Natural uranium" means uranium with the naturally occurring distribution of
21 uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder
22 by weight essentially uranium-238);

23 (b) "Depleted uranium" means uranium containing less uranium-235 than the

1 naturally occurring distribution of uranium isotopes;

2 (c) "Enriched uranium" means uranium containing more uranium-235 than the
3 naturally occurring distribution of uranium isotopes.

4 ~~(330)~~~~[(328)]~~ "Uranium fuel cycle" means the operations of milling of uranium ore,
5 chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium
6 fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium
7 fuel, and reprocessing of spent uranium fuel to the extent that these activities directly
8 support the production of electrical power for public use. Uranium fuel cycle shall not
9 include mining operations, operations at waste disposal sites, transportation of
10 radioactive material in support of these operations, and the reuse of recovered
11 nonuranium special nuclear and byproduct materials from the cycle.

12 ~~(331)~~~~[(329)]~~ "Useful beam" means the radiation that passes through the tube housing
13 port and the aperture of the beam limiting device if the exposure switch or timer is
14 activated.

15 ~~(332)~~~~[(330)]~~ "User" means an individual who personally utilizes or manipulates a
16 source of radiation.

17 ~~(333)~~~~[(334)]~~ "User seal check" or "fit check" means an action conducted by the
18 respirator user to determine if the respirator is properly seated to the face. Examples
19 include
20 negative pressure check, positive pressure check, irritant smoke check, or
21 isoamylacetate check.

22 ~~(334)~~~~[(332)]~~ "Variable-aperture beam limiting device" means a beam limiting device
23 that has capacity for stepless adjustment of the x-ray field size at a given SID.

1 (335)~~[(333)]~~ "Vendor" means a person who sells radiation producing machines or
2 accelerators registerable with the cabinet as specified by 902 KAR 100:110.

3 (336)~~[(334)]~~ "Vendor registrant" means a vendor who is registered with the cabinet.

4 (337)~~[(335)]~~ "Vendor registration" means registration of a vendor with the cabinet
5 described by 902 KAR 100:110.

6 (338)~~[(336)]~~ "Very high radiation area" means an area, accessible to individuals, in
7 which radiation levels from radiation sources external to the body may result in an
8 individual receiving an absorbed dose in excess of 500 rads (five (5) grays) in one (1)
9 hour at one (1) meter from a radiation source or one (1) meter from a surface that the
10 radiation penetrates.

11 (339)~~[(337)]~~ "Virtual source" means a point from which radiation appears to originate.

12 (340)~~[(338)]~~ "Visible area" means that portion of the input surface of the image
13 receptor over which incident x-ray photons are producing a visible image.

14 (341)~~[(339)]~~ "Visiting authorized nuclear pharmacist" means a nuclear pharmacist
15 who is not identified on the license of the licensee being visited.

16 (342)~~[(340)]~~ "Visiting authorized user" means an authorized user who is not identified
17 on the license of the licensee being visited.

18 (343)~~[(341)]~~ "Waste". See "low-level radioactive waste".

19 (344)~~[(342)]~~ "Waste collector" means an entity, operating under the cabinet, U.S.
20 Nuclear Regulatory Commission or agreement state license whose principal purpose is
21 to collect and consolidate low level waste generated by others and to transfer this
22 waste, without processing or repackaging the collected waste, to another licensed
23 waste collector, licensed waste processor, or licensed land disposal facility.

1 (345)~~(343)~~ "Waste description" means the physical, chemical, and radiological
2 description of a low-level radioactive waste as called for on NRC Form 541.

3 (346)~~(344)~~ "Waste generator" means an entity, operating under the cabinet, U.S.
4 Nuclear Regulatory Commission, or agreement state license, who:

5 (a) Possesses any material or component that contains radioactivity or is
6 radioactively contaminated for which the licensee foresees no further use; and

7 (b) Transfers this material or component to a licensed land disposal facility or to a
8 licensed waste collector or processor for handling or treatment prior to disposal. A
9 licensee performing processing or decontamination services may be waste generator if
10 the transfer of low-level radioactive waste from its facility is defined as "residual waste".

11 (347)~~(345)~~ "Waste processor" means an entity, operating under a cabinet, U.S.
12 Regulatory Commission or agreement state license, whose principal purpose is to
13 process, repackage, or treat low-level radioactive material or waste generated by others
14 prior to eventual transfer of waste to a licensed low-level radioactive waste land
15 disposal facility.

16 (348)~~(346)~~ "Waste type" means a waste within a disposal container having a unique
17 physical description, such as a specific waste descriptor code or description, or a waste
18 sorbed on or solidified in a specifically defined media.

19 (349)~~(347)~~ "Wedge filter" means an added filter effecting continuous progressive
20 attenuation on the useful beam or a part thereof.

21 (350)~~(348)~~ "Week" means seven (7) consecutive days starting on Sunday.

22 (351)~~(349)~~ "Weighting factor (W_T)", for an organ or tissue (T) means the proportion
23 of the risk of stochastic effects resulting from irradiation of that organ or tissue to the

- 1 total risk of stochastic effects if the whole body is irradiated uniformly. For calculating
- 2 the effective dose equivalent, the values of (W_T) are:

Organ Dose Weighting Factors	
Organ or tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	¹ 0.30
Whole Body	² 1.00

- 3 ¹0.30 results from 0.06 for each of five (5) "remainder" organs (excluding the skin
- 4 and the lens of the eye) that receive the highest doses.

- 5 ²For the purpose of weighting the external whole body dose (for adding it to the
- 6 internal dose), a single weighting factor, $W_T=1.0$, has been specified. The use of
- 7 other weighting factors for external exposure will be approved on a case-by-case
- 8 basis, pursuant to 10 C.F.R. Part 20, until a time as specific guidance is issued.

- 9 (352)~~(350)~~ "Well-bore" means a drilled hole in which wire line service operations
- 10 and subsurface tracer studies are performed.

1 (353)~~(354)~~ "Well-logging" means the lowering and raising of measuring devices or
2 tools which may contain sources of radiation in well-bores or cavities for the purpose of
3 obtaining information about the well or adjacent formations.

4 (354)~~(352)~~ "Whole body" means, for purposes of external exposure, head, trunk
5 (including male gonads), arms above the elbow, or legs above the knee.

6 (355)~~(353)~~ "Wire line" means a cable containing one (1) or more electrical
7 conductors which is used to lower and raise logging tools in the well-bore.

8 (356)~~(354)~~ "Wire line service operation" means an evaluation or mechanical service
9 which is performed in the well-bore using devices on a wire line.

10 (357)~~(355)~~ "Worker" means an individual engaged in activities licensed or registered
11 by the cabinet and controlled by a licensee or registrant, but does not include the
12 licensee or registrant.

13 (358)~~(356)~~ "Working level" or "WL" means a combination of short-lived radon
14 daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and
15 for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one (1) liter
16 of air that results in the ultimate emission of 1.3×10^5 MeV of potential alpha particle
17 energy.

18 (359)~~(357)~~ "Working level month" or "WLM" means an exposure to one (1) working
19 level for 170 hours (2,000 working hours per year/twelve (12) months per year =
20 approximately 170 hours per month).

21 (360)~~(358)~~ "Written directive" means an order in writing for a specific patient or
22 human research subject, dated and signed by an authorized user prior to the
23 administration of a radiopharmaceutical or radiation, except as specified in paragraph

(f) of this subsection, and containing the following information:

(a) For an administration of quantities greater than thirty (30) microcuries of sodium iodide I-125 or I-131: the dosage;

(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(d) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(e) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(f) For all other brachytherapy:

1. Prior to implementation: the radioisotope, number of sources, and source strengths; and

2. After implantation, but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

(361)~~[(356)]~~ "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes timers, phototimers, automatic brightness stabilizers, and similar devices which control the technique factors of an x-ray exposure.

(362)~~[(360)]~~ "X-ray equipment" means an x-ray system, subsystem, or component thereof. X-ray equipment is further classified as:

1 (a) "Mobile" means x-ray equipment mounted on a permanent base with wheels or
2 casters for moving while completely assembled.

3 (b) "Portable" means x-ray equipment designed to be hand-carried.

4 (c) "Stationary" means x-ray equipment which is installed in a fixed location.

5 (d) "Transportable" means x-ray equipment installed in a vehicle or trailer.

6 (363)~~[(364)]~~ "X-ray field" means that area of the intersection of the useful beam and
7 one (1) of the set of planes parallel to and including the plane of the image receptor,
8 whose perimeter is the locus of points at which the exposure rate is one-fourth (1/4) of
9 the maximum in the intersection.

10 (364)~~[(362)]~~ "X-ray high-voltage generator" means a device that transforms electrical
11 energy from the potential supplied by the x-ray control to the tube operating potential.
12 The device may also include means for transforming alternating current to direct
13 current, filament transformers for the x-ray tube, high-voltage switches, electrical
14 protective devices, and other appropriate elements.

15 (365)~~[(363)]~~ "X-ray subsystem" means a combination of two (2) or more components
16 of an x-ray system.

17 (366)~~[(364)]~~ "X-ray system" means an assemblage of components for the controlled
18 production of x-rays. It includes an x-ray high-voltage generator, an x-ray control, a tube
19 housing assembly, a beam-limiting device, and necessary supporting structures.
20 Additional components that function with the system are considered integral parts of the
21 system.

22 (367)~~[(365)]~~ "X-ray tube" means an electron tube designed to be used primarily for
23 the production of x-rays.

1 ~~(368)~~~~(366)~~ "Year" means the period of time, beginning in January, used to
2 determine compliance with the provisions of 902 KAR Chapter 100. The licensee or
3 registrant may change the starting date of the year used to determine compliance by the
4 licensee or registrant if:

5 (a) The change is made at the beginning of the year; and

6 (b) A day is not omitted or duplicated in consecutive years.

902 KAR 100:010 Definitions for 902 Chapter 100

REVIEWED:

Date

Steve Davis, MD
Acting Commissioner
Department for Public Health

APPROVED:

Date

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

A public hearing on this administrative regulation shall, if requested, be held on September 21, 2012, at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by September 14, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business October 1, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 902 KAR 100:010

Contact Person: Matt McKinley (502) 564-3700 extension 3701

(1) Provide a brief summary of:

(a) What this administrative regulation does: This regulation establishes definitions for use in 902 KAR 100.

(b) The necessity of this administrative regulation: The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:010 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How this administrative regulation conforms to the content of the authorizing statutes: The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: By adding fifty one (51) definitions and revising others, it will provide clear and objective information on which to base regulatory decisions.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: It adds and revises various definitions within 902 KAR 100:010.

(b) The necessity of the amendment to this administrative regulation: To ensure compliance with the U.S. Nuclear Regulatory Commission's requirements of

Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How the amendment conforms to the content of the authorizing statutes: See KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. This amendment conforms to the statute by providing definitions for its implementation.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will bring the state regulations into conformance with federal regulations, thus making administration and enforcement more effective.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will assist all 430 licensees in clarifying the understanding of regulatory terms.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Licensees will need to be familiar with these new definitions. They already are familiar with them as they are federal definitions already in use.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be cost associated with implementing these regulations. The licensees are already in compliance with the federal regulations.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The regulated entities will have consistent definitions between state and federal regulations.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional cost will be incurred as a result of amending this administrative regulation.

(b) On a continuing basis: No additional cost will be incurred as a result of amending this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: General funds are used to operate this

program. However, no additional funds will be required to implement this regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase in fees or funding will not be necessary to implement this regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This amendment does not increase fees either directly or indirectly.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 902 KAR 100:010 Contact Person: Matt McKinley 564-3700 x 3701

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No
2. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This regulation impacts all state or local governments where radioactive materials are in use.
3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by this administrative regulation.

The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:010 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. This administrative regulation has no effect on expenditures or revenues of state and local governments.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This regulation will generate no revenue for state or local governments the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This regulation will generate no revenue for state or local governments in subsequent years.

(c) How much will it cost to administer this program for the first year?
This program will not require any increase in funding for the first year.

(d) How much will it cost to administer this program for subsequent years?
This program will not require any increase in funding for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

1 Cabinet for Health and Family Services

2 Department of Public Health

3 Division of Public Health Protection and Safety

4 (Amendment)

5 902 KAR 100:019. Standards for protection against radiation.

6 RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. 20.1001-20.1906,
7 20.2101-20.2204, 20.2206, Appendixes A, B-20.1001-20.2401, 40 C.F.R. 190, 49
8 C.F.R. 100-180, 173.403(m),(w), 173.421-173.424

9 STATUTORY AUTHORITY: KRS 194.050, 211.090, 211.844, 10 C.F.R. 10.1001-
10 20.1906, 20.2101-20.2204, 20.2206, Appendixes A, B-20.1001-20.2401, 40 C.F.R. 190,
11 49 C.F.R. 100-180, 49 C.F.R. 173.403(m),(w), 173.421-173.424,

12 NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet
13 for Health and Family Services to provide by administrative regulation for the registra-
14 tion and licensing of the possession or use of sources of ionizing or electronic product
15 radiation and the handling and disposal of radioactive waste. This administrative regula-
16 tion establishes standards for the protection of the user and general public against radi-
17 ation exposure and establishes standards for protection against ionizing radiation result-
18 ing from activities conducted by persons issued licenses or registrations by the cabinet.
19 This administrative regulation establishes standards to control the receipt, possession,
20 use, transfer, and disposal of sources of radiation by a person, licensee, or registrant so
21 the total dose to an individual (including doses resulting from licensed and unlicensed

radioactive material and radiation sources other than background radiation) shall not exceed the standards for protection against radiation prescribed in this administrative regulation.

Section 1. Radiation Protection Implementation. (1) This administrative regulation shall not limit actions required in order to protect against an immediate danger to public health and safety.

(2) This administrative regulation shall apply to a person licensed or registered by the cabinet to receive, possess, use, transfer, or dispose of sources of radiation.

(3) The limits in this administrative regulation shall not apply to doses due to background radiation, exposure of patients to radiation for the purpose of medical diagnosis or therapy, or voluntary participation in medical research programs.

Section 2. Radiation Protection Programs. A person, licensee, or registrant shall:

(1) Develop, document, and implement a radiation protection program commensurate with the scope and extent of the person's activities and sufficient to ensure compliance with the provisions of this administrative regulation;

(2) Use procedures and engineering controls based upon sound radiation protection principles, to the extent practical, to achieve occupational doses and doses to members of the public that shall be as low as reasonably achievable (ALARA) pursuant to 902 KAR 100:015, Section 2;

(3) Annually review the radiation protection program content and implementation; and

(4) Establish a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, to implement the ALARA requirements of subsection (2) of this section and the requirements of Section 10 of this administrative regu-

lation.

(a) Any constraint shall ensure that the highest dose that could be received by a person shall not exceed a dose in excess of ten (10) millirems (0.1 mSv) per year.

(b) A licensee, if required to establish these constraints, shall report any exceedance as provided in Section 40 of this administrative regulation and take appropriate corrective action to ensure against recurrence.

Section 3. Occupational Dose Limits for Adults. (1) A person, licensee, or registrant shall control the occupational dose to individual adults, except for planned special exposures as described in Section 7 of this administrative regulation, to the following dose limits:

(a) An annual limit, which shall be the more limiting of the:

1. Total effective dose equivalent being equal to five (5) rems (0.05 Sv)~~[(0.50 Sv)]~~;

and

2. Sum of the deep-dose equivalent and the committed dose equivalent to an individual organ or tissue, other than the lens of the eye, being equal to fifty (50) rems (0.50 Sv).

(b) The annual limits to the lens of the eye, the skin, and the extremities, which shall be:

1. A lens dose equivalent of fifteen (15) rems (0.15 Sv); and

2. A shallow-dose equivalent of fifty (50) rems (five-tenths (0.50) Sv) to the skin of the whole body or to the skin of an extremity.

(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the

limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime as described in Section 7(3)(a) and (b) of this administrative regulation.

(3) The assigned deep-dose equivalent and shallow-dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent shall be the dose averaged over the contiguous ten (10) square centimeters of skin receiving the highest exposure. If the individual monitoring device was not in the region of highest potential 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.

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are established in 10 C.F.R., 20, Appendix B, Table 1, and shall be used to:

(a) Determine the individual's dose as required in Section 34 of this administrative regulation; and

(b) Demonstrate compliance with the occupational dose limits.

(5) In addition to the annual dose limits, the person, licensee, or registrant shall limit the soluble uranium intake by an individual to ten (10) milligrams in a week in consideration of chemical toxicity as established in 10 C.F.R., 20 Appendix B.

(6) A person, licensee, or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by a person as described in Section 32 of this administrative regulation.

Section 4. Compliance with Requirements for Summation of External and Internal Doses. (1) If a licensee or registrant is required to monitor by both Section 13(1) and (2)

1 of this administrative regulation, the licensee or registrant shall demonstrate compliance
2 with the dose limits by summing external and internal doses.

3 (2) If a licensee or registrant is required to monitor only by Section 13(1) or (2) of this
4 administrative regulation, summation shall not be required to demonstrate compliance
5 with the dose limits.

6 (3) A licensee or registrant may demonstrate compliance with the requirements for
7 summation of external and internal doses by meeting one (1) of the conditions specified
8 in subsection (5) of this section and the conditions in subsections (6) and (7) of this sec-
9 tion.

10 (4) The dose equivalents for the lens of the eye, the skin, and the extremities shall
11 not be included in the summation but shall be subject to separate limits established in
12 Section 3 of this administrative regulation.

13 (5) If the only intake of radionuclides occurs by inhalation, the total effective dose
14 equivalent limit shall not be exceeded if the sum of the deep-dose equivalent divided by
15 the total effective dose equivalent limit, and one (1) of the following, does not exceed
16 unity:

17 (a) Sum of the fractions of the inhalation ALI for each radionuclide;

18 (b) Total number of derived air concentration-hours (DAC-hours) for radionuclides di-
19 vided by 2,000; or

20 (c) Sum of the calculated committed effective dose equivalents to significantly irra-
21 diated organs or tissues (T) calculated from bioassay data using appropriate biological
22 models and expressed as a fraction of the annual limit.

23 (6) If the occupationally exposed individual also receives an intake of radionuclides

1 by oral ingestion greater than ten (10) percent of the applicable oral ALI, the licensee or
2 registrant shall account for this intake and include it in demonstrating compliance with
3 the limits.

4 (7) A licensee or registrant shall evaluate and, to the extent practical, account for in-
5 takes through wounds or skin absorption. The intake through intact skin has been in-
6 cluded in the calculation of DAC for hydrogen-3 and may not need to be further eva-
7 luated.

8 Section 5. Determination of External Dose from Airborne Radioactive Material. (1) If
9 determining the dose from airborne radioactive material, a licensee or registrant shall
10 include the contribution to the deep-dose equivalent, lens dose equivalent, and shallow-
11 dose equivalent from external exposure to the radioactive cloud.

12 (2) If the airborne radioactive material includes radionuclides other than noble gases
13 or the cloud of airborne radioactive material is not relatively uniform, airborne radioactiv-
14 ity measurements and DAC values shall not be used as the primary means to assess
15 the deep-dose equivalent.

16 (3) The determination of the deep-dose equivalent to an individual shall be based
17 upon measurements using instruments or individual monitoring devices.

18 Section 6. Determination of Internal Exposure. (1) For purposes of assessing dose
19 used to determine compliance with occupational dose equivalent limits, the licensee or
20 registrant shall, if required by Section 13 of this administrative regulation, take suitable
21 and timely measurements of:

22 (a) Concentrations of radioactive materials in the air in work areas;

23 (b) Quantities of radionuclides in the body;

1 (c) Quantities of radionuclides excreted from the body; or

2 (d) Combinations of these measurements.

3 (2) A licensee or registrant shall assume an individual inhales radioactive material at
4 the airborne concentration in which the individual is present, unless respiratory protec-
5 tive equipment is used, as provided in Section 19 of this administrative regulation, or the
6 assessment of intake is based on bioassays.

7 (3) If specific information on the physical and biochemical properties of the radionuc-
8 lides taken into the body, or the behavior or material in an individual is known, a licen-
9 see or registrant may:

10 (a) Use the information to calculate the committed effective dose equivalent, and, if
11 used, the licensee or registrant shall document the information in the individual's record;

12 (b) Upon prior approval by the cabinet, adjust the DAC or ALI values to reflect the ac-
13 tual physical and chemical characteristics of airborne radioactive material (for example,
14 aerosol size distribution or density); and

15 (c) Separately assess the contribution of fractional intakes of Class D, W, or Y com-
16 pounds of a radionuclide, as provided in 10 C.F.R., 20 Appendix A, to the committed ef-
17 fective dose equivalent.

18 (4) If a licensee or registrant chooses to assess intakes of Class Y material using the
19 measurements provided in subsection (1)(b) or (c) of this section, the licensee or regi-
20 strant may delay the recording and reporting of the assessments for periods up to seven

21 (7) months, unless otherwise required by Section 39 or 40 of this administrative regula-
22 tion, in order to permit the licensee or registrant to make additional measurements basic
23 to the assessments.

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

(a) Sum of the ratios of the concentration to the appropriate DAC value (D, W, Y) from 10 C.F.R., 20 Appendix B, for radionuclides in the mixture; or

(b) Ratio of the total concentration for radionuclides in the mixture to the most restrictive DAC value for a radionuclide in the mixture.

(6) If the identity of radionuclides in a mixture is known, but the concentration of one (1) or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of a radionuclide in the mixture.

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

(a) Licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in Section 3 of this administrative regulation and in complying with the monitoring requirements in Section 13(2) of this administrative regulation;

(b) Concentration of a disregarded radionuclide is less than ten (10) percent of its DAC; and

(c) Sum of these percentages for the disregarded radionuclides in the mixture does not exceed thirty (30) percent.

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

1 lent.

2 (a) If the ALI and the associated DAC are determined by the nonstochastic organ
3 dose limit of fifty (50) rems (five-tenths (0.50) Sv), the intake of radionuclides that result
4 in a committed effective dose equivalent of five (5) rems (0.05 Sv) (the stochastic ALI) is
5 listed in parentheses in 10 C.F.R., 20 Appendix B. A licensee or registrant may, as a
6 simplifying assumption, use the stochastic ALIs to determine committed effective dose
7 equivalent.

8 (b) If a licensee or registrant uses the stochastic ALIs, the licensee or registrant shall
9 also demonstrate that the limit in Section 3(1)(a)2 of this administrative regulation is
10 met.

11 Section 7. Planned Special Exposures. (1) A licensee or registrant may authorize an
12 adult worker to receive doses in addition to, and accounted for separately from the dos-
13 es received under, the limits specified in Section 3 of this administrative regulation pro-
14 vided each of the following conditions are satisfied:

15 (a) The licensee or registrant authorizes a planned special exposure only in an ex-
16 ceptional situation if alternatives that may avoid the dose estimated to result from the
17 planned special exposure are unavailable or impractical;

18 (b) The licensee or registrant, and employer if the employer is not the licensee or re-
19 gistrant, specifically authorize the planned special exposure, in writing, before the expo-
20 sure occurs;

21 (c) Before a planned special exposure, the licensee or registrant ensures that the in-
22 dividuals involved are:

23 1. Informed of the purpose of the planned operation;

2. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that may be involved in performing the task; and

3. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(2) Prior to permitting an individual to participate in a planned special exposure, a licensee or registrant shall ascertain prior doses as required by Section 32(2) of this administrative regulation during the lifetime of the individual for each individual involved.

(3) Subject to Section 3(2) of this administrative regulation, a licensee or registrant shall not authorize a planned special exposure that shall cause an individual to receive a dose from planned special exposures and doses in excess of the limits to exceed:

(a) The numerical values of the dose limits in Section 3(1) of this administrative regulation in a year; and

(b) Five (5) times the annual dose limits in Section 3(1) of this administrative regulation during the individual's lifetime.

(4) A licensee or registrant shall:

(a) Maintain records of the conduct of a planned special exposure pursuant to Section 33 of this administrative regulation; and

(b) Submit a written report pursuant to Section 41 of this administrative regulation.

(5) A licensee or registrant shall record the best estimate of the dose resulting from the planned special exposure in the individual's record and inform the individual, in writing, of the dose within thirty (30) days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual by Section 3(1) of this administrative regulation but

1 shall be included in evaluations required by Section 7(2) and (3) of this administrative
2 regulation.

3 Section 8. Occupational Dose Limits for Minors. The annual occupational dose limits
4 for minors shall be ten (10) percent of the annual dose limits specified for adult workers
5 in Section 3 of this administrative regulation.

6 Section 9. Dose Equivalent to an Embryo or Fetus. (1) A licensee or registrant shall
7 ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due
8 to occupational exposure of a declared pregnant woman, does not exceed five-tenths
9 (0.5) rem (5 mSv). Recordkeeping requirements are established in Section 42 of this
10 administrative regulation.

11 (2) A licensee or registrant shall make efforts to avoid substantial variation above a
12 uniform monthly exposure rate to a declared pregnant woman to satisfy the limit in sub-
13 section (1) of this section.

14 (3) The dose equivalent to an embryo or fetus shall be taken as the sum of:

15 (a) The deep-dose equivalent to the declared pregnant woman; and

16 (b) The dose equivalent to the embryo or fetus resulting from radionuclides in the
17 embryo or fetus and radionuclides in the declared pregnant woman.

18 (4) If the dose equivalent to the embryo or fetus is found to have exceeded five-
19 tenths (0.5) rem (five (5) mSv), or is within 0.05 rem (five-tenths (0.5) mSv) of this dose,
20 by the time the woman declares the pregnancy to a licensee or registrant, the licensee
21 or registrant shall be in compliance with subsection (1) of this section if the additional
22 dose equivalent to the embryo or fetus does not exceed 0.05 rem (five-tenths (0.5)
23 mSv) during the remainder of the pregnancy.

Section 10. Radiation Dose Limits for Individual Members of the Public. (1) A licensee or registrant shall conduct operations to ensure that the:

(a) Total effective dose equivalent to individual members of the public from licensed, registered, and other operations shall not exceed 0.1 rem (one (1) mSv) in a year, exclusive of the dose contributions from:

1. Background radiation;

2. A medical administration the individual received;

3. An exposure to individuals administered radioactive material and released in accordance with 902 KAR 100:072, Section 27;

4. Voluntary participation in medical research programs; and

5. The licensee's or registrant's disposal of radioactive material into sanitary sewerage under 902 KAR 100:021, Section 3; and

(b) Dose in an unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 902 KAR 100:072, Section 27, shall not exceed 0.002 rem (0.02 mSv) in one (1) hour.

(2) If a licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public specified in this section shall apply to those individuals.

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

1 (a) Demonstration of the need for, and the expected duration of, operations in excess
2 of the limit in subsection (1) of this section;

3 (b) A licensee's or registrant's program to assess and control dose within the five-
4 tenths (0.5) rem (five (5) mSv) annual limit; and

5 (c) The procedures to be followed to maintain the dose ALARA.

6 (4) In addition to the provisions of this administrative regulation, a person, licensee,
7 or registrant subject to the provisions of U.S. Environmental Protection Agency's appli-
8 cable environmental radiation standards in 40 C.F.R. 190 shall comply with those stan-
9 dards.

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

13 (6) In addition to the requirements in subsection (1)(a) of this section, a licensee may
14 permit visitors to an individual who cannot be released under 902 KAR 100:072, Section
15 27, to receive a radiation dose greater than one tenth (0.1) rem (1 mSv) if:

16 (a) The radiation dose received does not exceed five-tenths (0.5) rem (5 mSv); and

17 (b) The authorized user, as defined in 902 KAR 100:010, has determined before the
18 visit that it is appropriate.

19 Section 11. Compliance with Dose Limits for Individual Members of the Public. (1) To
20 demonstrate compliance with the dose limits for individual members of the public in
21 Section 10 of this administrative regulation, a licensee or registrant shall make or cause
22 to be made surveys of:

23 (a) Radiation levels in unrestricted and controlled areas; and

(b) Radioactive materials in effluents released to unrestricted and controlled areas.

(2) A licensee or registrant shall show compliance with the annual dose limit in Section 10 of this administrative regulation by:

(a) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation shall not exceed the annual dose limit; or

(b) Demonstrating that:

1. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the restricted area shall not exceed the values specified in 10 C.F.R., Appendix B; and

2. If an individual were continually present in an unrestricted area, the dose from external sources shall not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (five-tenths (0.5) mSv) in a year.

(3) Upon approval from the cabinet, a licensee or registrant may adjust the effluent concentration values in 10 C.F.R., 20 Appendix B, for members of the public, to take into account the actual physical and chemical characteristics of the effluents (for example, aerosol size distribution, solubility, density, radioactive decay equilibrium, or chemical form).

Section 12. Surveys and Monitoring. (1) A licensee or registrant shall make or cause to be made, surveys that are:

(a) Necessary for the licensee or registrant to comply with the provisions in this administrative regulation; and

(b) Reasonable under the circumstances to evaluate:

1 1. The magnitude and extent of radiation levels;

2 2. Concentrations or quantities of radioactive material; and

3 3. The potential radiological hazards.

4 (2) A licensee or registrant shall ensure that instruments and equipment used for
5 quantitative radiation measurements (for example, dose rate and effluent monitoring)
6 are calibrated periodically for the radiation measured.

7 (3) Personnel dosimeters, except direct and indirect reading pocket ionization cham-
8 bers and those dosimeters used to measure the dose to the extremities, that require
9 processing to determine the radiation doses used by licensees or registrants to comply
10 with Section 3 of this administrative regulation, other applicable provisions of 902 KAR
11 Chapter 100, or conditions specified in a license, shall be processed and evaluated by a
12 dosimetry processor:

13 (a) Holding current personnel dosimetry accreditation from the National Voluntary
14 Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and
15 Technology; and

16 (b) Approved in this accreditation process for the type of radiation or radiations in-
17 cluded in the NVLAP program that most closely approximates the type of radiation or
18 radiations for which the individual wearing the dosimeter is monitored.

19 Section 13. Conditions Requiring Individual Monitoring of External and Internal Occu-
20 pational Dose. (1) A licensee or registrant shall monitor exposures to radiation and ra-
21 dioactive material at levels sufficient to demonstrate compliance with the occupational
22 dose limits of this administrative regulation. At a minimum, the licensee or registrant
23 shall monitor occupational exposure to radiation, from licensed and unlicensed, regis-

tered and unregistered radiation sources under the licensee's or registrant's control and shall supply and require the use of individual monitoring devices by:

(a) Adults likely to receive, in one (1) year from radiation sources external to the body, a dose in excess of ten (10) percent of the limits in Section 3(1) of this administrative regulation;

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

(c) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1mSv). All of the occupational doses in Section 3 continue to be applicable to the declared pregnant worker as long as the embryo or fetus dose limit is not exceeded; and

(d) Individuals entering a high or very high radiation area.

(2) A licensee or registrant shall monitor, pursuant to Section 6 of this administrative regulation, the occupational intake of radioactive material by, and assess the committed effective dose equivalent to:

(a) Adults likely to receive, in one (1) year, an intake in excess of ten (10) percent of the applicable ALIs in 10 C.F.R., 20 Appendix B;

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

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

Section 14. Control of Access to High Radiation Areas. (1) A licensee or registrant shall ensure that each entrance or access point to a high radiation area shall have at least one (1) of the following features:

(a) A control device that, upon entry into the area, shall cause the level of radiation to be reduced below the level an individual may receive a deep-dose equivalent of 0.1 rem (one (1) mSv) in one (1) hour at thirty (30) centimeters from the radiation source or from a surface that the radiation penetrates;

(b) A control device that shall energize a conspicuous visible or audible alarm signal so the individual entering the high radiation area and the supervisor of the activity shall be made aware of the entry; or

(c) Entryways that shall be locked, except during periods that access to the areas is required, with positive control over each individual entry.

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

(3) A licensee or registrant may apply to the cabinet for approval of alternative methods for controlling access to high radiation areas.

(4) A licensee or registrant shall establish the controls required by subsections (1) and (3) of this section that shall not prevent individuals from leaving a high radiation area.

(5) Control shall not be required for an entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with 49 C.F.R. 100-180

1 if the packages will not remain in the area longer than three (3) days, and the dose rate
2 at one (1) meter from the external surface of a package will not exceed 0.01 rem (0.1
3 mSv) per hour.

4 (6) Control of entrance or access to rooms or other areas in hospitals shall not be re-
5 quired solely because of the presence of patients containing radioactive material if per-
6 sonnel are in attendance who:

7 (a) Take the necessary precautions to prevent the exposure of individuals to radiation
8 or radioactive material in excess of the limits established in this administrative
9 regulation; and

10 (b) Operate within the ALARA provisions of the licensee's or registrant's radiation
11 protection program.

12 (7) A registrant is not required to control entrance or access to rooms or other
13 areas containing sources of radiation capable of producing a high radiation area as de-
14 scribed in this section if the registrant has met the specific requirements for access and
15 control specified in 902 KAR 100:100, 100:115, and 100:155.

16 Section 15. Control of Access to Very High Radiation Areas. (1) In addition to the
17 provisions in Section 14 of this administrative regulation, a licensee or registrant shall
18 institute additional measures to ensure that an individual shall not be able to gain unau-
19 thorized or inadvertent access to areas in which radiation levels may be encountered at
20 500 rads (five (5) grays) or more in one (1) hour at one (1) meter from a radiation
21 source or a surface through which the radiation penetrates.

22 (2) A registrant shall not be required to control entrance or access to rooms or other
23 areas containing sources of radiation capable of producing a very high radiation area as

described in subsection (1) of this section if the registrant has met the specific requirements for access and control specified in 902 KAR 100:100, 100:115, and 100:155.

Section 16. Control of Access to Very High Radiation Areas for Irradiators. (1) This section shall apply to radiation from sources of radiation used in sealed sources in non-self-shielded irradiators.

(2) This section shall not apply to:

(a) Sources of radiation used in teletherapy, radiography, or completely self-shielded irradiators in which the source:

1. Is both stored and operated within the same shielding radiation barrier; and
2. In the designed configuration of the irradiator is always physically inaccessible to an individual and cannot create high levels of radiation in an area that is accessible to an individual; and

(b) Sources from which the radiation shall be incidental to some other use or to nuclear reactor-generated radiation.

(3) Areas where radiation levels may exist in excess of 500 rads (five (5) grays) in one (1) hour at one (1) meter from a source of radiation used to irradiate materials shall meet the following requirements;

(a) An entrance or access point shall be equipped with entry control devices that:

1. Function automatically to prevent an individual from inadvertently entering the area if very high radiation levels exist;
2. Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below a level where it is possible for an individual to receive a deep-dose equivalent in

1 excess of 0.1 rem (one (1) mSv) in one (1) hour; and

2 3. Prevent operation of the source of radiation if the source would produce radiation
3 levels in the area that may result in a deep-dose equivalent to an individual in excess of
4 0.1 rem (one (1) mSv) in one (1) hour.

5 (b) Additional control devices shall be provided so that, upon failure of the entry con-
6 trol devices to function as required by subsection (3)(a) of this section:

7 1. The radiation level within the area, from the source of radiation, is reduced below a
8 level where it is possible for an individual to receive a deep-dose equivalent in excess of
9 0.1 rem (one (1) mSv) in one (1) hour; and

10 2. Conspicuous visible and audible alarm signals are generated to make an individual
11 attempting to enter the area aware of the hazard, and at least one (1) other authorized
12 individual who is physically present, familiar with the activity, and prepared to render or
13 summon assistance, aware of the failure of the entry control devices;

14 (c) A licensee or registrant shall provide control devices so that, upon failure or re-
15 moval of physical radiation barriers other than the source's shielded storage container:

16 1. The radiation level from the source of radiation shall be reduced below a level
17 where it is possible for an individual to receive a deep-dose equivalent in excess of 0.1
18 rem (one (1) mSv) in one (1) hour; and

19 2. Conspicuous visible and audible alarm signals shall be generated to make poten-
20 tially affected individuals aware of the hazard, and a licensee, registrant, or at least one
21 (1) other individual who is familiar with the activity and prepared to render or summon
22 assistance, aware of the failure or removal of the physical barrier;

23 (d) If the shield for the stored source is a liquid, the licensee or registrant shall pro-

vide means to:

1. Monitor the integrity of the shield; and

2. Automatically signal loss of adequate shielding;

(e) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of paragraphs (c) and (d) of this subsection;

(f) An area shall be equipped with devices that automatically generate conspicuous visible and audible alarm signals:

1. To alert personnel in the area before the source can be put into operation;

2. In sufficient time for an individual in the area to operate a clearly identified control device, which is installed in the area and can prevent the source from being put into operation;

(g) An area shall be controlled by use of administrative procedures and devices as are necessary to ensure that the area is cleared of personnel prior to use of the source;

(h) An area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after use of the source of radiation, the radiation level from the source of radiation in the area is below a level where it is possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (one (1) mSv) in one (1) hour;

(i) The entry control devices required in paragraph (a) of this subsection shall have been tested for proper functioning as follows:

1. Daily prior to initial operation with the source of radiation, unless operations were continued uninterrupted from a previous day;

2. Prior to resumption of operation of the source of radiation after an unintended interruption; and

3. By adherence to a submitted schedule for periodic tests of the entry control and warning systems;

(j) A licensee or registrant shall not conduct operations if control devices are not functioning properly, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls; and

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

(4)(a) Persons holding licenses or registrations, or applicants for licenses or registrations, for radiation sources may apply to the cabinet for approval of the use of alternative safety measures if they:

1. Are governed by the provisions of subsection (3) of this section; and

2. May be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with provisions of subsection (3) of this section (for example, those for the automatic control of radiation levels).

(b) Alternative safety measures shall provide a degree of personnel protection equivalent to those specified in subsection (3) of this section.

(c) At least one (1) of the alternative measures shall include an entry-preventing inter-

lock control, based on a measurement of the radiation, that ensures the absence of high radiation levels before an individual may gain access to the area in which sources of radiation are used.

(5) Entry control devices required by subsections (3) and (4) of this section shall be established in a way that an individual shall not be prevented from leaving the area.

Section 17. Use of Process or Other Engineering Controls. The licensee or registrant shall use, to the extent practicable, process or other engineering controls (such as containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

Section 18. Use of Other Controls. (1) If it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, a licensee or registrant shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one (1) or more of the following means:

- (a) Control of access;
- (b) Limitation of exposure times;
- (c) Use of respiratory protection equipment; or
- (d) Other controls.

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

Section 19. Use of Individual Respiratory Protection Equipment. (1) If a licensee or

registrant uses respiratory protection equipment to limit the intake of radioactive material:

(a)1. The licensee or registrant shall use only respiratory protection equipment that shall be tested and certified by the National Institute for Occupational Safety and Health (NIOSH); or

2. Prior to using equipment that has not been tested or certified by NIOSH, or for which there exists no schedule for testing or certification, the licensee or registrant shall submit to the cabinet an application for authorized use of that equipment, except as provided in this administrative regulation.

a.

The application shall include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated condition of use; and

b. The material and performance characteristics shall be demonstrated either by licensee or registrant testing or on the basis of reliable test information;

(b)

A licensee or registrant shall implement and maintain a respiratory protection program that shall include:

1. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

2. Surveys and bioassays, as appropriate, to evaluate actual intakes;

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

- 1 4. Written procedures regarding:
 - 2 a. Respirator selection;
 - 3 b. Supervision and training of respirator users;
 - 4 c. Monitoring, including air sampling and bioassays;
 - 5 d. Fit testing;
 - 6 e. Breathing air quality;
 - 7 f. Inventory and control;
 - 8 g. Storage, issuance, maintenance, repair, testing, and quality assurance of respira-
 - 9 tory protection equipment;
 - 10 h. Recordkeeping; and
 - 11 i. Limitations on periods of respirator use and relief from respirator use;
- 12 5. Determination by a physician prior to initial fitting of a face sealing respirator, and
13 either every twelve (12) months or periodically at a frequency determined by a physi-
14 cian, that the individual user shall be medically fit to use the respiratory protection
15 equipment; and
- 16 6. Fit testing, with a fit factor ten (10) times the APF for negative pressure devices
17 and a fit factor greater than or equal to 500 for any positive pressure, continuous flow,
18 and pressure-demand devices, before the first field use of tight fitting, face-sealing res-
19 pirators and periodically thereafter at a frequency not to exceed one (1) year. Fit testing
20 shall be performed with the facepiece operating in the negative pressure mode;
- 21 (c) A licensee or registrant shall issue a written policy statement on respirator usage
22 covering the:
 - 23 1. Use of process or other engineering controls, instead of respirators;

1 2. Routine, nonroutine, and emergency use of respirators; and

2 3. Periods of respirator use and relief from respirator use;

3 (d) A licensee or registrant shall advise a respirator user that the user may leave the
4 area for relief from respirator use in the event of:

5 1. Equipment malfunction;

6 2. Physical or psychological distress;

7 3. Procedural or communication failure;

8 4. Significant deterioration of operating conditions; or

9 5. Other conditions that may require relief;

10 (e)

11 A licensee or registrant, when selecting respiratory devices, shall:

12 1. Consider limitations appropriate to type and mode of use;

13 2. Provide visual correction, adequate communication, low temperature work envi-
14 ronments, and concurrent use of other safety or radiological equipment; and

15 3. Use equipment in a way as not to interfere with the proper operation of the respira-
16 tor;

17 (f) Standby rescue persons shall:

18 1. Be required if one-piece atmosphere-supplying suits or any combination of sup-
19 plied air respiratory protection device and personnel protective equipment are used from
20 which an unaided individual would have difficulty extricating himself or herself;

21 2. Be equipped with respiratory protection devices or other apparatus appropriate for
22 the potential hazards;

23 3. Observe or otherwise maintain continuous communication with the workers (visual,

voice, signal line, telephone, radio, or other suitable means); and

4. Be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress;

(g) A sufficient number of standby rescue persons shall be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed;

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

1. Oxygen content (v/v) of 19.5-23.5%;

2. Hydrocarbon (condensed) content of five (5) milligrams per cubic meter of air or less;

3. Carbon monoxide (CO) content of ten (10) parts per million (ppm) or less;

4. Carbon dioxide content of 1,000 ppm or less; and

5. Lack of noticeable odor;

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

(j)1. In estimating the dose to individuals from intake of airborne radioactive mate-

1 rials, the concentration of radioactive material in the air that is inhaled when respirators
2 are worn is initially assumed to be the ambient concentration in air without respiratory
3 protection divided by the assigned protection factor.

4 2. If the dose is later found to be greater than the estimated dose, the corrected value
5 shall be used.

6 3. If the dose is later found to be less than the estimated dose, the corrective value
7 may be used.

8 (2) The licensee shall obtain authorization from the cabinet before using assigned
9 protection factors in excess of those specified in 10 C.F.R. 20, Appendix A. The cabinet
10 may authorize a licensee to use higher assigned protection factors on receipt of an ap-
11 plication that:

12 (a) Describes the situation for which a need exists for higher protection factors; and

13 (b) Demonstrates that the respiratory protection equipment provides these higher
14 protection factors under the proposed conditions of use.

15 Section 20. Further Restrictions on the Use of Respiratory Protection Equipment. The
16 cabinet may impose restrictions in addition to those in Sections 18 and 19 of this admin-
17 istrative regulation and 10 C.F.R. 20, Appendix A to:

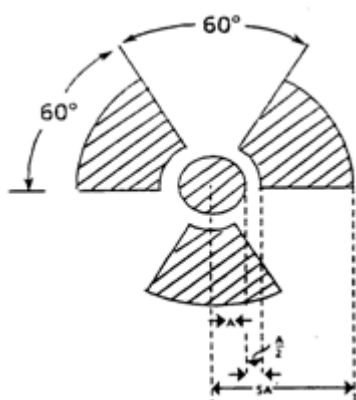
18 (1) Ensure that the respiratory protection program of the licensee shall be adequate
19 to limit doses to individuals from intakes of airborne
20 radioactive materials consistent with maintaining total effective dose equivalent ALARA;
21 and

22 (2) Limit the extent to which a licensee shall use respiratory protection equipment in-
23 stead of process or other engineering controls.

Section 21. Security of Sources of Radiation. A licensee or registrant shall secure from unauthorized removal or access, licensed materials stored in controlled or unrestricted areas.

Section 22. Control of Sources of Radiation Not in Storage. A licensee or registrant shall control and maintain constant surveillance of licensed or registered material in a controlled or unrestricted area and not in storage.

Section 23. Caution Signs and Standard Radiation Symbol. (1) Unless otherwise authorized by the cabinet, the symbol prescribed by this section shall use the colors magenta, purple, or black on yellow background. The symbol prescribed by this section shall be the three (3) bladed design:



RADIATION SYMBOL

(a) Cross-hatched area shall be magenta, purple, or black; and

(b) The background shall be yellow.

(2) Exception to color requirements for standard radiation symbol. A licensee or registrant may label sources, source holders, or device components containing sources of radiation subjected to high temperatures with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(3) Additional information on signs and labels. In addition to the contents of signs and

1 labels prescribed in this section, a licensee or registrant may provide on or near the re-
2 quired signs and labels additional information, as appropriate, to make individuals
3 aware of potential radiation exposures and to minimize the exposures.

4 Section 24. Posting Requirements. (1) Posting of radiation areas. A licensee or regi-
5 strant shall post a radiation area with a conspicuous sign or signs bearing the radiation
6 symbol and the words: "CAUTION, RADIATION AREA".

7 (2) Posting of high radiation areas. A licensee or registrant shall post a high radiation
8 area with a conspicuous sign or signs bearing the radiation symbol and the words:
9 "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA".

10 (3) Posting of very high radiation areas. A licensee or registrant shall post a very high
11 radiation area with a conspicuous sign or signs bearing the radiation symbol and words:
12 "GRAVE DANGER, VERY HIGH RADIATION AREA".

13 (4) Posting of airborne radioactivity areas. A licensee or registrant shall post an air-
14 borne radioactivity area with a conspicuous sign or signs bearing the radiation symbol
15 and the words: "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIR-
16 BORNE RADIOACTIVITY AREA".

17 (5) Posting of areas or rooms in which licensed or registered material shall be used
18 or stored. A licensee or registrant shall post an area or room in which there is used or
19 stored an amount of licensed or registered material exceeding ten (10) times the quanti-
20 ty of the material specified in 902 KAR 100:030 with a conspicuous sign or signs bear-
21 ing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or
22 "DANGER, RADIOACTIVE MATERIAL(S)".

23 Section 25. Exceptions to Posting Requirements. (1) A licensee or registrant shall not

1 be required to post caution signs in areas or rooms containing sources of radiation for
2 periods of less than eight (8) hours if the following conditions are met:

3 (a) The sources of radiation are constantly attended during these periods by an indi-
4 vidual who takes the precautions necessary to prevent the exposure of individuals to
5 radiation or radioactive materials in excess of the limits established in this administrative
6 regulation; and

7 (b) The area or room are subject to the licensee's or registrant's control.

8 (2) Rooms or other areas in hospitals occupied by patients shall not be required to be
9 posted with caution signs pursuant to Section 24 of this administrative regulation if the
10 patient could be released from licensee control in accordance with 902 KAR 100:072,
11 Section 27.

12 (3) A room or area is not required to be posted with a caution sign because of the
13 presence of a sealed source if the radiation level at thirty (30) centimeters from the sur-
14 face of the source container or housing does not exceed 0.005 rem (0.05 mSv) per
15 hour.

16 (4) Rooms in hospitals or clinics that are used for teletherapy are exempt from the
17 requirement to post caution signs under Section 24 of this administrative regulation if:

- 18 1. Access to the room is controlled pursuant to 902 KAR 100:072, Section 50; and
19 2. Personnel in attendance take necessary precautions to prevent the inadvertent
20 exposure of workers, other patients, and members of the public to radiation in excess of
21 the limits established in this administrative regulation.

22 Section 26. Labeling Containers. (1) A licensee or registrant shall ensure a container
23 of licensed or registered material bears a durable, clearly visible label with the radiation

symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL".

(a) The label shall provide the following information:

1. Radionuclide present;
2. An estimate of the quantity of radioactivity;
3. Date the activity is estimated;
4. Radiation levels;
5. Kinds of materials; and
6. Mass enrichment.

(b) Information in this subsection shall permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) A licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas:

- (a) Remove or deface the radioactive material label; or
- (b) Clearly indicate the container no longer contains radioactive materials.

Section 27. Exemptions to Labeling Requirements. (1) A licensee or registrant shall not be required to label:

(a) Containers holding licensed or registered material in quantities less than the quantities listed in 902 KAR 100:030;

(b) Containers holding licensed or registered material in concentrations less than those specified in 10 C.F.R. 20, Appendix B;

(c) Containers attended by an individual who takes precautions necessary to prevent

1 the exposure of individuals in excess of the limits established by this administrative reg-
2 ulation;

3 (d) Containers if they are in transport and packaged and labeled in accordance with
4 49 C.F.R. Parts 100-180; or

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

10 (f) Installed manufacturing or process equipment, such as chemical process equip-
11 ment, piping, and tanks.

12 (2) Labeling of packages containing radioactive materials shall be required by the
13 U.S. Department of Transportation (DOT) if the amount and type of radioactive material
14 exceeds the limits for an excepted quantity or article pursuant to 49 C.F.R. 173.403 and
15 173.421-173.424.

16 Section 28. Procedures for Receiving and Opening Packages. (1) A licensee or regi-
17 strant who expects to receive a package containing quantities of radioactive material in
18 excess of a Type A quantity pursuant to 902 KAR 100:010 shall make arrangements to
19 receive:

20 (a) The package if the carrier offers it for delivery; or

21 (b) Notification of the arrival of the package at the carrier's terminal and take posses-
22 sion of the package expeditiously.

23 (2)(a) A licensee or registrant shall monitor the external surfaces of a labeled

1 package for:

2 1. Radioactive contamination unless the package contains only radioactive material
3 in the form of a gas or in special form as defined in 902 KAR 100:010; and

4 2. Radiation levels unless the package contains quantities of radioactive material that
5 are less than or equal to the Type A quantity defined in 902 KAR 100:010; and

6 (b) All packages known to contain radioactive material for radioactive contamination
7 and radiation levels if there is evidence of potential contamination such as packages
8 that are crushed, wet, or damaged.

9 (3) A licensee or registrant shall perform the monitoring required by subsection (2) of
10 this section as soon as practicable after receipt of the package, but not later than three
11 (3) hours:

12 (a) After the package is received at the licensee's facility if received during the licen-
13 see's or registrant's normal working hours; or

14 (b) From the beginning of the next working day if received after working hours.

15 (4) A licensee or registrant shall immediately notify the final delivery carrier and the
16 Manager of the Radiation Health Branch by telephone if:

17 (a) Removable radioactive surface contamination exceeds the limits of 902 KAR
18 100:070, Section 17; or

19 (b) External radiation levels exceed the limits of 902 KAR 100:070, Section 17.

20 (5) A licensee or registrant shall:

21 (a) Establish, maintain, and retain written procedures for safely opening packages in
22 which radioactive material is received; and

23 (b) Ensure that the procedures are followed and due consideration is given to special

1 instructions for the type of package being opened.

2 (6) A licensee or registrant transferring special form sources in licensee or registrant
3 owned or operated vehicles to and from a work site shall be exempt from the contami-
4 nation monitoring requirements of subsection (2) of this section, but shall not be exempt
5 from the survey requirement for measuring radiation levels that are required to ensure
6 the source shall remain properly lodged in its shield.

7 Section 29. General Provisions for Records. (1)(a) A licensee or registrant shall use
8 the units curie, rad, and rem, including multiples and subdivisions, and shall clearly indi-
9 cate the units of quantities on records required by this administrative regulation.

10 (b)1. All quantities shall be recorded as stated in paragraph (a) of this section, except
11 that the licensee may record quantities in the International System of Units (SI) in pa-
12 rentheses following each of the units specified in paragraph (a) of this section.

13 2. Information shall be recorded in SI or in SI and units as specified in paragraph (a)
14 of this section when recording information on shipment manifests, as required in 902
15 KAR 100:021, Section 9.

16 (2) A licensee or registrant shall make a clear distinction among the quantities en-
17 tered on the records required by this administrative regulation, such as:

18 (a) Total effective dose equivalent;

19 (b) Shallow-dose equivalent;

20 (c) Eye dose equivalent;

21 (d) Deep-dose equivalent; and

22 (e) Committed effective dose equivalent.

23 Section 30. Records of Radiation Protection Programs. (1) A licensee or registrant

1 shall maintain records of the radiation protection program, including:

2 (a) The provisions of the program; and

3 (b) Audits and other reviews of program content and implementation.

4 (2) A licensee or registrant shall retain records required by subsection (1)(a) of this
5 section until the cabinet terminates each pertinent license requiring the record.

6 (3) A licensee or registrant shall retain records required by subsection (1)(b) of this
7 section for at least three (3) years after the record is made.

8 Section 31. Records of Surveys. (1) A licensee or registrant shall:

9 (a) Maintain records showing the results of surveys and calibrations required by Sec-
10 tions 12 and 28(2) of this administrative regulation; and

11 (b) Retain records for at least three (3) years after the record is made.

12 (2) A licensee or registrant shall retain the following records until the cabinet termi-
13 nates the pertinent license or registration requiring the record:

14 (a) Results of surveys to determine the dose from external sources of radiation and
15 used, in the absence of or in combination with individual monitoring data, in the as-
16 sessment of individual dose equivalents;

17 (b) Results of measurements and calculations used to determine individual intakes of
18 radioactive material and used in the assessment of internal dose;

19 (c) Results of air sampling, surveys, and bioassays required pursuant to Section
20 19(1)(b)1. and 2. of this administrative regulation; and

21 (d) Results of measurements and calculations used to evaluate the release of ra-
22 dioactive effluents to the environment.

23 Section 32. Determination of Prior Occupational Dose. (1) For an individual likely to

1 receive, in a year, an occupational dose requiring monitoring under Section 13 of this
2 administrative regulation, the licensee or registrant shall:

3 (a) Determine the occupational radiation dose received during the current year; and

4 (b) Attempt to obtain the records of lifetime cumulative occupational radiation dose.

5 (2) Prior to permitting an individual to participate in a planned special exposure, a li-
6 censee or registrant shall determine:

7 (a) The internal and external doses from previous planned special exposures; and

8 (b) Doses in excess of the limits, including doses received during accidents and
9 emergencies, received during the lifetime of the individual.

10 (3) In complying with the requirements of subsection (1) of this section, a licensee or
11 registrant may:

12 (a) Accept, as a record of the occupational dose the individual received during the
13 current year, a written signed statement from the individual or from the individual's most
14 recent employer for work involving radiation exposure, that discloses the nature and
15 amount of an occupational dose the individual may have received during the current
16 year;

17 (b) Accept, as the record of lifetime cumulative radiation dose, an up-to-date NRC
18 Form 4, Cumulative Occupational Dose History, or equivalent, signed by the individual
19 and counter-signed by an:

20 1. Appropriate official of the most recent employer for work involving radiation expo-
21 sure; or

22 2. The individual's current employer if the individual is not employed by the licensee
23 or registrant; or

1 (c) Obtain reports of the individual's dose equivalent from the most recent employer
2 for work involving radiation exposure, or the individual's current employer if the individu-
3 al is not employed by the licensee or registrant, by telephone, telegram, electronic me-
4 dia, or letter. If the authenticity of the transmitted report cannot be established, a licen-
5 see or registrant shall request a written verification of the dose data.

6 (4) A licensee or registrant shall record the exposure history, as required by subsec-
7 tion (1) of this section, on NRC Form 4, Cumulative Occupational Dose History, or other
8 clear and legible record, of the information required on that form.

9 (a) The form or record shall:

10 1. Show each period the individual received occupational exposure to radiation or ra-
11 dioactive material; and

12 2. Be signed by the individual who received the exposure.

13 (b) For each period a licensee or registrant obtains reports, the licensee or registrant
14 shall use the dose shown in the report in preparing NRC Form 4, Cumulative Occupa-
15 tional Dose History.

16 (c) For a period in which a licensee or registrant does not obtain a report, the licen-
17 see shall place a notation on NRC Form 4, Cumulative Occupational Dose History, indi-
18 cating the periods of time for which data are not available.

19 (5) If a licensee is unable to obtain a complete record of an individual's current and
20 previously accumulated occupational dose, the licensee or registrant shall assume:

21 (a) In establishing administrative controls under Section 3(6) of this administrative
22 regulation for the current year, that the allowable dose limit for the individual is reduced
23 by 1.25 rems (twelve and five-tenths (12.5) mSv) for each quarter for which records

1 were unavailable and the individual was engaged in activities that may have resulted in
2 occupational radiation exposure; and

3 (b) That the individual is not available for planned special exposures.

4 (6) A licensee or registrant shall:

5 (a) Retain the records on NRC Form 4, Cumulative Occupational Dose History, or
6 equivalent, at least until the cabinet terminates the pertinent license or registration re-
7 quiring this record; and

8 (b) Retain records used in preparing NRC Form 4, Cumulative Occupational Dose
9 History, for at least three (3) years after the record is made.

10 Section 33. Records of Planned Special Exposures. (1) For each use of the provi-
11 sions of Section 7 of this administrative regulation for planned special exposures, a li-
12 censee or registrant shall maintain records that include:

13 (a) The name of the management official who authorized the planned special expo-
14 sure;

15 (b) A copy of the signed authorization; and

16 (c) Description of:

17 1. The exceptional circumstances requiring the use of a planned special exposure;

18 2. What actions were necessary;

19 3. Why the actions were necessary;

20 4. How doses were maintained ALARA;

21 5. What individual and collective doses were expected to result; and

22 6. The doses actually received in the planned special exposure.

23 (2) A licensee or registrant shall retain the records at least until the cabinet termi-

1 nates the pertinent license or registration requiring these records.

2 Section 34. Records of Individual Monitoring Results. (1) A licensee or registrant shall
3 maintain records of doses received:

4 (a) By individuals for whom monitoring was required by Section 13 of this administra-
5 tive regulation; and

6 (b) During planned special exposures, accidents, and emergency conditions.

7 (2) The recordkeeping requirements shall include, if applicable:

8 (a) Deep-dose equivalent to the whole body;

9 (b) Lens dose equivalent;

10 (c) Shallow-dose equivalent to the skin and extremities;

11 (d) Estimated intake of radionuclides;

12 (e) Committed effective dose equivalent assigned to the intake of radionuclides;

13 (f) Specific information used to calculate the committed effective dose equivalent un-
14 der Section 6(1) and (3), and Section 13 if required, of this administrative regulation;

15 (g) Total effective dose equivalent, if required by Section 4 of this administrative regu-
16 lation; and

17 (h) Total of the deep-dose equivalent and the committed dose to the organ receiving
18 the highest total dose.

19 (3) A licensee or registrant shall make entries of the records specified in subsection
20 (1) of this section at least annually.

21 (4) A licensee or registrant shall maintain the records specified in subsection (1) of
22 this section on NRC Form 5, Occupational Dose Record for a Monitoring Period, in ac-
23 cordance with the instructions for NRC Form 5, or in clear and legible records contain-

ing the information required by NRC Form 5.

(5) The records required under this section shall be protected from public disclosure because of their personal privacy nature.

(6) A licensee or registrant shall maintain the:

(a) Records of dose to an embryo or fetus with the records of dose to the declared pregnant woman; and

(b) Declaration of pregnancy on file, which may be maintained separately from the dose records.

(7) A licensee or registrant shall retain each required form or record at least until the cabinet terminates the pertinent license or registration requiring the record.

(8) Assessments of dose equivalent and records made using units in effect before a licensee's or registrant's adoption of this administrative regulation need not to be changed.

Section 35. Records of Dose to Individual Members of the Public. (1) A licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public.

(2) A licensee or registrant shall retain the records required by subsection (1) of this section at least until the cabinet terminates the pertinent license or registration requiring the record.

Section 36. Records of Testing Entry Control Devices for Very High Radiation Areas.

(1) A licensee or registrant shall maintain records of tests made under Section 16(3)(i) of this administrative regulation on entry control devices for very high radiation areas. These records shall include the date, time, and results of each test of function.

(2) A licensee or registrant shall retain the records required by subsection (1) of this section for at least three (3) years after the record is made.

Section 37. Form of Records. (1) Records required by 902 KAR Chapter 100 shall be legible throughout the specified retention period.

(2) The record shall be:

(a) The original;

(b) A reproduced copy; or

(c) A microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period.

(3) The record may be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period.

(4) Records such as letters, drawings, and specifications shall include pertinent information such as stamps, initials, and signatures.

(5) A licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

Section 38. Reports of Theft or Loss of Licensed or Registered Sources of Radiation.

(1) Telephone reports.

(a) A licensee or registrant shall report by telephone as follows:

1. Immediately after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 902 KAR 100:030 under circumstances in which it appears to the licensee or registrant that an exposure may result to

persons in unrestricted areas; or

2. Within thirty (30) days after the occurrence of lost, stolen, or missing licensed or registered material becomes known to the licensee or registrant, licensed or registered material in a quantity greater than ten (10) times the quantity pursuant to 902 KAR 100:030 still missing at this time.

(b) Reports shall be made to the cabinet.

(2) Written reports.

(a) A licensee or registrant required to make a report pursuant to subsection (1) of this section shall, within thirty (30) days after making the telephone report, make a written report setting forth the following information:

1. Description of the licensed or registered material involved, including:

a. Kind;

b. Quantity; and

c. Chemical and physical form;

2. Description of the circumstances under which the loss or theft occurred;

3. Statement of disposition, or probable disposition, of the licensed or registered material involved;

4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

5. Actions that have been or shall be taken to recover the material; and

6. Procedures or measures that have been or shall be adopted to ensure against a recurrence of the loss or theft of licensed or registered material.

1 (b) Reports shall be made to the cabinet.

2 (3) Subsequent to filing the written report, a licensee or registrant shall report addi-
3 tional substantive information on the loss or theft within thirty (30) days after the licen-
4 see or registrant learns of the information.

5 (4) A licensee or registrant shall prepare and file a report with the cabinet as required
6 by this section so that names of individuals who may have received exposure to radia-
7 tion shall be stated in a separate and detachable part of the report.

8 Section 39. Notification of Incidents. (1) Immediate notification. A licensee or regi-
9 strant shall immediately report an event involving radioactive material possessed by the
10 licensee or registrant that may have caused, or threatens to cause, one (1) or more of
11 the following conditions:

12 (a) An individual may receive:

- 13 1. A total effective dose equivalent of twenty-five (25) rems (0.25 Sv) or more;
14 2. A lens dose equivalent of seventy-five (75) rems (0.75 Sv) or more; or
15 3. A shallow-dose equivalent to the skin or extremities of 250 rads (two and five-
16 tenths (2.5) Gy) or more;

17 (b) The release of radioactive material, inside or outside of a restricted area, so that,
18 had an individual been present for twenty-four (24) hours, the individual may have re-
19 ceived an intake five (5) times the occupational annual limit on intake. The provisions of
20 this paragraph shall not apply to locations in which personnel are not normally stationed
21 during routine operations, such as in hot-cells or process enclosure;

22 (c) A loss of one (1) working week or more of the operation of facilities affected; or

23 (d) Damage to property in excess of \$200,000.

(2) Twenty-four (24) hour notification. A licensee or registrant shall, within twenty-four (24) hours of discovery of the event, report an event involving loss of control of licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or shall threaten to cause, one (1) or more of the following conditions:

(a) An individual to receive, in a period of twenty-four (24) hours:

1. A total effective dose equivalent exceeding five (5) rems (0.05 Sv);

2. A lens dose equivalent exceeding fifteen (15) rems (0.15 Sv); or

3. A shallow-dose equivalent to the skin or extremities exceeding fifty (50) rems (five-tenths (0.5) Sv);

(b) The release of radioactive material, inside or outside of a restricted area so that, had an individual been present for twenty-four (24) hours, the individual may have received an intake in excess of one (1) occupational annual limit on intake. The provisions of this paragraph shall not apply to locations in which personnel are not normally stationed during routine operations, such as in hot-cells or process enclosures;

(c) A loss of one (1) day or more of the operation of facilities affected; or

(d) Damage to property in excess of \$2,000.

(3) A licensee or registrant shall prepare and file a report with the cabinet as required by this section so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(4) Licensees or registrant shall make reports required by subsections (1) and (2) of this section to the cabinet by telephone. ~~by:~~

~~(a) Telephone;~~

~~(b) Telegram;~~

1 ~~(c) Mailgram; or~~

2 ~~(d) Facsimile.]~~

3 (5) The provisions of this section shall not include doses that result from planned
4 special exposures that are within the limits for planned special exposures, and are re-
5 ported under Section 41 of this administrative regulation.

6 Section 40. Reports of Exposures, Radiation Levels, and Concentrations of Radioac-
7 tive Material Exceeding the Limits. (1) Reportable events. In addition to the notification
8 required by Section 39 of this administrative regulation, a licensee or registrant shall
9 submit a written report within thirty (30) days after learning of one (1) or more of the fol-
10 lowing occurrences:

11 (a) An incident for which notification shall be required by Section 39 of this adminis-
12 trative regulation; or

13 (b) Doses in excess of one (1) of the following:

- 14 1. Occupational dose limits for adults in Section 3 of this administrative regulation;
15 2. Occupational dose limits for a minor in Section 8 of this administrative regulation;
16 3. Limits for an embryo or fetus of a declared pregnant woman in Section 9 of this
17 administrative regulation;
18 4. Limits for an individual member of the public in Section 10 of this administrative
19 regulation;

20 5. Applicable limit in the license or registration; or

21 6. ALARA constraints for air emissions established under Section 2(4);

22 (c) Levels of radiation or concentrations of radioactive material in:

- 23 1. A restricted area in excess of an applicable limit in the license or registration; or

2. An unrestricted area in excess of ten (10) times an applicable limit set forth in this administrative regulation, the license, or the registration, regardless of exposure of an individual in excess of the limits in Section 10 of this administrative regulation occurs; or

(d) For a person, agency, or licensee subject to the provisions of 40 C.F.R. 190, levels of radiation or releases of radioactive material in excess of those standards, or conditions related to those standards.

(2) Contents of reports.

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

1. Estimates of each individual's dose;
2. The levels of radiation and concentrations of radioactive material involved;
3. The cause of the elevated exposures, dose rates, or concentrations; and
4. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints and environmental standards, and associated license or registration conditions.

(b) A report filed under subsection (1) of this section shall include for each individual exposed:

1. Name of the individual;
2. Social Security number; and
3. Date of birth.

(c) The report shall be prepared so that information is stated in a separate and detachable part.

(d) With respect to the limit for the embryo or fetus, the identifiers shall be of the de-

1 clared pregnant woman.

2 (3) A licensee or registrant who makes a report under subsection (1) of this section
3 shall submit the report, in writing, to the Manager of the Radiation Health Branch, De-
4 partment for Health Services, 275 East Main Street, Frankfort, Kentucky
5 40621.

6 Section 41. Reports of Planned Special Exposures. (1) A licensee or registrant shall
7 submit a written report to the Manager of the Radiation Health Branch, Department for
8 Health Services, 275 East Main Street, Frankfort, Kentucky 40621, within thirty (30)
9 days following a planned special exposure conducted in accordance with Section 7 of
10 this administrative regulation.

11 (2) A licensee or registrant shall:

12 (a) Inform the Manager of the Radiation Health Branch that a planned special expo-
13 sure was conducted;

14 (b) Indicate the date the planned special exposure occurred; and

15 (c) Provide the information required by Section 33 of this administrative regulation.

16 Section 42. Reports of Individual Monitoring. (1) This section shall apply to persons
17 licensed or registered by the cabinet to:

18 (a) Possess or use sources of radiation for purposes of radiography authorized by
19 902 KAR 100:100;

20 (b) Receive radioactive waste from other persons for disposal pursuant to 902 KAR
21 100:022; or

22 (c) Possess or use, for processing or manufacturing for distribution required by 902
23 KAR 100:058, byproduct material in amounts exceeding one (1) of the following quanti-

1 ties:

	Quantity of Radionuclide ^a in curies
Cesium-137	1
Cobalt-60	1
Gold-198	100
Iodine-131	1
Iridium-192	10
Krypton-85	1,000
Promethium- 147	10
Technetium- 99m	1,000

2 ^aIf necessary, the cabinet may require as a license or registration condition, KRS
3 211.842-211.852 or 902 KAR 100:015, Section 8, reports from licensees or registrants
4 who are licensed or registered to use radionuclides not on this list, in quantities suffi-
5 cient to cause comparable radiation levels.

6 (2) A licensee or registrant in a category listed in subsection (1) of this section shall:

7 (a) Submit an annual report of the results of individual monitoring carried out by the
8 licensee for each individual for whom monitoring was required by Section 13 of this ad-
9 ministrative regulation during that year; and

10 (b) Use Form NRC 5, Occupational Dose Record for a Monitoring Period, or other
11 clear and legible record, which contains all the information required by Form NRC 5.

(3) A licensee or registrant may include additional data for individuals for whom monitoring may be provided, but not required.

(4) A licensee or registrant shall:

(a) File the report required by subsection (2) of this section covering the preceding year on or before April 30 of each year; and

(b) Submit the report to the Manager of the Radiation Health Branch, Department for Health Services, 275 East Main Street, Frankfort, Kentucky 40621.

Section 43. Protection Factors for Respirators. Protection Factors shall be determined as established in 10 C.F.R. 20, Appendix A.

Section 44. Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of radionuclides for occupational exposure, effluent concentrations, and concentrations for release to sanitary sewerage shall be determined as established in 10 C.F.R. 20, Appendix B.

Section 45. Material Incorporated by Reference. (1) The following material is incorporated by reference:

(a) "Cumulative Occupational Dose History", NRC Form 4, June 1992;

(b) "Occupational Dose Record for a Monitoring Period", NRC Form 5, June 1992; and

(c) "Commodity Specification for Air", August 2004.

(2) This material may be inspected, copied, or obtained, subject to copyright law, at the Office of the Commissioner of Public Health, 275 East Main Street, Frankfort, Kentucky 40621, 8 a.m. until 4:30 p.m., Monday through Friday.

902 KAR 100:019 Standards for Protection Against Radiation

REVIEWED:

Date

Steve Davis, MD
Acting Commissioner
Department for Public Health

APPROVED:

Date

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

A public hearing on this administrative regulation shall, if requested, be held on September 21, 2012, at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by September 14, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business October 1, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 902 KAR 100:019

Contact Person: Matt McKinley (502) 564-3700 extension 3701

(1) Provide a brief summary of:

(a) What this administrative regulation does: This regulation establishes standards for the protection against radiation.

(b) The necessity of this administrative regulation: The U.S. Nuclear Regulatory Commission has amended their regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:019 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How this administrative regulation conforms to the content of the authorizing statutes: The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: By updating the Kentucky Administrative Regulations to be consistent with the Code of Federal Regulations thereby ensuring that Kentucky licensees are bound by the same requirements as their counterparts across the country.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: It updates Calculations of Dose and Dose Equivalent, Dose limits for minors and declared pregnant women, Analysis of airborne intakes may now consider factors other than radiological factors, Numerous revisions to the requirements for the

use of respiration equipment including a new protection factor table and, Posting requirements for teletherapy rooms

(b) The necessity of the amendment to this administrative regulation: To ensure compliance with the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How the amendment conforms to the content of the authorizing statutes: See KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. This amendment conforms to that requirement by bring state regulations into conformance with federal regulations.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will bring the state regulations into compliance with federal regulations.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will assist all 430 licensees in making Kentucky Administrative Regulations consistent with the Code of Federal Regulations.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: All license holders will need to be aware of the new requirements in this regulation. However, the license holders are already familiar with them as they are in compliance with federal regulations.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): This regulation will not require any cost of compliance for the regulated entities.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The regulated entities will have consistent regulations between state and federal agencies.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional cost will be incurred as a result of amending this administrative regulation.

(b) On a continuing basis: No additional cost will be incurred as a result of amending this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: This program is operated with general funds. No additional funds will be required to implement or enforce this regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase in fees or funding will not be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This regulation does not establish any fees directly or indirectly.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 902 KAR 100:019 Contact Person: Matt McKinley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No

2. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? All units of state and local government where radioactive material is present are impacted by this regulation.

3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by this administrative regulation.

The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:019 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be

in effect. This regulation will have no effect on the expenditures or revenues of state and local governments

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No revenue will be generated the first year for state and local governments by this regulation.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenue will be generated by this regulation for state and local governments in subsequent years.

(c) How much will it cost to administer this program for the first year?
It will not cost any additional funds to administer this regulation the first year.

(d) How much will it cost to administer this program for subsequent years?
No additional costs will be incurred by the program to administer this regulation in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

Summary of Material Incorporated by Reference

902 KAR 100:019 Standards for Protection Against Radiation

Material Incorporated by Reference. (1) The following forms are incorporated by reference:

(a) NRC Form 4, "Two Cumulative Occupational Exposure History," (June 1992 edition)"; and,

(b) NRC Form 5, "Two Occupational Dose Record for a Monitoring Period," (June 1992 edition).

The number of total pages in this material is 4.

1 **CABINET FOR HEALTH AND FAMILY SERVICES**

2 **Department of Public Health**

3 **Division of Public Health Protection and Safety**

4 **(Amendment)**

5 **902 KAR 100:042. Decommissioning and financial surety.**

6 RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. 20.1401-20.1406, 30,
7 Appendices A-E, 30.35, 30.36, 40.36, 70.25, 15 U.S.C. 2B, 78m

8 STATUTORY AUTHORITY: KRS 194A.050, 211.090(3), 211.844

9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet
10 for Health and Family Services to regulate the possession or use of sources of ionizing
11 or electronic product radiation and the handling and disposal of radioactive waste. This
12 administrative regulation establishes requirements for decommissioning and financial
13 assurance of radioactive material licensees.

14 Section 1. General Provisions and Scope. (1) This administrative regulation shall ap-
15 ply to the decommissioning and financial assurance requirements of a facility licensed
16 under 902 KAR 100:040 or 100:022, as well as other facilities subject to the cabinet's
17 jurisdiction under KRS 211.842 to 211.852. For a low-level waste disposal facility li-
18 censed pursuant to~~[under]~~ 902 KAR 100:022, the criteria for decommissioning shall ap-
19 ply to only an ancillary surface facility that supports radioactive waste disposal activities.

20 (2) This administrative regulation shall not apply to a site that has:

21 (a) Been decommissioned prior to the effective date of this administrative regulation;

1 (b) Previously submitted and received cabinet approval on a license termination or
2 decommissioning plan prior to the effective date of this administrative regulation; or

3 (c) Submitted a license termination or decommissioning plan with an application, as
4 required by 902 KAR 100:040, Section 7.

5 (3) After a site has been decommissioned and the license terminated in accordance
6 with this administrative regulation, the cabinet shall require additional cleanup if, based
7 on new information, it determines that necessary criteria were not met and residual ra-
8 dioactivity at the site may result in significant threat to public health and safety.

9 (4) To calculate Total Effective Dose Equivalent (TEDE) to the average member of
10 the critical group, the licensee shall determine the peak annual TEDE dose expected
11 within the first 1,000 years after decommissioning.

12 Section 2. Radiological Criteria for Unrestricted Use. (1) A site shall be considered
13 acceptable for unrestricted use if:

14 (a) The residual radioactivity that is distinguishable from background radiation results
15 in a TEDE to an average member of the critical group that does not exceed twenty-five
16 (25) millirem (0.25 mSv) per year, including radioactivity from groundwater sources of
17 drinking water; and

18 (b) The residual radioactivity has been reduced to As Low as Reasonably Achievable
19 (ALARA) levels.

20 (2) Determination of ALARA levels shall take into account every foreseeable potential
21 detriment that may result from decontamination and waste disposal.

22 Section 3. Criteria for License Termination Under Restricted Conditions. The cabinet
23 shall terminate a license under restricted conditions if one (1) or more of the following

1 circumstances exist at the site:

2 (1) The licensee demonstrates that further reductions in residual radioactivity neces-
3 sary to comply with Section 2 of this administrative regulation:

4 (a) May result in net public or environmental harm; or

5 (b) The residual levels associated with restricted conditions are ALARA. Determina-
6 tion of ALARA levels shall take into account every foreseeable potential detriment that
7 may result from decontamination and waste disposal;

8 (2) The licensee has made provisions for legally enforceable institutional controls that
9 provide reasonable assurance that the TEDE from residual radioactivity distinguishable
10 from background to the average member of the critical group will not exceed twenty-five
11 (25) mrem (0.25 mSv) per year;

12 (3) The licensee has provided sufficient financial assurance to enable an indepen-
13 dent third party, including a governmental custodian of a site, to assume and carry out
14 responsibilities for necessary control and maintenance of the site. Acceptable financial
15 assurance mechanisms shall include:

16 (a) Funds placed into an account segregated from the licensee's assets and outside
17 the licensee's administrative control, as described in Section 15(2)(a) of this administra-
18 tive regulation;

19 (b) Surety method, insurance, or other guarantee method as described in Section
20 15(2)(b) of this administrative regulation;

21 (c) For a federal, state, or local government licensee, a statement of intent as de-
22 scribed in Section 15(2)(d) of this administrative regulation; or

23 (d) For a governmental entity assuming custody and ownership of a site, an ar-

1 rangement deemed acceptable by the governmental entity.

2 (4) The licensee has submitted a decommissioning or license termination plan to the
3 cabinet indicating the licensee's intent to decommission in accordance with Section
4 14(1) of this administrative regulation and specifying that the licensee intends to de-
5 commission by restricting use of the site. The licensee shall document in the plan how
6 the advice of potentially affected individuals and institutions in the community has been
7 sought, analyzed, and incorporated, as appropriate.

8 (a) A licensee proposing to decommission by restricting use of the site shall seek ad-
9 vice from potentially- affected parties, as follows:

10 1. If institutional controls proposed by the licensee:

11 a. Provides reasonable assurance that the TEDE from residual radioactivity distin-
12 guishable from background to the average member of the critical group will not exceed
13 twenty-five (25) mrem (0.25 mSv) TEDE per year;

14 b. Are enforceable; and

15 c. Will not impose undue burdens on the local community or other affected parties.

16 2. If the licensee has provided sufficient financial assurance to enable an indepen-
17 dent third party, including a governmental custodian of a site, to assume and carry out
18 responsibilities for necessary control and maintenance of the site;

19 (b) In seeking advice on the issues identified in paragraph (a) of this subsection, the
20 licensee shall provide for:

21 1. Participation by representatives of a broad cross section of potentially-affected
22 community interests;

23 2. An opportunity for a comprehensive, collective discussion on the issues by the par-

1 participants; and

2 3. A publicly available summary of the results of the discussions, including a descrip-
3 tion of the participants' viewpoints and the extent of agreement and disagreement
4 among the participants; and

5 (5) Residual radioactivity at the site has been reduced so that if the institutional con-
6 trols were no longer in effect, there is reasonable assurance that the TEDE from resi-
7 dual radioactivity distinguishable from background to the average member of the critical
8 group is ALARA and shall not exceed:

9 (a) 100 mrem (1 mSv) per year; or

10 (b) 500 mrem (5 mSv) per year, if the licensee:

11 1. Demonstrates that further reductions in residual radioactivity necessary to comply
12 with the value in subsection (5)(a) of this section are not technically achievable, are
13 prohibitively expensive, or may result in net public or environmental harm;

14 2. Makes provisions for durable institutional controls;

15 3. Provides sufficient financial assurance to enable a responsible government entity
16 or independent third party, including a governmental custodian of a site, to:

17 a. Carry out periodic rechecks of the site at least every five (5) years to assure that
18 the institutional controls remain in place as necessary to meet the criteria established in
19 subsection (2) of this section; and

20 b. Assume and carry out responsibilities for necessary control and maintenance of
21 the institutional controls. Acceptable financial assurance mechanisms shall be as estab-
22 lished in subsection (3) of this section.

23 Section 4. Alternate Criteria for License Termination. (1) The cabinet may terminate a

license using alternate criteria greater than the dose criterion established in Sections 2 and 3(2) or (4)(a)1a of this administrative regulation, if the licensee:

(a) Submits an analysis of possible sources of exposure in support of assurance that:

1. Public health and safety continues to be protected; and

2. It is unlikely that the dose from manmade sources combined, other than medical, are more than the 100 mrem/year (1 mSv/y) limit of 902 KAR 100:019, Section 10(1)(a);

(b) Has employed restrictions on site use, to the extent practical, according to the provisions of Section 3 of this administrative regulation;

(c) Reduces doses to ALARA levels, taking into consideration potential detriments expected to result from decontamination and waste disposal; and

(d) Has submitted a decommissioning or license termination plan to the cabinet indicating the licensee's intent to decommission in accordance with Section 14(1) of this administrative regulation, and specifying that the licensee proposes to decommission by use of alternate criteria.

1. The licensee shall document in the plan how the advice of potentially-affected individuals and institutions in the community has been sought, analyzed, and addressed, as appropriate.

2. In seeking advice, the licensee shall provide for:

a. Participation by representatives of a broad cross section of potentially-affected community interests;

b. An opportunity for a comprehensive, collective discussion on the issues by the participants; and

c. A publicly available summary of the results of discussions, including a description

1 of the participant's viewpoints and the extent of agreement and disagreement among
2 the participants.

3 (2) The use of alternate criteria to terminate a license requires the approval of the
4 cabinet, after consideration of recommendations that address comments provided by
5 state and federal agencies and public comments submitted pursuant to Section 5 of this
6 administrative regulation.

7 Section 5. Public Notification and Public Participation. Upon receipt of a license ter-
8 mination or decommissioning plan from the licensee, or a proposal by the licensee for
9 release of a site pursuant to Section 3 or 4 of this administrative regulation, or if the cab-
10 inets determines a notice to be in the public interest, the cabinet shall:

11 (1) Notify and solicit comments from:

12 (a) Local and state governments in the vicinity of the site; and

13 (b) Other state and federal agencies, if the licensee proposes to release a site pur-
14 suant to Section 4 of this administrative regulation.

15 (2) Publish a notice to solicit comments from potentially affected parties. Publication
16 shall be in a medium readily accessible to individuals in the vicinity of the site, and may
17 be:

18 (a) Local newspaper;

19 (b) Letters to state and local organizations; or

20 (c) Other appropriate media.

21 Section 6. Minimization of Contamination. An applicant for a license or for an
22 amendment in its entirety shall:

23 (1) Describe in the application how facility design and procedures for operation shall

1 minimize contamination of the facility and the environment to the extent practicable;

2 (2) Facilitate eventual decommissioning; and

3 (3) Minimize the generation of radioactive waste, to the extent practicable.

4 Section 7. Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning. (1) An applicant or licensee shall provide reasonable assurance of the availability of funds for decommissioning based upon:

8 (a) Obtaining a parent company to guarantee the availability of funds for decommissioning costs; and

10 (b) A demonstration that the parent company meets financial requirements.

11 (2) Financial test.

12 (a) To pass the financial test, the parent company shall meet one (1) of the following criteria:

14 1. The parent company shall have:

15 a. Two (2) of the following three (3) ratios:

16 (i) A ratio of total liabilities to net worth less than two (2);

17 (ii) A ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than one-tenth (0.1); or

19 (iii) A ratio of current assets to current liabilities greater than one and five-tenths (1.5);

20 b. Net working capital and tangible net worth each at least six (6) times the current decommissioning cost estimates for the total of facilities or parts of the facilities, or prescribed amount if a certification is used;

23 c. Tangible net worth of at least \$10,000,000; and

1 d. Assets located in the United States amounting to at least ninety (90) percent of the
2 total assets or at least six (6) times the current decommissioning cost estimates for the
3 total of facilities or parts of the facilities, or prescribed amount if a certification is used; or

4 2. The parent company shall have:

5 a. A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued
6 by Standard and Poor's, or AAA, AA, A, or BAA as issued by Moody's;

7 b. Tangible net worth each at least six (6) times the current decommissioning cost es-
8 timates for the total of facilities or parts of the facilities, or prescribed amount if a certifi-
9 cation is used;

10 c. Tangible net worth of at least \$10,000,000; and

11 d. Assets located in the United States amounting to at least ninety (90) percent of the
12 total assets or at least six (6) times the current decommissioning cost estimates for the
13 total of facilities or parts of the facilities, or prescribed amount if a certification is used; or

14 (b) The parent company's independent certified public accountant shall compare the
15 data used by the parent company in the financial test, which shall be derived from the
16 independently audited, year-end financial statements for the latest fiscal year, with the
17 amounts in the financial statement. The licensee shall inform the cabinet, within ninety
18 (90) days, of matters coming to the auditor's attention that cause the auditor to believe
19 that:

20 1. The data specified in the financial test requires adjustment; and

21 2. The company no longer passes the test.

22 (c)1. After the initial financial test, the parent company shall repeat the passage of the
23 test within ninety (90) days after the close of each succeeding fiscal year.

1 2. a. If the parent company no longer meets the requirements of subsection (2)(a) of
2 this section, the licensee shall notify the cabinet of its intent to establish alternate finan-
3 cial assurance.

4 b. The notice shall be sent by certified mail within ninety (90) days after the end of the
5 fiscal year for which the year-end financial data show that the parent company no longer
6 meets the financial test requirements.

7 c. The licensee shall provide alternate financial assurance within 120 days after the
8 end of a fiscal year.

9 (3) Parent company guarantee. The terms of a parent company guarantee that an
10 applicant or licensee obtains shall provide that:

11 (a) The parent company guarantee shall remain in force unless the guarantor notifies
12 the licensee and the cabinet, by certified mail, return receipt requested, of cancellation.
13 Cancellation shall not occur during the 120 days beginning on the date of receipt of the
14 notice of cancellation as evidenced by the return receipts.

15 (b) If the licensee fails to provide sufficient alternate financial assurance within ninety
16 (90) days after receipt by the licensee and cabinet of a notice of cancellation of the par-
17 ent company guarantee from the guarantor, the guarantor shall provide an alternative
18 financial assurance in the name of the licensee.

19 (c) The parent company guarantee and financial test provisions shall remain in effect
20 until the cabinet has terminated the license.

21 (d) If a trust is established for decommissioning costs, the trustee and trust shall be
22 acceptable to the cabinet. An acceptable trustee shall include an appropriate state or
23 federal government agency or an entity that has the authority to act as a trustee and

1 whose trust operations are regulated and examined by a federal or state agency.

2 Section 8. Criteria Relating to Use of Financial Tests and Self-guarantees for Provid-
3 ing Reasonable Assurance of Funds for Decommissioning. (1) An applicant or licensee
4 may provide reasonable assurance of the availability of funds for decommissioning
5 based upon:

6 (a) Furnishing its own guarantee of funds available for decommissioning costs pur-
7 suant to subsection (3) of this section; and

8 (b) A demonstration that the company passes the financial test established in sub-
9 section (2) of this section.

10 (2) Financial test.

11 (a) To pass the financial test, a company shall meet the following criteria:

12 1. Tangible net worth shall be at least ten (10) times the total current decommission-
13 ing cost estimate for the total of facilities or parts of the facilities or the current amount
14 required if certification is used.

15 2. Assets located in the United States shall amount to at least ninety (90) percent of
16 total assets or at least ten (10) times the total current decommissioning cost estimate for
17 the total of facilities or parts of the facilities or the current amount required if certification
18 is used.

19 3. A current rating for its most recent bond issuance of AAA, AA, or A as issued by
20 Standard and Poor's, or Aaa, Aa, or A as issued by Moody's.

21 (b) To pass the financial test, a company shall meet the following additional require-
22 ments:

23 1. The company shall have at least one (1) class of equity securities registered pur-

1 suant to 15 U.S.C. 2B.

2 2. The company's independent certified public accountant shall compare the data
3 used by the company in the financial test, which shall be derived from the independently
4 audited, year-end financial statements for the latest fiscal year, with the amounts in the
5 financial statement. The licensee shall inform the cabinet, within ninety (90) days, of
6 matters coming to the attention of the auditor that cause the auditor to believe that:

7 a. The data specified in the financial test requires adjustment; and

8 b. The company no longer passes the test.

9 3. After the initial financial test, the company shall repeat passage of the test within
10 ninety (90) days after the close of each succeeding fiscal year.

11 (c) If the licensee no longer meets the requirements of paragraph (a) of this subsec-
12 tion, the licensee shall notify the cabinet immediately of its intent to establish alternate
13 financial assurance within 120 days of the notice.

14 (3) Company self-guarantee. The terms of a self-guarantee that an applicant or licen-
15 see furnishes shall provide that:

16 (a) The guarantee shall remain in force unless the licensee sends notice of cancella-
17 tion by certified mail, return receipt requested, to the cabinet. Cancellation shall not oc-
18 cur during the 120 days beginning on the date of receipt of the notice of cancellation by
19 the cabinet, as evidenced by the return receipt.

20 (b) The licensee shall provide alternative financial assurance as specified in 902 KAR
21 Chapter 100 within ninety (90) days following receipt by the cabinet of a notice of can-
22 cellation of the guarantee.

23 (c) The guarantee and financial test provisions shall remain in effect until the cabinet

1 has terminated the license or until another financial assurance method acceptable to the
2 cabinet has been put into effect by the licensee.

3 (d) The licensee shall promptly forward to the cabinet and the licensee's independent
4 auditor the reports covering the latest fiscal year filed by the licensee with the Securities
5 and Exchange Commission pursuant to the requirements of 15 U.S.C. 78m.

6 (e) If the licensee's most recent bond issuance ceases to be rated "A" or above by ei-
7 ther Standard and Poor's or Moody's, the licensee shall notify to the cabinet, in writing,
8 within twenty (20) days after publication of the change by the rating service. If the licen-
9 see's most recent bond issuance ceases to be rated "A" or above by both Standard and
10 Poor's and Moody's, the licensee shall no longer meet the requirements of subsection
11 (2)(a) of this section.

12 (f) An applicant or licensee shall provide to the cabinet a written commitment by a
13 corporate officer stating that the licensee shall fund and carry out the required decom-
14 missioning activities or, upon issuance of an order by the cabinet, the licensee
15 shall set up and fund a trust in the amount of the current cost estimates for decommis-
16 sioning.

17 Section 9. Criteria Relating To Use of Financial Tests and Self-guarantee for Provid-
18 ing Reasonable Assurance of Funds for Decommissioning by Commercial Companies
19 that Have No Outstanding Rated Bonds. (1) An applicant or licensee may provide rea-
20 sonable assurance of the availability of funds for decommissioning based upon:

21 (a) Furnishing its own guarantee of the availability of funds for decommissioning
22 costs pursuant to subsection (3) of this section; and

23 (b) A demonstration that the company passes the financial test established in sub-

1 section (2) of this section.

2 (2) Financial test.

3 (a) To pass the financial test a company shall meet the following criteria:

4 1. Tangible net worth greater than \$10,000,000, or at least ten (10) times the total
5 current decommissioning cost estimate, or the current amount required if certification is
6 used, whichever is greater, for decommissioning activities for which the company is re-
7 sponsible as self-guaranteeing licensee and as parent-guarantor.

8 2. Assets located in the United States amounting to at least ninety (90) percent of to-
9 tal assets or at least ten (10) times the total current decommissioning cost estimate, or
10 the current amount required if certification is used for decommissioning activities for
11 which the company is responsible as self-guaranteeing licensee and as parent-
12 guarantor.

13 3. A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total
14 liabilities divided by net worth less than one and five-tenths (1.5).

15 (b) A company shall also meet the following financial requirements:

16 1. The company's independent certified public accountant shall compare the data
17 used by the company in the financial test, which shall be derived from the independently
18 audited year-end financial statement based on United States generally accepted ac-
19 counting practices, for the latest fiscal year with the amounts in the financial statement.
20 The licensee shall inform the cabinet within ninety (90) days of matters that cause the
21 auditor to believe that:

22 a. The data specified in the financial test requires adjustment; and

23 b. The company no longer passes the test.

1 2. After the initial financial test, the company shall repeat passage of the test within
2 ninety (90) days after the close of each succeeding fiscal year.

3 3.a. If the licensee no longer meets the requirements of paragraph (a) of this subsec-
4 tion, the licensee shall notify the cabinet of intent to establish alternative financial assur-
5 ance.

6 b. The notice shall be sent by certified mail, return receipt requested, within ninety
7 (90) days after the end of the fiscal year for which the year-end financial data show that
8 the licensee no longer meets the financial test requirements.

9 c. The licensee shall provide alternative financial assurance within 120 days after the
10 end of the fiscal year.

11 (3) Company self-guarantee. The terms of a self-guarantee which an applicant or li-
12 censee furnishes shall provide that:

13 (a) The guarantee shall remain in force unless the licensee sends notice of cancella-
14 tion by certified mail, return receipt requested, to the cabinet. Cancellation shall not oc-
15 cur until an alternative financial assurance mechanism is in place.

16 (b) The licensee shall provide alternative financial assurance, as specified in this ad-
17 ministrative regulation, within ninety (90) days following receipt by the cabinet of a no-
18 tice of cancellation of the guarantee.

19 (c) The guarantee and financial test provisions shall remain in effect until the cabinet
20 has terminated the license or until another financial assurance method acceptable to the
21 cabinet has been put into effect by the licensee.

22 (d) An applicant or licensee shall provide to the cabinet a written commitment by a
23 corporate officer stating that the licensee shall fund and carry out the required decom-

missioning activities or, upon issuance of an order by the cabinet, the licensee shall set up and fund a trust in the amount of the current cost estimates for decommissioning.

Section 10. Criteria Relating to Use of Financial Tests and Self-guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Nonprofit Colleges, Universities, and Hospitals. (1) An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based upon:

(a) Furnishing its own guarantee of the availability of funds for decommissioning costs; and

(b) A demonstration that the applicant or licensee passes the financial test established in subsection (2) of this section.

(2) Financial test.

(a) A college or university shall meet either of the following criteria:

1. For an applicant or licensee that issues bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's, or Aaa, Aa, or A as issued by Moody's.

2. For an applicant or licensee that does not issue bonds, unrestricted endowment consisting of assets located in the United States of at least \$50,000,000, or at least thirty (30) times the total current decommissioning cost estimate, or the current amount required if certification is used, whichever is greater, for decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

(b) A hospital shall meet the following criteria:

1. For an applicant or licensee that issues bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as is-

1 sued by Standard and Poor's, or Aaa, Aa, or A as issued by Moody's; or

2 2. For an applicant or licensee that does not issue bonds:

3 a. The result of total revenues minus total expenditures divided by total revenues
4 shall be equal to or greater than 0.04;

5 b. Long term debt divided by net fixed assets shall be less than or equal to 0.67;

6 c. The sum of current assets plus depreciation funds, divided by current liabilities,
7 shall be greater than or equal to 2.55; and

8 d. Operating revenues shall be at least 100 times the total current decommissioning
9 cost estimate, or the current amount required if certification is used, for decommission-
10 ing activities for which the hospital is responsible as a self-guaranteeing license.

11 (c) A licensee shall meet the following requirements:

12 1. A licensee's independent certified public accountant shall compare the data used
13 by the licensee in the financial test, which shall be derived from the independently au-
14 dited year-end financial statements, based on United States generally accepted ac-
15 counting practices, for the latest fiscal year, with the amounts in the financial statement.
16 The licensee shall inform the cabinet, within ninety (90) days, of matters coming to the
17 attention of the auditor that cause the auditor to believe that:

18 a. The data specified in the financial test requires adjustment; and

19 b. The licensee no longer passes the test.

20 2. After the initial financial test, a licensee shall repeat passage of the test within ni-
21 nety (90) days after the close of each succeeding fiscal year.

22 3. If a licensee no longer meets the requirements of subsection (1) of this section, the
23 licensee shall notify the cabinet of its intent to establish alternative financial assurance.

1 The notice shall be sent by certified mail, return receipt requested, within ninety (90)
2 days after the end of the fiscal year for which the year-end financial data show that the
3 licensee no longer meets the financial test requirements. The licensee shall provide al-
4 ternate financial assurance within 120 days after the end of the fiscal year.

5 (3) Self-guarantee. The terms of a self-guarantee that an applicant or licensee fur-
6 nishes shall provide that:

7 (a) The guarantee shall remain in force unless the licensee sends notice of cancella-
8 tion by certified mail, return receipt requested, to the cabinet. Cancellation shall not oc-
9 cur unless an alternative financial assurance mechanism is in place.

10 (b) The licensee shall provide alternative financial assurance, as specified in this ad-
11 ministrative regulation, within ninety (90) days following receipt by the cabinet of a no-
12 tice of cancellation of the guarantee.

13 (c) The guarantee and financial test provisions shall remain in effect until the cabinet
14 has terminated the license or until another financial assurance method acceptable to the
15 cabinet has been put into effect by the licensee.

16 (d) An applicant or licensee shall provide to the cabinet a written commitment by a
17 corporate officer or officer of the institution stating that the licensee shall:

- 18 1. Fund and carry out the required decommissioning activities; or
19 2. Upon issuance of an order by the cabinet, set up and fund a trust in the amount of
20 current cost estimates for decommissioning.

21 (e) If the licensee's most recent bond issuance ceases to be rated "A" or above by ei-
22 ther Standard and Poor's or Moody's, the licensee shall notify the cabinet, in writing,
23 within twenty (20) days after publication of the change by the rating service.

Section 11. Financial Assurance and Recordkeeping for Decommissioning for Radioactive Material. (1)(a) An applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities in Section 16 of this administrative regulation shall submit a decommissioning funding plan as described in Section 15(1) of this administrative regulation.

(b) A decommissioning funding plan shall also be submitted if a combination of isotopes is involved, and if R divided by 10^5 is greater than one (1) (known as the "unity rule"), where R is defined as the sum of the ratios of the quantity of an isotope to the applicable value in Section 16 of this administrative regulation.

(c) A holder of, or applicant for, a specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities in Section 16, or if a combination of isotopes is involved if R , divided by 10^{12} is greater than one (1) (known as the "unity rule"), where R is defined as the sum or the ratios of the quantity of an isotope to the applicable value in Section 16 of this administrative regulation, shall submit a decommissioning funding plan as described in Section 15(1) of this administrative regulation.

(2) An applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in subsection (4) of this section shall:

(a) Submit a decommissioning funding plan as described in Section 15(1) of this administrative regulation; or

(b) Submit a certification that financial assurance for decommissioning has been pro-

1 vided in the amount prescribed by subsection (4) of this section, using one (1) of the
2 methods described in Section 15 of this administrative regulation. For an applicant, the
3 certification may state that the appropriate assurance shall be obtained after the appli-
4 cation has been approved and the license issued, but before the receipt of licensed ma-
5 terial. If an applicant defers execution of the financial instrument until after the license
6 has been issued, a signed original of the financial instrument obtained to satisfy the re-
7 quirements of Section 15 of this administrative regulation shall be submitted to the cabi-
8 net before receipt of licensed material. If an applicant does not defer execution of the fi-
9 nancial instrument, the applicant shall submit to the cabinet, as part of the certification,
10 a signed original of the financial instrument obtained to satisfy the
11 requirements of Section 15 of this administrative regulation.

12 (3)(a) A holder of a specific license of a type described in subsection (1) or (2) of this
13 section, shall provide financial assurance for decommissioning in accordance with the
14 criteria established in this section.

15 (b) A holder of a specific license of a type described in subsection (1) of this section
16 shall submit a decommissioning funding plan as described in Section 15(1) of this ad-
17 ministrative regulation or a certification of financial assurance for decommissioning in an
18 amount at least equal to \$1,125,000 in accordance with the criteria established in this
19 section. If a licensee submits a certification of financial assurance rather than a decom-
20 missioning funding plan, the licensee shall include a decommissioning funding plan in
21 an application for license renewal.

22 (c) A holder of a specific license of a type described in subsection (2) of this section
23 shall submit a decommissioning funding plan as described in Section 15 of this adminis-

1 trative regulation, or a certification of financial assurance for decommissioning in accor-
2 dance with the criteria established in this section.

3 (d) A waste collector or waste processor, as defined in 902 KAR 100:010, shall pro-
4 vide financial assurance in an amount based on a decommissioning funding plan as de-
5 scribed in Section 15 of this administrative regulation. The decommissioning funding
6 plan shall include the cost of disposal of the maximum amount (curies) of radioactive
7 material permitted by the license, and the cost of disposal of the maximum quantity, by
8 volume, of radioactive material that could be present at the licensee's facility at any
9 time, in addition to the cost to remediate the licensee's site to meet the license termina-
10 tion criteria of 902 KAR 100:019. The decommissioning funding plan shall be submitted
11 by December 3, 2006.

12 (4) The following is a list of required amounts of financial assurance for decommis-
13 sioning, listed by quantity of radioactive material:

14 (a) Greater than 10^4 but less than or equal to 10^5 times the applicable quantities es-
15 tablished in Section 16 of this administrative regulation, in unsealed form. For a combi-
16 nation of isotopes, if R, as defined in subsection (1) of this section, divided by 10^4 is
17 greater than one (1) but R divided by 10^5 is less than or equal to one (1), the amount
18 shall be \$1,125,000.

19 (b) Greater than 10^3 but less than or equal to 10^4 times the applicable quantities es-
20 tablished in Section 16 of this administrative regulation, in unsealed form. For a combi-
21 nation of isotopes, if R, as defined in subsection (1) of this section, divided by 10^3 is
22 greater than one (1) but R divided by 10^4 is less than or equal to one (1), the amount
23 shall be \$225,000.

(c) Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities established in Section 16 of this administrative regulation, in sealed sources or plated foils. For a combination of isotopes, if R, as defined in subsection (1) of this section, divided by 10^{10} is greater than one (1), the amount shall be \$113,000.

(d)1. A licensee required to submit the \$1,125,000 amount shall do so by June 30, 2010.

2. A licensee required to submit the \$113,000 or \$225,000 amount shall do so by June 30, 2010.

3. A licensee having possession limits exceeding the upper bounds of this list shall base financial assurance on a decommissioning funding plan.

Section 12. Financial Assurance and Recordkeeping for Decommissioning for Source Material. Criteria for providing financial assurance for decommissioning, except for licenses authorizing the receipt, possession, and use of source material for uranium or thorium milling, or radioactive material at sites formerly associated with such milling, shall be as follows:

(1) An applicant for a specific license authorizing the possession and use of more than 100 millicuries (mCi) of source material in a readily dispersible form shall submit a decommissioning funding plan as described in Section 15(1) of this administrative regulation.

(2) An applicant for a specific license authorizing possession and use of quantities of source material greater than 10 millicuries (mCi) but less than or equal to 100 millicuries (mCi) in a readily dispersible form shall submit:

(a) A decommissioning funding plan as described in Section 15(1) of this administra-

1 tive regulation; or

2 (b) A certification that financial assurance for decommissioning has been provided in
3 the amount of \$225,000 using one (1) of the methods described in Section 15 of this
4 administrative regulation.

5 1. The certification may state that the appropriate assurance shall be obtained after
6 the application has been approved and the license issued, but before the receipt of li-
7 censed material.

8 2. If an applicant defers execution of the financial instrument until after the license
9 has been issued, a signed original of the financial instrument obtained to satisfy the re-
10 quirements of Section 15 of this administrative regulation shall be submitted to the cabi-
11 net prior to receipt of licensed material.

12 3. If an applicant does not defer execution of the financial instrument, the applicant
13 shall submit to the cabinet, as part of the certification, a signed original of the financial
14 instrument obtained to satisfy the requirements of Section 15 of this administrative regu-
15 lation.

16 (c)1. A holder of a specific license covered by subsection (1) of this section or by this
17 subsection, shall provide financial assurance for decommissioning in accordance with
18 the criteria established in this section.

19 2. A holder of a specific license of a type described in subsection (1) of this section
20 shall submit a decommissioning funding plan as described in Section 15(1) of this ad-
21 ministrative regulation, or a certification of financial assurance for decommissioning in
22 an amount at least equal to \$1,125,000, in accordance with the criteria in this section. If
23 the licensee submits the certification of financial assurance rather than a decommission-

ing funding plan, the licensee shall include a decommissioning funding plan in an application for license renewal.

3. A holder of a specific license of a type described in this subsection shall submit a decommissioning funding plan, as described in Section 15(1) of this administrative regulation, or a certification of financial assurance for decommissioning in accordance with the criteria established in this section.

Section 13. Financial Assurance and Recordkeeping for Decommissioning for Special Nuclear Material. (1)(a) An applicant for a specific license of the type authorizing the possession and use of unsealed nuclear material in quantities exceeding 10^5 times the applicable quantity established in Section 16 of this administrative regulation shall submit a decommissioning funding plan as described in Section 15(1) of this administrative regulation.

(b) A decommissioning funding plan shall be submitted if a combination of isotopes is involved, and if R divided by 10^5 is greater than one (1) (known as the "unity rule"), where R is the sum of the ratios of the quantity of each isotope to the applicable value in Section 16 of this administrative regulation.

(2) An applicant for a specific license authorizing possession and use of unsealed special nuclear material in quantities specified in subsection (4) of this section, shall submit:

(a) A decommissioning funding plan as described in Section 15(1) of this administrative regulation; or

(b) A certification that financial assurance for decommissioning has been provided in an amount established in subsection (4) of this section, using one (1) of the methods

described in Section 15 of this administrative regulation.

1. The certification may state that the appropriate assurance shall be obtained after the application has been approved and the license issued, but before the receipt of licensed material.

2. If an 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 Section 15 of this administrative regulation shall be submitted to the cabinet before receipt of licensed material.

3. If an applicant does not defer execution of the financial instrument, the applicant shall submit to the cabinet, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of Section 15 of this administrative regulation.

(3)(a) A holder of a specific license that is of a type described in subsection (1) of this section, shall provide financial assurance for decommissioning in accordance with the criteria established in this section.

(b) A holder of a specific license of a type described in subsection (1) of this section shall submit a decommissioning funding plan as described in Section 15(1) of this administrative regulation, or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000, in accordance with the criteria established 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 an application for license renewal.

(c) Each holder of a specific license of a type described in subsection (1) of this sec-

tion shall submit:

1. A decommissioning funding plan, described in Section 15(1) of this administrative regulation; or

2. A certification of financial assurance for decommissioning, in accordance with the criteria established in this section.

(4) The following is a table of required amounts of financial assurance for decommissioning, listed by quantity of material:

(a) Greater than 10^4 but less than or equal to 10^5 times the applicable quantities established in Section 16 of this administrative regulation. For a combination of isotopes, if R , as defined in subsection (1) of this section, divided by 10^4 is greater than one (1) but R divided by 10^5 is less than or equal to one (1), the amount shall be \$1,125,000.

(b) Greater than 10^3 but less than or equal to 10^4 times the applicable quantities established in Section 16 of this administrative regulation. For a combination of isotopes, if R , as defined in subsection (1) of this section, divided by 10^3 is greater than one (1) but R divided by 10^4 is less than or equal to one (1), the amount shall be \$225,000.

(c) A licensee having possession limits exceeding the upper bounds of this section shall base financial assurance on a decommissioning funding plan.

Section 14. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas. (1) Within sixty (60) days of the occurrence one (1) of the following events, a licensee shall notify the cabinet in writing and shall either begin decommissioning its site, separate building, or outdoor area containing residual radioactivity, so that the building or outdoor area is suitable for release in accor-

1 dance with cabinet requirements established in this administrative regulation, or shall
2 submit within twelve (12) months of notification a decommissioning plan, if required by
3 subsection (4)(a) of this section, and shall begin decommissioning upon approval of that
4 plan if:

5 (a) The license has expired pursuant to 902 KAR 100:040, Section 7;

6 (b) The licensee has decided to permanently cease principal activities, as established
7 in this section, at the entire site, in a separate building or outdoor area that contains re-
8 sidual radioactivity, so that the building or outdoor area is unsuitable for release in ac-
9 cordance with cabinet requirements established in this administrative regulation;

10 (c) Principal activities under the license have not been conducted for a period of
11 twenty-four (24) months; or

12 (d) Principal activities have not been conducted for a period of twenty-four (24)
13 months in a separate building or outdoor area that contains residual radioactivity, so
14 that the building or outdoor area is unsuitable for release in accordance with cabinet re-
15 quirements.

16 (2) Coincident with the notification required by subsection (1) of this section, the li-
17 censee shall maintain in effect all decommissioning financial assurances established by
18 the licensee pursuant to Sections 11, 12, and 13 of this administrative regulation in con-
19 junction with a license issuance or renewal or as required by this section. The amount of
20 the financial assurance shall be increased or decreased, as appropriate, to cover the
21 detailed cost estimate for decommissioning established pursuant to subsection (4)(d)5
22 of this section.

23 (a) A licensee who has not provided financial assurance to cover the detailed cost es-

1 timate submitted with the decommissioning plan shall do so within one year (1) after the
2 effective date of this administrative regulation.

3 (b) Following approval of the decommissioning plan, and with cabinet approval, a li-
4 censee may reduce the amount of the financial assurance as decommissioning
5 proceeds and radiological contamination is reduced at the site.

6 (3)(a) The cabinet may grant a request to extend the time periods established in this
7 section if the cabinet determines that an extension is not detrimental to public health or
8 safety and is in the public interest.

9 (b) The request shall be submitted at least thirty (30) days before the notification re-
10 quired by subsection (1) of this section.

11 (c) The schedule for decommissioning established in subsection (1) of this section
12 shall not commence until the cabinet has made a determination on the request.

13 (4)(a) A decommissioning plan shall be submitted if required by a license condition or
14 if the procedures and activities necessary to carry out decommissioning of the site, a
15 separate building, or outdoor area have not been approved by the cabinet previously,
16 and the decommissioning procedures may increase potential risk to the health or safety
17 of workers or to the public, as in the following cases:

18 1. Procedures involving techniques not applied routinely during cleanup or mainten-
19 ance operations;

20 2. Workers entering areas not normally occupied where surface contamination and
21 radiation levels are significantly higher than routinely encountered during operation;

22 3. Procedures potentially resulting in significantly greater airborne concentrations of
23 radioactive materials than are present during operation; or

1 4. Procedures potentially resulting in significantly greater releases of radioactive ma-
2 terial to the environment than those associated with operation.

3 (b) The cabinet may approve an alternate schedule for submittal of a decommission-
4 ing plan required pursuant to subsection (1) of this section if the cabinet determines that
5 the alternative schedule is necessary to the effective conduct of decommissioning oper-
6 ations and presents no undue risk from radiation to public health or safety, and is in the
7 public interest.

8 (c) A procedure with a potential health or safety impact, including a procedure listed
9 in paragraph (a) of this subsection, shall not be carried out prior to approval of the de-
10 commissioning plan.

11 (d) A proposed decommissioning plan for a site, separate building, or outdoor area
12 shall include:

13 1. A description of the conditions of the site, separate building, or outdoor area suffi-
14 cient to evaluate the acceptability of the plan;

15 2. A description of planned decommissioning activities;

16 3. A description of methods used to ensure protection of workers and the environ-
17 ment against radiation hazards during decommissioning;

18 4. A description of the planned final radiation survey;

19 5. An updated detailed cost estimate for decommissioning, comparison of that esti-
20 mate with present funds set aside for decommissioning, and a plan for assuring the
21 availability of adequate funds for completion of decommissioning; and

22 6. For decommissioning plans calling for completion of decommissioning later than
23 twenty-four (24) months after plan approval, a justification for the delay based on the cri-

1 teria in subsection (6) of this section.

2 (e) The proposed decommissioning plan shall be approved by the cabinet if the in-
3 formation demonstrates completion as soon as practicable and adequate protection for
4 the health and safety of workers and the public.

5 (5)(a) A licensee shall complete decommissioning of the site, separate building, or
6 outdoor area as soon as practicable, but within twenty-four (24) months following the in-
7 itiation of decommissioning, except as provided in subsection (6) of this section.

8 (b) If decommissioning involves the entire site, the licensee shall request license ter-
9 mination as soon as practicable, but within twenty-four (24) months following the initia-
10 tion of decommissioning, except as provided in subsection (6) of this section.

11 (6) The cabinet shall approve a request for an alternative schedule for completion of
12 decommissioning of the site, separate building, or outdoor area, and license termination
13 if appropriate, if the cabinet determines that the alternative is warranted by considera-
14 tion of the following:

15 (a) If it is technically feasible to complete decommissioning within the allotted twenty-
16 four (24) month period;

17 (b) If sufficient waste disposal capacity is available to allow completion of decommis-
18 sioning within the allotted twenty-four (24) month period;

19 (c) If a significant volume reduction in wastes requiring disposal can be achieved by
20 allowing short-lived radionuclides to decay;

21 (d) If a significant reduction in radiation exposure to workers can be achieved by al-
22 lowing short-lived radionuclides to decay; and

23 (e) Other site-specific factors, such as the regulatory requirements of other govern-

ment agencies, lawsuits, groundwater treatment activities, monitored natural groundwater restoration, actions that may result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(7) As the final step in decommissioning, the licensee shall:

(a) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed cabinet Form RPS-10, incorporated by reference in 902 KAR 100:040, or equivalent information; and

(b) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning established in Sections 1 through 6 of this administrative regulation. The licensee shall, as appropriate:

1. Report levels:

a. Of gamma radiation in units of microroentgen (μR) (millisieverts, mSv) per hour at one (1) meter from surfaces;

b. Of radioactivity, including alpha and beta, in units of disintegrations per minute, microcuries (megabecquerels) per 100 square centimeters removable and fixed radiation for surfaces;

c. Microcuries (megabecquerels) per milliliter for water; and

d. Picocuries (Becquerels) per gram for solids such as soils or concrete; and

2. Specify the survey instruments used and certify that each instrument is properly calibrated and tested.

(8) Specific licenses, including expired licenses, shall be terminated by written notice

1 to the licensee if the cabinet determines that:

2 (a) Radioactive material has been properly disposed of;

3 (b) Reasonable effort has been made to eliminate residual radioactive contamination,
4 if present; and

5 (c) A radiation survey has been performed that demonstrates that the premises are
6 suitable for release in accordance with the criteria for decommissioning established in
7 Sections 1 through 6 of this administrative regulation;

8 (d) Other information submitted by the licensee is sufficient to demonstrate that the
9 premises are suitable for release in accordance with the criteria for decommissioning
10 established in Sections 1 through 6 of this administrative regulation; or

11 (e) Records required by 902 KAR 100:040, Section 7(3)(e), and Section 15(3) of this
12 administrative regulation have been received.

13 Section 15. Financial Assurance Methods. (1) A decommissioning funding plan shall
14 contain a cost estimate for decommissioning and a description of the method of assur-
15 ing funds for decommissioning from subsection (2) of this section, including means for
16 adjusting cost estimates and associated funding levels periodically over the life of the
17 facility. Cost estimates shall be adjusted at intervals not to exceed three (3) years. The
18 decommissioning funding plan shall also contain:

19 (a) A certification by the licensee that financial assurance for decommissioning has
20 been provided in the amount of the cost estimate for decommissioning; and

21 (b) A signed original of the financial instrument obtained to satisfy the requirements of
22 subsection (2) of this section.

23 (2) Financial assurance for decommissioning shall be provided by one (1) or more of

1 the following methods:

2 (a) A prepayment deposited prior to the start of operation into an account segregated
3 from licensee assets and outside the licensee's administrative control of cash or liquid
4 assets so that the amount of funds may be sufficient to pay decommissioning costs.
5 Prepayment shall be in the form of a trust, escrow account, government fund, certificate
6 of deposit, or deposit of government securities.

7 (b) A surety method, insurance, or other guarantee method.

8 1. These methods guarantee that decommissioning costs shall be paid.

9 2. A surety method shall be in the form of a surety bond, letter of credit, or line of cre-
10 dit.

11 3. A parent company guarantee of funds for decommissioning costs based on a fi-
12 nancial test may be used if the guarantee and test are as contained in Section 7 of this
13 administrative regulation.

14 4. A parent company guarantee shall not be used in combination with another finan-
15 cial method to satisfy the requirements of this section.

16 5. For commercial corporations that issue bonds, a guarantee of funds by the appli-
17 cant or licensee for decommissioning costs based on a financial test may be used. If
18 used, the guarantee and test shall be in accordance with Section 8 of this administrative
19 regulation.

20 6. For commercial companies that do not issue bonds, a guarantee of funds by the
21 applicant or licensee for decommissioning costs may be used if the guarantee and test
22 are in accordance with Section 9 of this administrative regulation.

23 7. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a

1 guarantee of funds by the applicant or licensee may be used if the guarantee and test
2 are in accordance with Section 10 of this administrative regulation.

3 8. A guarantee by the applicant or licensee shall not be used in combination with
4 another financial method used to satisfy the requirements of this section, or in a situa-
5 tion in which the applicant or licensee has a parent company holding majority control of
6 the voting stock of the company.

7 9. A surety method, or insurance used to provide financial assurance for decommis-
8 sioning, shall contain the following conditions:

9 a. The surety method or insurance shall be open-ended or, if written for a specified
10 term, shall be renewed automatically unless the issuer notifies the cabinet, the benefi-
11 ciary, and the licensee at least ninety (90) days prior to the renewal date of its intention
12 not to renew. The surety method or insurance shall provide that the full face amount be
13 paid to the beneficiary automatically, prior to expiration, without proof of forfeiture, if the
14 licensee fails to provide a replacement acceptable to the cabinet within thirty (30) days
15 after receipt of notification of cancellation.

16 b. The surety method or insurance shall be payable to a trust established for decom-
17 missioning costs. The trustee and trust shall be acceptable to the cabinet. An accepta-
18 ble trustee shall include an appropriate state or federal government agency or an entity
19 that has the authority to act as a trustee, and whose trust operations are regulated and
20 examined by a federal or state agency.

21 c. The surety method or insurance shall remain in effect until the cabinet has termi-
22 nated the license.

23 (c) An external sinking fund in which deposits are made at least annually, coupled

1 with a surety method or insurance, the value of which may decrease by the amount be-
2 ing accumulated in the sinking fund.

3 1. An external sinking fund shall be a fund established and maintained by setting
4 aside funds periodically in an account segregated from licensee assets and outside the
5 licensee's administrative control, in which the total amount of funds may be sufficient to
6 pay decommissioning costs at the time termination of operation is expected.

7 2. An external sinking fund shall be in the form of a trust, escrow account, govern-
8 ment fund, certificate of deposit, or deposit of government securities.

9 3. The surety or insurance provisions shall be as stated in subsection (2)(b) of this
10 section.

11 (d) For a federal, state, or local government licensee, a statement of intent containing
12 a cost estimate for decommissioning or an amount based on the tables in Sections 11,
13 12, and 13 of this administrative regulation and indicating that funds for decommission-
14 ing shall be obtained as necessary.

15 (e) If a governmental entity is assuming custody and ownership of a site, an ar-
16 rangement that is deemed acceptable by the governmental entity.

17 (3)(a) Each person licensed pursuant to~~[under]~~ 902 KAR 100:040 shall keep records
18 of information pertinent to the decommissioning of a facility in an identified location until
19 the site is released for unrestricted use.

20 (b) Before licensed activities shall be transferred or assigned in accordance with 902
21 KAR 100:040, Section 6, a licensee shall transfer the records described in this subsec-
22 tion to the new licensee.

23 (c) The new licensee shall be responsible for maintaining these records until the li-

1 cense is terminated.

2 (d) If records pertinent to the decommissioning of a facility are kept for other purpos-
3 es, reference to the records and their locations shall be used.

4 (e) Information the cabinet considers pertinent to decommissioning shall consist of:

5 1. Records of spills or other unusual occurrences involving the spread of contamina-
6 tion in and around the facility, equipment, or site.

7 a. The records may be limited to instances in which contamination remains after a
8 cleanup procedure or if there is reasonable likelihood that contaminants may have
9 spread to inaccessible areas as in the case of possible seepage into porous materials
10 such as concrete.

11 b. The records shall include all known information on identification of involved nuc-
12 lides, quantities, forms, and concentrations.

13 2. As-built drawings and modifications of structures and equipment in restricted areas
14 where radioactive materials are used, or stored, and of locations of possible inaccessi-
15 ble contamination, such as buried pipes, which may be subject to contamination.

16 a. If required drawings are referenced, each relevant document need not be indexed
17 individually.

18 b. If drawings are not available, the licensee shall substitute appropriate records of
19 available information concerning these areas and locations.

20 3. A list contained in a single document and updated every two (2) years, except for
21 areas containing only sealed sources, provided the sources have not leaked or no con-
22 tamination remains after a leak, or radioactive materials having half-lives of less than
23 sixty-five (65) days, or depleted uranium used only for shielding or as penetrators in un-

used munitions:

a. Areas designated and formerly designated restricted areas as defined in 902 KAR 100:010, Section 1. For requirements prior to January 26, 1994, see 902 KAR 100:010, Section 1 contained in the 1990 edition of 902 KAR Chapter 100;

b. Areas outside of restricted areas that require documentation under subsection (3) of this section;

c. Areas outside of restricted areas where current and previous wastes have been buried as documented under 902 KAR 100:021, Section 11; and

d. Areas outside of restricted areas that contain material so that, if the license expired, the licensee shall be required to either decontaminate the area to meet the criteria for decommissioning in this administrative regulation or to apply for approval for disposal under 902 KAR 100:021, Section 2.

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.

Section 16. Quantities¹ of Licensed Material.

Materials	Microcuries
Americium-241	.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10

Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10

Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 9.2h	100
Europium-152 13 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100

Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10

Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molbdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100

Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10

Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Seleium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	<u>0.10</u> [0.12]
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100

Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural) ¹	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10

Tungsten-187	100
Uranium (natural) ²	100
Uranium-233	.01
Uranium-234 -- Uranium-235	.01
Vandium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
An alpha emitting radionuclide not	.01

listed above or mix- tures of alpha emit- ters of unknown composition	
A radionuclide other than an alpha emit- ting radionuclides, not listed above, or mixtures of beta emitters of unknown composition	.1

1 ¹Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

2 ²Based on alpha disintegration rate of U-238, U-234, and U-235.

3 Note: For purposes of 902 KAR 100:021, Section 3, if there is involved a combination of
4 isotopes in known amounts, the limit for the combination shall be derived as follows: De-
5 termine, for each isotope in the combination, the ratio between the quantity present in
6 the combination and the limit otherwise established for the specific isotope if not in
7 combination. The sum of such ratios for all the isotopes in the combination shall not ex-
8 ceed one ("1") ("unity").

902 KAR 100:042 Decommissioning and financial surety

REVIEWED:

Date

Steve Davis, MD
Acting Commissioner
Department for Public Health

APPROVED:

Date

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

PUBLIC HEARING AND COMMENT PERIOD

A public hearing on this administrative regulation shall, if requested, be held on September 21, 2012, at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by September 14, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business October 1, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 902 KAR 100:042

Contact Person: Matt McKinley (502) 564-3700 extension 3701

(1) Provide a brief summary of:

(a) What this administrative regulation does: This regulation is used to establish levels of radioactive material possession and use at which a licensee must set aside a specified sum of money to be used for site decommissioning. This is meant to indemnify the state in the event a licensee becomes unable or unwilling to fulfill its obligation to properly dispose of licensed radioactive material and waste. It is being amended to establish financial assurance requirements for waste collectors and processors, to define “periodically over the life of the facility” as “intervals not to exceed three (3) years with regard to adjusting cost estimates for decommissioning funding plans, and to increase monetary amounts by fifty percent (50%).

(b) The necessity of this administrative regulation: The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:042 to meet the U.S. Nuclear Regulatory Commission’s requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How this administrative regulation conforms to the content of the authorizing statutes: The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This amended regulation will adjust the financial obligation of licensees who meet the financial assurance criterion to keep pace with the increasing cost of site decommissioning requirements. It also establishes specific requirements for waste collectors and processors. This will help reduce the financial liability of the state in the event a licensee becomes unable or unwilling to fulfill its obligation to properly dispose of licensed radioactive ma-

terial and waste.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: It updates requirements in Sections 11 through 13, specifically to establish financial assurance requirements for waste collectors and processors, to define “periodically over the life of the facility” as “intervals not to exceed three (3) years with regard to adjusting cost estimates for decommissioning funding plans, and to increase monetary amounts by fifty percent (50%).

(b) The necessity of the amendment to this administrative regulation: This amendment is being promulgated so this regulation is in compliance with the U.S. Nuclear Regulatory Commission’s requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. This amendment updates requirements of license holders.

(d) How the amendment will assist in the effective administration of the statutes: This amendment is being promulgated so this regulation is in compliance with the U.S. Nuclear Regulatory Commission’s requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended, a requirement of the statutes

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation only applies to licensees who meet the financial surety criterion. Currently, only 2 licensees, Kentucky’s two major universities, have been identified as being affected. In the unlikely event either of them would decommission their radioactive materials, the general assembly would ultimately be responsible for guaranteeing the surety provisions of this regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: No action is required by the affected entities in (3) unless they go out of business and decommission their radioactive materials, in which case this regulation takes effect. They would be required to guarantee surety of the decommissioning.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): None

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): None

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional cost will be incurred as a result of amending this administrative regulation.

(b) On a continuing basis: No additional cost will be incurred as a result of amending this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No additional cost will be incurred as a result of amending this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: The administrative body will not require an increase in fees or funding to implement this amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation sets financial limits for surety. It does not establish fees directly or indirectly.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 902 KAR 100:042 Contact Person: Matt McKinley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes x ☒ No ☐

2. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? All parts of state and local government are covered by this regulation. However, only the two major Kentucky universities and the cities in which they reside are impacted as they alone meet the criteria of this regulation.

3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by this administrative regulation.

The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:042 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire depart-

ments, or school districts) for the first full year the administrative regulation is to be in effect. There is no revenue impact on state or local agencies as a result of this regulation. However there is an expenditure impact for the two state universities in that they will be required to increase their level of financial surety.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No revenue will be generated by this regulation.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenue will be generated by this regulation.

(c) How much will it cost to administer this program for the first year? No additional costs are associated with administering this program.

(d) How much will it cost to administer this program for subsequent years? No additional costs are associated with administering this program.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

1 **CABINET FOR HEALTH AND FAMILY SERVICES**

2 **Department of Public Health**

3 **Division of Public Health Protection and Safety**

4 **(Amendment)**

5 **902 KAR 100:058. Specific licenses to manufacture, assemble, repair, or distri-**
6 **bute products.**

7 RELATES TO: KRS 211.842 - 211.852, 211.990(4), 10 C.F.R. 32.11, 32.18, 32.19,
8 32.51 - 32.74, 32.101 - 32.103, 32.110, 40.34, 40.35

9 STATUTORY AUTHORITY: KRS 13B.170, 194A.050, 211.090(3), 211.844

10 NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet
11 for Health and Family Services to regulate the possession or use of sources of ionizing
12 or electronic product radiation and the handling and disposal of radioactive waste. This
13 administrative regulation establishes requirements for issuing specific licenses to per-
14 sons who manufacture, assemble, repair, or distribute commodities, products, or devic-
15 es, that contain radioactive material.

16 Section 1. Registration of Product Information. (1) A manufacturer or initial distributor
17 of a sealed source, or device containing a sealed source, whose product is intended for
18 use under a specific license, shall submit a request to the cabinet for evaluation of radi-
19 ation safety information about its product and for its registration.

20 (2) The request for review of a sealed source or device shall include sufficient
21 information to provide reasonable assurance that the radiation safety properties of the

1 source or device are adequate to protect health and minimize danger to life and property.

2 (3) The request shall include information on:

3 (a) Design;

4 (b) Manufacture;

5 (c) Prototype testing;

6 (d) Quality control program;

7 (e) Labeling;

8 (f) Proposed uses; and

9 (g) Leak testing.

10 (4) For a device, the request shall also include sufficient information about:

11 (a) Installation;

12 (b) Service and maintenance;

13 (c) Operating and safety instructions; and

14 (d) Potential hazards.

15 (5) The cabinet shall evaluate a sealed source or device using radiation safety criteria
16 in accepted industry standards. If the standards and criteria do not readily apply to a
17 particular case, the cabinet shall formulate reasonable standards and criteria, with the
18 help of the manufacturer or distributor. The cabinet shall use criteria and standards suf-
19 ficient to ensure that the radiation safety properties of the device or sealed source are
20 adequate to protect health and minimize danger to life and property.

21 (6) After completion of the evaluation, the cabinet shall issue a certificate of registra-
22 tion to the person making the request. The certificate shall acknowledge the availability
23 of the submitted information for inclusion in an application for a specific license propos-

ing use of the product.

(7) A person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(a) The statements and representations, including quality control program, contained in the request; and

(b) The provisions of the registration certificate.

Section 2. Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations. (1) In addition to the requirements established in 902 KAR Chapter 100 a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another, to be transferred to a person exempt under 902 KAR 100:045, Section 2(1)(a) shall be issued if:

(a) The applicant submits a description of the:

1. Product or material into which the radioactive material will be introduced;

2. Intended use of the radioactive material and the product or material into which it is introduced;

3. Method of introduction;

4. Initial concentration of the radioactive material in the product or material;

5. Control methods to assure that no more than the specified concentration shall be introduced into the product or material;

6. Estimated time interval between introduction and transfer of the product or material; and

7. Estimated concentrations of the radioactive material in the product or material at the time of transfer; and

(b) The applicant provides reasonable assurance that the:

1. Concentrations of the radioactive material at the time of transfer shall not exceed the concentrations established in 902 KAR 100:085;

2. Reconcentration of the radioactive material in concentrations exceeding those in 902 KAR 100:085 is not likely;

3. Use of lower concentrations is not feasible; and

4. Product or material is not likely to be incorporated in a food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) A person licensed pursuant to this administrative regulation shall:

(a) Maintain records of transfer of radioactive material;

(b) File an annual report with the cabinet that shall include the:

1. Type and quantity of a product or material into which radioactive material has been introduced during the reporting period;

2. Name and address of the person who owned or possessed the product or material into which radioactive material has been introduced at the time of introduction;

3. Type and quantity of radionuclide introduced into a product or material; and

4. Initial concentrations of the radionuclide in the product or material at the time of transfer of the radioactive material by the licensee;

(c) Indicate in the report if no transfers of radioactive material have been made during the reporting period;

(d) File a report by July 30 covering the year ending the previous June 30; and

(e) Maintain the record of a transfer for a period of one (1) year after the event is in-

cluded in a report to the cabinet.

Section 3. Resins Containing Scandium-46 and Designed for Sand-Consolidation in Oil Wells: Requirements for License to Manufacture or Initially Transfer for Sale or Distribution. An application for a specific license to manufacture or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use as indicated in 902 KAR 100:045, Section 3(3), shall be approved if:

(1) The applicant satisfies the requirements specified in 902 KAR 100:040, Section 4;

(2) The product is designed to be used only for sand-consolidation in oil wells;

(3) The applicant submits the following information:

(a) A general description of the product to be manufactured or initially transferred;

and

(b) A description of control procedures used to assure that the concentration of scandium-46 in the final product at the time of distribution shall not exceed 1.4×10^{-3} microcurie/milliliter; and

(4) A container of the product bears a durable, legible label approved by the cabinet based on the following information:

(a) The product name;

(b) A statement that the product contains radioactive scandium and is designed and manufactured only for sand-consolidation in oil wells;

(c) Instructions necessary for proper use; and

(d) The manufacturer's name.

Section 4. Licensing the Manufacture and Distribution of a Device to a Person Generally Licensed under 902 KAR 100:050. (1) In addition to the requirements established

in 902 KAR Chapter 100 an application for a specific license to distribute certain devices containing radioactive material, excluding special nuclear material, to a person generally licensed shall be issued only if the applicant submits sufficient information relating to the:

(a) Design;

(b) Manufacture;

(c) Prototype testing;

(d) Quality control;

(e) Labels;

(f) Proposed uses;

(g) Installation;

(h) Servicing;

(i) Leak testing;

(j) Operating and safety instructions; and

(k) Potential hazards of the device to provide reasonable assurance that:

1. Under accident conditions, such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that a person would receive an

external radiation dose or dose commitment in excess of the following organ doses:

a. Whole body, head and trunk, active blood-forming organs, gonads, or lens of eye - 15 rems (150 mSv);

b. Hands and forearms, feet and ankles, or localized areas of skin averaged over areas no larger than one (1) square centimeter - 200 rems (2 Sv); or

c. Other organs - 50 rems (500 mSv).

2. Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device shall not be released or inadvertently removed from the device, and it is unlikely that a person will receive in a period of one (1) calendar year a dose in excess of ten (10) percent of the limits specified in 902 KAR 100:019, Section 3; and

3. The device can be safely operated by individuals not having training in radiological protection.

(2) A device identified in subsection (1) of this section shall bear a durable, legible, clearly visible label or labels, in accordance with 902 KAR 100:050, which contain in a clearly identified and separate statement:

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

(b) The requirement, or lack of requirement, for leak testing or for testing an "on-off" mechanism and indicator, including the maximum time interval for the testing and the identification of radioactive material by:

1. Isotope;

2. Quantity of radioactivity; and

3. Date of determination of the quantity; and

(c) The information called for in the following statement, in the same or substantially similar form:

"The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of

the U.S. Nuclear Regulatory Commission or an Agreement State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

The model, serial number, and name of the manufacturer or distributor may be omitted from this label if the information is elsewhere specified in labeling affixed to the device.

(3)(a) If the applicant desires that the device identified in subsection (1) of this section be required to be tested for proper operation of the "on-off" mechanism and indicator or for leakage of radioactive material, subsequent to the initial tests required by this administrative regulation at intervals longer than six (6) months but not exceeding three (3) years, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by:

1. Performance characteristics of the device or similar devices; and
2. Design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator.

(b) In determining the acceptable interval for the test for leakage of radioactive material, the cabinet may consider information that shall include:

1. Primary containment or source capsule;
2. Protection of primary containment;
3. Method of sealing containment;
4. Containment construction materials;
5. Form of contained radioactive material;

- 1 6. Maximum temperature withstood during prototype tests;
- 2 7. Maximum pressure withstood during prototype tests;
- 3 8. Maximum quantity of contained radioactive material;
- 4 9. Radiotoxicity of contained radioactive material; and
- 5 10. Operating experience with identical devices or similarly designed and constructed
- 6 devices.

7 (4)(a) If the applicant desires authorization of the general licensee established in 902
8 KAR 100:050, Section 3, or pursuant to equivalent regulations of the U.S. Nuclear Reg-
9 ulatory Commission or an Agreement State, to install the device, collect the sample to
10 be analyzed by a specific licensee for leakage of radioactive material, service the de-
11 vice, test the "on-off" mechanism and indicator, or remove the device from installation,
12 the applicant shall include in the application:

- 13 1. Written instructions to be followed by the general licensee;
- 14 2. Estimated calendar quarter doses associated with the activity or activities; and
- 15 3. Basis for the estimates.

16 (b) The information shall demonstrate that performance of the activity by an individual
17 untrained in radiological protection, handling, storage, and use of devices under the
18 general license, is unlikely to cause that individual to receive a dose in excess of ten
19 (10) percent of the annual limits specified in 902 KAR 100:019, Section 3.

20 (5) A person licensed pursuant to this administrative regulation to distribute devices
21 to generally licensed persons shall:

22 (a) Furnish a copy of the general license identified in 902 KAR 100:050, Section 3, to
23 each person to whom the licensee, directly or through an intermediate person, transfers

1 radioactive material in a device for use as authorized by a general license;

2 (b) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory
3 Commission's or Agreement State's regulation equivalent to 902 KAR 100:050, Section
4 3, or alternatively, furnish a copy of the general license to each person to whom the li-
5 censee directly or through an intermediate person transfers radioactive material in a de-
6 vice for use pursuant to the general license of the U.S. Nuclear Regulatory Commission
7 or the Agreement State. If a copy of the general license identified in 902 KAR 100:050,
8 Section 3, is furnished to the person, it shall be accompanied by a note explaining that
9 the use of the device is regulated by the U.S. Nuclear Regulatory Commission or
10 Agreement State under requirements substantially the same as those in 902 KAR
11 100:050, Section 3;

12 (c) Report to the cabinet transfers of the devices to persons for use under the general
13 license.

14 1. The report shall identify:

15 a. A general licensee by name and address;

16 b. An individual by name or position who may constitute a point of contact between
17 the cabinet and the general licensee;

18 c. The type and model number of device transferred; and

19 d. The quantity and type of radioactive material contained in the device.

20 2. If one (1) or more intermediate persons possess the device temporarily at the in-
21 tended place of use prior to its possession by the user, the report shall include identifi-
22 cation of each intermediate person by name, address, contact, and relationship to the
23 intended user.

1 3. If no transfers have been made to persons generally licensed during the reporting
2 period, the report shall so indicate.

3 4. The report shall cover a calendar quarter and shall be filed within thirty (30) days of
4 the close of the quarter.

5 (d) Furnish reports to other agencies as follows:

6 1. Report to the U.S. Nuclear Regulatory Commission transfers of such devices to
7 persons for use under the U.S. Nuclear Regulatory Commission general license in Sec-
8 tion 31.5 of 10 C.F.R. Part 31; or

9 2. Report to the responsible state agency transfers of devices manufactured and dis-
10 tributed for use under a general license in that state's regulations equivalent to 902 KAR
11 100:050, Section 3; and

12 3. The reports shall identify:

13 a. A general licensee by name and address;

14 b. An individual by name or position who may constitute a point of contact between
15 the agency and the general licensee;

16 c. The type and model of the device transferred; and

17 d. The quantity and type of radioactive material contained in the device.

18 4. If one (1) or more intermediate persons possess the device temporarily at the in-
19 tended place of use prior to its possession by the user, the report shall include identifi-
20 cation of each intermediate person by name, address, contact, and relationship to the
21 intended user;

22 5. The report shall be submitted within thirty (30) days after the end of the calendar
23 quarter in which the device is transferred to the generally licensed person;

6. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission; and

7. If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency;

(e) Keep records showing the name, address, and the point of contact for a general licensee to which the licensee, directly or through an intermediate person, transfers radioactive material in devices for use as authorized by a general license or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall show:

1. The date of transfer;

2. The radionuclide and the quantity of radioactivity in each device transferred;

3. The identity of the intermediate person; and

4. Compliance with the report requirements; and

(f) Maintain the records required by paragraphs (c) and (d) of this subsection for a period of five (5) years from the date of the recorded transfer.

Section 5. Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed pursuant to 902 KAR 100:050 shall be approved if:

(1) The applicant satisfies the requirements specified in 902 KAR 100:040, Section 4;

1 and

2 (2) The applicant satisfies the requirements of U.S. Nuclear Regulatory Commission
3 10 C.F.R. Part 32, Sections 32.2(b), 32.53, 32.54, 32.55, 32.56, 32.101, and 32.110 or
4 their equivalent.

5 Section 6. Special Requirements for License to Manufacture and Distribute Calibra-
6 tion Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to
7 Persons Generally Licensed pursuant to 902 KAR 100:050. An application for a specific
8 license to manufacture or distribute calibration and reference sources containing ameri-
9 cium-241, plutonium or radium-226 to persons generally licensed pursuant to 902 KAR
10 100:050 shall be approved if:

11 (1) The applicant satisfies the requirements established in 902 KAR 100:040, Section
12 4; and

13 (2) The applicant satisfies the requirements of U.S. Nuclear Regulatory Commission
14 10 C.F.R. Part 32, Sections 32.57, 32.58, 32.59, and 32.102, and 10 C.F.R. Part 70,
15 Section 70.39, or their equivalent.

16 Section 7. Licensing the Manufacture and Distribution of Ice Detection Devices Con-
17 taining Strontium-90. An application for a specific license to manufacture and
18 distribute ice detection devices to persons generally licensed shall be approved if:

19 (1) The applicant satisfies the requirements established in 902 KAR 100:040, Section
20 4; and

21 (2) The criteria of U.S. Nuclear Regulatory Commission 10 C.F.R. Part 32, Sections
22 32.2(b), 32.61, 32.62, 32.103, and 32.110 are met.

23 Section 8. Manufacture and Distribution of Radioactive Material for Certain In Vitro

Clinical or Laboratory Testing under a General License. An application for a specific license to manufacture or distribute radioactive material for use pursuant to the general license established in 902 KAR 100:050, Section 4, shall be approved if:

(1) The applicant satisfies the general requirements specified in 902 KAR 100:040, Section 4;

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) Iodine-125 in units not exceeding ten (10) microcuries (370 kBq) each;

(b) Iodine-131 in units not exceeding ten (10) microcuries (370 kBq) each;

(c) Carbon-14 in units not exceeding ten (10) microcuries (370 kBq) each;

(d) Hydrogen-3 (tritium) in units not exceeding fifty (50) microcuries (1.85 MBq) each;

(e) Iron-59 in units not exceeding twenty (20) microcuries (704 kBq) each;

(f) Selenium-75 in units not exceeding ten (10) microcuries (370 kBq) each;

(g) Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 MBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or

(h) Cobalt-57 in units not exceeding fifty (50) microcuries (370 kBq) each;

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed:

1. Ten (10) microcuries (370 kBq) of iodine-131, iodine-125, selenium-75, cobalt-57, or carbon-14;

2. Fifty (50) microcuries (1.85 MBq) of hydrogen-3 (tritium);

3. Twenty (20) microcuries (740 kBq) of iron-59; or

4. Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129

1 and 0.005 microcurie (185 Bq) of americium-241 each; and

2 (b) Displaying the radiation caution symbol described in 902 KAR 100:019, Section
3 23, and the words, "Caution, Radioactive Material" and "Not for Internal or External Use
4 in Humans or Animals";

5 (4) The following statement, or a substantially similar statement which contains the
6 information called for in the following statement, appears on a label affixed to a pre-
7 packaged unit, or appears in a leaflet or brochure which accompanies the package:

8 "This radioactive material may be received, acquired, possessed, and used only by
9 physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or
10 laboratory tests not involving internal or external administration of the material, or the
11 radiation therefrom, to human beings or animals. Its receipt, acquisition, possession,
12 use, and transfer are subject to the administrative regulations and a general license or
13 the equivalent of the United States Nuclear Commission or of an Agreement State.

14 (Name of Manufacturer)"; and

15 (5) The label affixed to the unit, or the leaflet or brochure that accompanies the pack-
16 age, contains adequate information regarding precautions to be observed in handling
17 and storing the radioactive material. For a mock iodine-125 reference or calibration
18 source, the information accompanying the source shall contain directions to the licensee
19 regarding the waste disposal requirements established in 902 KAR 100:021, Section 1.

20 Section 9. Manufacture and Distribution of Radiopharmaceuticals Containing Ra-
21 dioactive Material for Medical Use Under Specific Licenses. (1) An application for a
22 specific license to manufacture, prepare or transfer for commercial distribution radio-
23 pharmaceuticals containing radioactive material for use by persons licensed pursuant to

902 KAR 100:072, shall be approved if the applicant:

(a) Satisfies the requirements specified in 902 KAR 100:040, Section 4;

(b) Submits evidence that the applicant is at least one (1) of the following:

1. Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

2. Registered or licensed with a state agency as a drug manufacturer;

3. Licensed as a pharmacy by the State Board of Pharmacy; or

4. Operating as a nuclear pharmacy within the federal medical institution.

(c) Submits information on:

1. The radionuclide;

2. Chemical and physical form;

3. Maximum activity per vial, syringe, generator, or other container of the radioactive drug; and

4. Shielding provided by the packaging of the radioactive material to show it is appropriate for safe handling and storage of radiopharmaceuticals by medical use licensees; and

(d) Satisfies the following labeling requirements:

1. The label shall be affixed to the transport radiation shield, if it is constructed of lead, glass, plastic, or other material of a radioactive drug to be transferred for commercial distribution. The label shall include:

a. The radiation symbol;

b. The words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL";

1 c. The name of the radioactive drug or its abbreviation; and
2 d. The quantity of radioactivity at a specified date and time. For radioactive drugs with
3 a half life greater than 100 days, the time may be omitted.

4 2. A label shall be affixed to a syringe, vial, or other container used to hold a radioac-
5 tive drug to be transferred for commercial distribution. The label shall include:

6 a. The radiation symbol;
7 b. The words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE
8 MATERIAL" and

9 c. An identifier that ensures the syringe, vial, or other container can be correlated with
10 the information on the transport radiation shield label.

11 (2) A licensee described by subsection (1)(b)3 or 4 of this section may:

12 (a) Prepare radioactive drugs for medical use, as defined in 902 KAR 100:010, if the
13 radioactive drug is prepared by an authorized nuclear pharmacist, as specified in para-
14 graphs (b) and (c) of this subsection, or an individual under the supervision of an
15 authorized nuclear pharmacist, as specified in 902 KAR 100:072, Section 12;

16 (b) Allow a pharmacist to work as an authorized nuclear pharmacist if the individual:

17 1. Qualifies as an authorized nuclear pharmacist as defined in 902 KAR 100:010;
18 2. Meets the requirements specified in 902 KAR 100:072, Sections 63 and 66, and
19 the licensee has received an approved license amendment identifying the individual as
20 an authorized nuclear pharmacist; or

21 3. Is designated as an authorized nuclear pharmacist in accordance with paragraph
22 (c) of this subsection.

23 (c) Designate a pharmacist as an authorized nuclear pharmacist if the individual is

1 identified as an authorized user on a nuclear pharmacy license issued by the cabinet.

2 (3) The actions authorized in subsections (2)(a) and (b) of this section are permitted
3 in spite of more restrictive language in license conditions.

4 (4) A licensee shall provide to the cabinet a copy of an individual's certification by the
5 Board of Pharmaceutical Specialties, the cabinet, the U.S. Nuclear Regulatory Commis-
6 sion, or an agreement state license, and a copy of the state pharmacy licensure or reg-
7 istration, no later than thirty (30) days after the date that the licensee allows the individ-
8 ual to work as an authorized nuclear pharmacist, pursuant to subsection (2)(b)1 and 3
9 of this section.

10 (5) A licensee shall:

11 (a) Possess and use instrumentation to measure the radioactivity of radioactive
12 drugs;

13 (b) Have procedures for use of the instrumentation;

14 (c) Measure, by direct measurement or by combination of measurements and calcu-
15 lations, the amount of radioactivity in dosages of alpha-, beta- or photon-emitting ra-
16 dioactive drugs prior to transfer for commercial distribution;

17 (d) Perform accuracy, linearity, and geometry dependence tests on an instrument be-
18 fore initial use, periodically, and following repair, as appropriate for the instrument, and
19 make necessary adjustments; and

20 (e) Check an instrument for constancy and proper operation at the beginning of each
21 day of use.

22 (6) Nothing in this section relieves a licensee from complying with applicable FDA,
23 other federal, and state requirements governing radioactive drugs.

Section 10. Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed as authorized by 902 KAR 100:072 for use as a calibration, transmission, or reference source or for medical uses listed in 902 KAR 100:072, Sections 37, 45 and 46 shall be approved if:

(1) The applicant satisfies the requirements established in 902 KAR 100:040, Section 4;

(2) The applicant submits sufficient information regarding a type of source or device pertinent to an evaluation of its radiation safety, including:

(a) The radioactive material contained, its chemical and physical form, and amount;

(b) Details of design and construction of the source or device;

(c) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(d) For devices containing radioactive material, the radiation profile of a prototype device;

(e) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(f) Procedures and standards for calibrating sources and devices;

(g) Legend and methods for labeling sources and devices as to their radioactive content; and

(h) Instructions for handling and storing the source or device from the radiation safety

standpoint. The instructions shall be included on a durable label attached to the source or device, or attached to a permanent storage container for the source or device. Instructions too lengthy for a label may be summarized on the label and printed in detail on a brochure referenced on the label;

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains:

(a) Information on the radionuclide;

(b) Quantity; and

Date of assay; and

(d) A statement that the name of source or device is licensed by the cabinet for distribution to persons licensed as authorized by 902 KAR 100:072, or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State;

(4) If an applicant desires the source or device to be tested for leakage of radioactive material at intervals longer than six (6) months, he shall include in the application sufficient information to demonstrate that the longer interval is justified by:

(a) Performance characteristics of the source or device, or similar sources or devices; and

(b) Design features having a significant bearing on the probability or consequence of leakage of radioactive material from the source; and

(5) In determining the acceptable interval for tests of leakage of radioactive material, the cabinet shall consider information that includes:

(a) Primary containment or source capsule;

(b) Protection of primary containment;

- 1 (c) Method of sealing containment;
- 2 (d) Containment construction materials;
- 3 (e) Form of contained radioactive material;
- 4 (f) Maximum temperature withstood during prototype tests;
- 5 (g) Maximum pressure withstood during prototype tests;
- 6 (h) Maximum quantity of contained radioactive material;
- 7 (i) Radiotoxicity of contained radioactive material; and
- 8 (j) Operating experience with identical sources or devices, or similarly designed and
- 9 constructed sources or devices.

10 Section 11. Requirements for License to Manufacture and Distribute Industrial Prod-
11 ucts Containing Depleted Uranium for Mass-volume Applications. (1) An application for
12 a specific license to manufacture or distribute an industrial product or device containing
13 depleted uranium for use authorized by 902 KAR 100:050, Section 2, or equivalent reg-
14 ulations of the U.S. Nuclear Regulatory Commission or an Agreement State shall be
15 approved if:

16 (a) The applicant satisfies the general requirements specified in 902 KAR 100:040,
17 Section 4;

18 (b) The applicant submits sufficient information relating to the:

- 19 1. Design;
- 20 2. Manufacture;
- 21 3. Prototype testing;
- 22 4. Quality control procedures;
- 23 5. Labeling or marking;

1 6. Proposed uses; and

2 7. Potential hazards of the industrial product or device;

3 (c) The applicant provides reasonable assurance that possession, use, or transfer of
4 the depleted uranium in the product or device is not likely to cause an individual to re-
5 ceive in a period of one (1) year a radiation dose in excess of ten (10) percent of the
6 limits specified in 902 KAR 100:019, Section 3; and

7 (d) The applicant submits sufficient information regarding the industrial product or de-
8 vice, and the presence of depleted uranium for a mass-volume application in the prod-
9 uct or device, to provide reasonable assurance that unique benefits will accrue to the
10 public because of the usefulness of the product or device.

11 (2) For an industrial product or device that is unique benefits are questionable, the
12 cabinet may approve an application for a specific license pursuant to this section only if
13 the product or device is found to combine a high degree of utility and low probability of
14 uncontrolled disposal and dispersal of significant quantities of depleted uranium into the
15 environment.

16 (3) The cabinet shall deny an application for a specific license pursuant to this section
17 if the end use of the industrial product or device cannot reasonably be foreseen.

18 (4) A person licensed as authorized by this section shall:

19 (a) Maintain the level of quality control required by the license in:

20 1. Manufacture of the industrial product or device; and

21 2. Installation of the depleted uranium into the product or device;

22 (b) Label or mark each unit to identify:

23 1. The manufacturer of the product or device;

2. The number of the license under which the product or device was manufactured or distributed;

3. The fact that the product or device contains depleted uranium;

4. The quantity of depleted uranium in the product or device; and

5. That the receipt, possession, use, or transfer of the product or device is subject to a general license, or the equivalent, and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;

(c) Assure that the depleted uranium, before being installed in a product or device, has been impressed with the legend "DEPLETED URANIUM" clearly legible through plating or other covering;

(d) Furnish a copy of the general license contained in:

1. 902 KAR 100:050 to a person to whom depleted uranium is transferred in a product or device for use authorized by the general license; or

2. The U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 902 KAR 100:050, and a copy of an applicable U.S. Nuclear Regulatory Commission's or Agreement State's certificate, to a person to whom depleted uranium is transferred in a product or device for use as authorized by the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 902 KAR 100:050;

(e) Furnish the following to either the cabinet, U.S. Nuclear Regulatory Commission, or agreement state:

1 1. A report of each transfer of an industrial product or device to a person for use pur-
2 suant to the general license in 902 KAR 100:050. The report shall identify:

- 3 a. A general licensee by name and address;
- 4 b. An individual, by name or position, who constitutes a point of contact between the
5 cabinet and the general licensee;
- 6 c. The type and model number of device transferred; and
- 7 d. The quantity of depleted uranium contained in the product or device.

8 2. The report identified in subparagraph 1 of this paragraph shall be submitted within
9 thirty (30) days after the end of a calendar quarter in which the product or device is
10 transferred to the generally licensed person. If no transfers have been made to persons
11 generally licensed pursuant to 902 KAR 100:050 during the reporting period, the report
12 shall so indicate; and

13 (f) Keep records showing the name, address, and point of contact for a general licen-
14 see to whom he transfers depleted uranium in an industrial product or device for use au-
15 thorized by the general license provided in 902 KAR 100:050 or equivalent regulations
16 of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall
17 be maintained for a period of three (3) years from the date of transfer and shall show
18 the date of each transfer, the quantity of depleted uranium in a product or device trans-
19 ferred, and compliance with the report requirements of this section.

20 Section 12. Licensing the Distribution of Naturally Occurring and Accelerator Pro-
21 duced Radioactive Material (NARM) in Exempt Quantities. (1) An application for a spe-
22 cific license to distribute NARM to persons exempted from these regulations authorized
23 by 902 KAR 100:045 shall be approved if:

1 (a) The radioactive material is not contained in a food, beverage, cosmetic, drug, or
2 other commodity designed for ingestion or inhalation by, or application to, a human be-
3 ing;

4 (b) The radioactive material is in the form of processed chemical elements, com-
5 pounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or
6 encapsulated sources, or similar substances, identified as radioactive and to be used
7 for its radioactive properties, but is not incorporated into a manufactured or assembled
8 commodity, product, or device intended for commercial distribution; and

9 (c) The applicant submits copies of prototype labels and brochures in accordance
10 with 10 C.F.R. 32.18 and 32.19 and the cabinet approves the labels and brochures.

11 (2) The license issued pursuant to this section is subject to the following conditions:

12 (a) No more than ten (10) exempt quantities shall be sold or transferred in a single
13 transaction. However, an exempt quantity may be composed of fractional parts of one
14 (1) or more of the exempt quantity, if the sum of the fractions does not exceed unity.

15 (b) An exempt quantity shall be packaged separately and individually. No more than
16 ten (10) packaged exempt quantities shall be contained in an outer package for transfer
17 to persons exempt as authorized by 902 KAR 100:045. The dose rate at the external
18 surface of the outer package shall not exceed five-tenths (0.5) millirem per hour.

19 (c) The immediate container of each quantity or separately packaged fractional quan-
20 tity of radioactive material shall bear a durable, legible label which:

- 21 1. Identifies the radionuclide and the quantity of radioactivity; and
- 22 2. Bears the words "Radioactive Material."

23 (d) In addition to the labeling information required by this subsection, the label affixed

to the immediate container, or an accompanying brochure, shall:

1. State that the contents are exempt from licensing agency requirements;

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

3. Establish appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(3)(a) A person licensed pursuant to this section shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use in accordance with 902 KAR 100:045 or the equivalent regulations of a licensing agency, and stating the kinds and quantities of radioactive material transferred.

(b) An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the cabinet.

(c) A report shall cover the year ending June 30 and shall be filed within thirty (30) days after June 30. If no transfers of radioactive material have been made, as authorized by this section, during the reporting period, the report shall so indicate.

Section 13. Licensing the Incorporation of Naturally Occurring and Accelerator Produced Radioactive Material (NARM) into Gas and Aerosol Detectors. (1) An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt pursuant to 902 KAR 100:045 shall be approved if the application satisfies requirements equivalent to those contained in U.S. Nuclear Regulatory Commission 10 C.F.R. Part 32.26.

- 1 (2) The maximum quantity of radium-226 in a device shall not exceed one-tenth (0.1)
- 2 microcurie (3.7 kBq).

902 KAR 100:058 Specific licenses to manufacture, assemble, repair, or distribute products

REVIEWED:

Date

Steve Davis, MD
Acting Commissioner
Department for Public Health

APPROVED:

Date

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

A public hearing on this administrative regulation shall, if requested, be held on September 21, 2012, at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by September 14, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business October 1, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 902 KAR 100:058

Contact Person: Matt McKinley (502) 564-3700 extension 3701

(1) Provide a brief summary of:

(a) What this administrative regulation does: In 2005, 902 KAR 100:073 was superseded by 902 KAR 100:072 and was subsequently repealed. This regulation is being amended to update the previous 902 KAR 100:073 references to 902 KAR 100:072 references.

(b) The necessity of this administrative regulation: The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:058 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How this administrative regulation conforms to the content of the authorizing statutes: The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: It will update sections of other regulations by reference with the correct reference.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: It updates references in section 9 and 10 and corrects the spelling of a word in section 4.

(b) The necessity of the amendment to this administrative regulation: To ensure compliance with the U.S. Nuclear Regulatory Commission's requirements of

Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended. This specific amendment is to bring the regulation into compliance with existing state regulations by reference.

(c) How the amendment conforms to the content of the authorizing statutes:

KRS 211.842(2) authorizes the Cabinet for Health and Family Services to issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. This amendment updates the regulations that govern those licenses.

(d) How the amendment will assist in the effective administration of the statutes:

The amendment corrects the references to an existing regulation, thus making administration of the regulation accurate.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: There are 10 nuclear pharmacies and 2 distributors of industrial gauges licensed by the Kentucky Radiation Health Branch who actively conduct business in Kentucky and would be impacted by this regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: No action is required by the regulated entities. The regulation is correcting a reference to a known requirement.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No cost is required by the regulated entities. The regulation is correcting a reference to a known requirement.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The entities will have a correct regulation to refer to.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional cost will be incurred as a result of amending this administrative regulation.

(b) On a continuing basis: No additional cost will be incurred as a result of amending this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforce-

ment of this administrative regulation: No additional cost will be incurred as a result of amending this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase in fees or funding will not be necessary to implement this regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This regulation does not establish directly or indirectly any fees.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 902 KAR 100:058 Contact Person: Matt McKinley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No

2. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? ALL
3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by this administrative regulation.

The U.S. Nuclear Regulatory Commission has amended their regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:058 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. .

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not impact expenditures or revenues of state or local agencies

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not impact expenditures or revenues of state or local agencies

(c) How much will it cost to administer this program for the first year? There will be no cost to implement this regulation.

(d) How much will it cost to administer this program for subsequent years? There will be no cost to implement this regulation.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

1 **CABINET FOR HEALTH AND FAMILY SERVICES**

2 **Department of Public Health**

3 **Division of Public Health Protection and Safety**

4 **(Amendment)**

5 **902 KAR 100:070. Transportation of radioactive material.**

6 RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. 71, 39 C.F.R. 111.1, 49
7 C.F.R. 170-189

8 STATUTORY AUTHORITY: KRS 13B.170, 194A.050, 211.090(3), 211.844

9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet
10 for Health and Family Services to provide by administrative regulation for the registra-
11 tion and licensing of the possession or use of sources of ionizing or electronic product
12 radiation and the handling and disposal of radioactive waste. This administrative regula-
13 tion establishes requirements for transportation of radioactive material.

14 Section 1. Applicability. (1) Applies to a licensee authorized by a specific or general
15 license issued by the cabinet to receive, possess, use, or transfer radioactive material,
16 when:

17 (a) The licensee delivers that material to a carrier for transport;

18 (b) Transports the material outside the site of usage as specified in the cabinet li-
19 cense; or

20 (c) Transports the material on public highways.

21 (2) No provision of this administrative regulation authorizes the possession of ra-

1 dioactive material.

2 Section 2. Requirement for a License. A person shall not deliver radioactive material
3 to a carrier for transport, or transport radioactive material, unless:

4 (1) Authorized in a general or specific license issued by the cabinet; or

5 (2) Exempted pursuant to Section 3 of this administrative regulation.

6 Section 3. Exemptions. (1) A licensee is exempt from all the requirements of this ad-
7 ministrative regulation with respect to shipment or carriage of the following low-level ma-
8 terials:

9 (a) Natural material and ores containing naturally occurring radionuclides that are not
10 intended to be processed for use of these radionuclides, provided the activity concentra-
11 tion of the material does not exceed ten (10) times the values specified in 10 C.F.R. 71,
12 Appendix A; and

13 (b) Materials for which the activity concentration is not greater than the activity con-
14 centration values, or for which the consignment activity is not greater than the limit for
15 an exempt consignment found in 10 C.F.R. 71, Appendix A.

16 (2) ~~[A licensee shall be exempt from requirements in this administrative regulation,~~
17 ~~except for Sections 4 and 12 of this administrative regulation, with respect to shipment~~
18 ~~or carriage of the following packages, provided the packages do not contain fissile ma-~~
19 ~~terial, or the material is exempt from classification as fissile material under Section 14;~~

20 ~~(a) A package that contains no more than a Type A quantity of radioactive material;~~

21 ~~(b) A package transported within the United States that contains no more than twenty~~
22 ~~(20) Curies (0.74 TBq) of special form plutonium-244; or~~

23 ~~(c) The package contains only LSA or SCO radioactive material, provided:~~

1 ~~1. The LSA or SCO material has an external radiation dose of less than or equal to~~
2 ~~one (1) rem/hour (10 mSv/hour), at a distance of three (3) meters from the unshielded~~
3 ~~material; or~~

4 ~~2. The package contains only LSA-1 or SCO-1 material.~~

5 (3)] A physician licensed by the Commonwealth to dispense drugs in the practice of
6 medicine shall be exempt from Section 4 of this administrative regulation with respect to
7 transport by the physician of radioactive material for use in the practice of medicine.
8 However, a physician operating under this exemption shall be licensed pursuant to 902
9 KAR 100:072 or equivalent regulations of the NRC or an agreement state.

10 Section 4. Transportation of Licensed Material. (1) Each [A] licensee who transports
11 licensed material outside of the confines of his plant or other place of use specified in
12 the cabinet license, or if transport is ~~[who transports]~~ on a public highway, or who deliv-
13 ers licensed material to a carrier for transport, shall:

14 (a) Comply with the applicable requirements, appropriate to the mode of transport, of
15 the regulations of the U.S. Department of Transportation in 49 C.F.R. 107, 171 through
16 180 ~~[489]~~, and 390 through 397; and

17 (b) Assure that special instructions needed to open the package safely are sent to, or
18 have been made available to, the consignee for the consignee's use in accordance with
19 902 KAR 100:019, Section 28(5).

20 (2) If the regulations of the U.S. Department of Transportation (DOT) are not applica-
21 ble to a shipment of licensed material, the licensee shall conform to the standards and
22 requirements of the Department of Transportation regulations, specified in subsection
23 (1)(a) of this section, to the same extent as if the shipment was subject to the DOT

1 regulations.

2 Section 5. General Licenses for Carriers. (1) A general license shall be issued to a
3 common or contract carrier, not exempt under Section 3 of this administrative regula-
4 tion, to receive, possess, transport, and store radioactive material in the regular course
5 of carriage for another, or storage incident to the transportation and storage, if the
6 transportation and storage is in accordance with the applicable requirements, appropri-
7 ate to the mode of transport, of the U.S. Department of Transportation relating to the
8 loading and storage of packages, placarding of the transporting vehicle, and incident
9 reporting.

10 (2) A general license shall be issued to a private carrier to transport radioactive ma-
11 terial, if the transportation is in accordance with the applicable requirements, appropri-
12 ate to the mode of transport, of the U.S. Department of Transportation relating to the
13 loading and storage of packages, placarding of the transporting vehicle, and incident
14 reporting.

15 (3) The notification of incidents referred to in the U.S. Department of Transportation
16 requirements identified in subsection (1) of this section shall be filed with, or made to,
17 the cabinet.

18 (4) A person authorized by a general license described in this section, who transports
19 radioactive material, is exempt from the requirements of 902 KAR 100:019 and 902
20 KAR 100:165.

21 Section 6. General License: NRC Approved Packages. (1) A general license shall be
22 issued to a licensee of the cabinet to transport or to deliver to a carrier for transport, li-
23 censed material in a package for which a license, certificate of compliance (CoC), or

1 other approval has been issued by the NRC.

2 (2) The general license shall apply only to a licensee who:

3 (a) Has a quality assurance program approved by the NRC as satisfying the provi-
4 sions of 10 C.F.R. 71.101 through 137;

5 (b) Has a copy of the certificate of compliance, or other approval of the package, and
6 has the drawings and other documents referenced in the approval relating to the use
7 and maintenance of the packaging and to the actions to be taken prior to shipment;

8 (c) Complies with the terms and conditions of the license, certificate, or other approv-
9 al, as applicable, and the applicable requirements of this administrative regulation and
10 10 C.F.R. 71.0 through 71.11, 71.81 through 71.100, and 71.101 through 71.137; and

11 (d) Submits in writing to Document Control Desk, Director, Spent Fuel Project Office,
12 Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commis-
13 sion, Washington, DC 20555-0001, using an appropriate method listed in 10 C.F.R.
14 71.1(a), before the licensee's first use of the package, the licensee's name and license
15 number and the package identification number specified in the package approval.

16 (3) The general license identified in subsection (1) of this section shall apply only if
17 the package approval authorizes use of the package under the general license.

18 (4) For a Type B or fissile material package, the design of which was approved by the
19 NRC before April 1, 1996, the general license shall be subject to additional restrictions
20 contained in Section 7 of this administrative regulation.

21 Section 7. Previously Approved Type B Packages. (1) A Type B package previously
22 approved by the NRC, but not designated as B(U) or B(M) in the NRC Certificate of
23 Compliance, may be used under the general license of Section 6 of this administrative

1 regulation, with the following limitations:

2 (a) Fabrication of the packaging was satisfactorily completed before August 31, 1986,
3 as demonstrated by its model number, in accordance with NRC regulations;

4 (b) The package shall not be used for a shipment to a location outside the United
5 States after August 31, 1986, except under multilateral approval by the U.S. Department
6 of Transportation, as defined in 49 C.F.R. 173.403; and

7 (2) A serial number that uniquely identifies each package that conforms to the ap-
8 proved design is assigned to, and legibly and durably marked on, the outside of each
9 package.

10 (3) A Type B(U) package, a Type B(M) package, an LSA material package, or a fis-
11 sile material package, previously approved by the NRC but without the designation "-85"
12 in the identification number of the NRC Certificate of Compliance, may be used under
13 the general license of Section 6 of this administrative regulation, with the following con-
14 ditions:

15 (a) Fabrication of the package shall have been satisfactorily completed by April 1,
16 1999, as demonstrated by its model number, in accordance with NRC regulations, 10
17 C.F.R.;

18 (b) A package used for shipment to a location outside the United States shall be sub-
19 ject to multilateral approval by the U.S. Department of Transportation, as defined in 49
20 C.F.R. 173.403; and

21 (c) A serial number that uniquely identifies each package that conforms to the ap-
22 proved design shall be assigned to, and legibly and durably marked on the outside of,
23 each package.

1 Section 8. General License: DOT Specification Container. (1) A general license shall
2 be issued to a licensee of the cabinet to transport, or to deliver to a carrier for transport,
3 licensed material in a specification container for fissile material, or for a Type B quantity
4 of radioactive material, as specified in 49 C.F.R. Parts 173 and 178.

5 (2) The general license shall apply only to a licensee who:

6 (a) Has a quality assurance program approved by the cabinet as satisfying the re-
7 quirements of 10 C.F.R. 71.101 through 71.137;

8 (b) Has a copy of the specification; and

9 (c) Complies with the terms and conditions of the specification, and the applicable re-
10 quirements of this administrative regulation and 10 C.F.R. 71.0 through 71.11, 71.81
11 through 71.100, and 71.101 through 71.137.

12 (3) The general license shall be subject to the limitation that the specification con-
13 tainer shall not be used for a shipment to a location outside the United States except by
14 multilateral approval, as defined in 49 C.F.R. 173.403.

15 (4) This section expires October 1, 2008.

16 Section 9. General License: Use of Foreign Approved Package. (1)(a) A general li-
17 cense shall be issued to a licensee of the cabinet to transport, or to deliver to a carrier
18 for transport, licensed material in a package, the design of which has been approved in
19 a foreign national competent authority certificate and revalidated by the U.S. Depart-
20 ment of Transportation as meeting the applicable requirements of 49 C.F.R. 171.12.

21 (b) Except as provided in this section, the general license shall apply only to a licen-
22 see who has a quality assurance program approved by the NRC as satisfying the
23 applicable provisions of 10 C.F.R. 71.101 through 71.137.

(2) The general license shall apply only to shipments made to or from locations outside the United States.

(3) The general license shall apply to a licensee who:

(a) Has copies of the applicable certificate, the revalidation, the drawings, and other documents referenced in the certificate relating to the:

1. Use and maintenance of the packaging; and

2. Actions to be taken prior to shipment; and

(b) Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of this administrative regulation and 10 C.F.R. 71.0 through 71.11, 71.81 through 71.100, and 71.101 through 71.137.

(4) With respect to the quality assurance provisions of 10 C.F.R. 71.101 through 71.137, the licensee shall be exempt from design, construction, and fabrication considerations.

Section 10. Preliminary Determinations. Before the first use of a packaging for the shipment of radioactive material:

(1) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that may significantly reduce the effectiveness of the packaging;

(2) If the maximum normal operating pressure will exceed thirty-five (35) kilopascal (five (5) lbf/in²) gauge, the licensee shall test the containment system at an internal pressure at least fifty (50) percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure; and

(3) The licensee shall mark the packaging, conspicuously and durably, with its model

number, serial number, gross weight, and a package identification number assigned by the NRC, in accordance with 10 C.F.R. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the NRC.

Section 11. Routine Determinations. Before making a shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this administrative regulation and of the license. The licensee shall determine that:

(1) The package is proper for the contents to be shipped;

(2) The package is in unimpaired physical condition except for superficial defects, such as marks or dents;

(3) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(4) A system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(5) A pressure relief device is operable and set in accordance with written procedures;

(6) The package has been loaded and closed in accordance with written procedures;

(7) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(8) A 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 design requirements specified by 10 C.F.R. 71.45.

(9) The level of nonfixed, or removable, radioactive contamination on the external surfaces of each package offered for shipment is ALARA, and within the limits specified by the U.S. Department of Transportation in 49 C.F.R. 173.443;

(10) External radiation levels around the package and around the vehicle, if applicable, shall not exceed the limits specified in 49 C.F.R. 71.47 during transportation.

(11) Accessible package surface temperatures shall not exceed the limits specified in 10 C.F.R. 71.43(g) at any time during transportation.

Section 12. Air Transport of Plutonium. In addition to the requirements of a general license and exemptions stated in this administrative regulation or included by citation of U.S. Department of Transportation regulations, 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:

(1) The plutonium is contained in a medical device designed for individual human application;

(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 10 C.F.R. 71, Appendix A and in which the radioactivity is essentially uniformly distributed;

(3) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in an isotope or form and is shipped in accordance with Section 4 of this administrative regulation;

(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; or

(5) For a shipment of plutonium by air which is subject to subsection (4) of this sec-

tion, the licensee shall, through special arrangement with the carrier, require compliance with 49 C.F.R. 175.704, applicable to the air transport of plutonium;

(6) Nothing in this section shall be interpreted as removing or diminishing the requirements of 10 C.F.R. 73.24.

Section 13. Advance Notification of Transport of Irradiated Reactor Fuel and Nuclear Waste. (1)(a) Before the transport of nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or before the delivery of nuclear waste to a carrier for transport, a licensee shall provide advance notification of the transport to the governor, or governor's designee, of each state through which the waste will be transported.

(b) Advance notification shall be required for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements in 10 C.F.R. 73.37(f).

(2) Advance notification shall also be required for licensed material, other than irradiated fuel, if:

(a) The nuclear waste is required to be in Type B packaging for transportation;

(b) The nuclear waste is being transported to, through, or across a state boundary to a disposal site, or to a collection point for transport to a disposal site; and

(c) The quantity of licensed material in a single package exceeds the least of the following:

1. 3,000 times the A_1 value of the radionuclides as specified in 10 C.F.R. 71, Appendix A for special form radioactive material;

2. 3,000 times the A_2 value of the radionuclides as specified in 10 C.F.R. 71 Appen-

dix A for normal form radioactive material; or

3. 27,000 curies (1000 TBq).

(3) Each advance notification shall be in writing and contain the following information:

(a) The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

(b) A description of the nuclear waste contained in the shipment as required by 49 C.F.R. 172.202 and 172.203(d);

(c) The point of origin of the shipment and the seven (7) day period during which departure of the shipment is estimated to occur;

(d) The seven (7) day period during which arrival of the shipment at state boundaries is estimated to occur;

(e) The destination of the shipment, and the seven (7) day period during which arrival of the shipment is estimated to occur; and

(f) A point of contact with a telephone number for current shipment information.

(4) The notification shall be made in writing to the office of each appropriate governor or governor's designee and to the cabinet.

(a) A notification delivered by mail shall be postmarked at least seven (7) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.

(b) A notification delivered by messenger shall reach the office of the governor, or governor's designee, at least four (4) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for three (3) years.

(5) The licensee who finds that schedule information previously furnished will not be met, shall telephone a responsible individual in the office of the governor, or governor's designee and the cabinet and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain for three (3) years a record of the name of the individual contacted.

(6) A licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the cabinet. The licensee shall state in the notice that it is a cancellation and shall identify the advance notification that is being cancelled. A copy of the notice shall be retained by the licensee for three (3) years.

Section 14. Exemption from Classification as Fissile Material. Fissile material meeting the requirements of at least one (1) of the subsections (1) through (6) of this section are exempt from classification as fissile material and from the fissile material package standards of 10 C.F.R. 71.55 and 71.59, but are subject to all other requirements of this administrative regulation, except as noted.

(1) Individual package containing two (2) grams or less fissile material;

(2) Individual or bulk packaging containing fifteen (15) grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass for solid nonfissile material;

(3)(a) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

1 1. There is at least 2000 grams of solid nonfissile material for every gram of fissile
2 material; and

3 2. There is no more than 180 grams of fissile material distributed within 360 kilo-
4 grams of contiguous nonfissile material.

5 (b) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may
6 be present in the package but shall not be included in determining the required mass of
7 solid nonfissile material.

8 (4) Uranium enriched in uranium-235 to a maximum of one (1) percent by weight, and
9 with total plutonium and uranium content of up to one (1) percent of the mass of ura-
10 nium-235, provided that the mass of any beryllium, graphite, and hydrogenous material
11 enriched in deuterium constitutes less than five (5) percent of the uranium mass;

12 (5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two (2)
13 percent by mass, with a total plutonium and uranium-233 content not exceeding two
14 one-thousands (0.002) percent of the mass of uranium, and with a minimum nitrogen to
15 uranium atomic ratio (N/U) of two (2). The material shall be contained in at least a DOT
16 Type A package.

17 (6) Packages containing, individually, a total plutonium mass of not more than 1,000
18 grams, of which not more than twenty (20) percent by mass may consist of plutonium-
19 239, plutonium-241, or any combination of these radionuclides.

20 Section 15. General License: Fissile Material (1) A general license is issued to any
21 licensee of the cabinet to transport fissile material, or to deliver fissile material to a car-
22 rier for transport, if the material is shipped in accordance with this section of this admin-
23 istration regulation. The fissile material need not be contained in a package which

meets the standards of 10 C.F.R. 71.41 through 71.65 and 71.71 through 71.77, however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of 49 C.F.R. 173.417(a).

(2) The general license shall apply only to a licensee who has a quality assurance program approved by the U.S. Nuclear Regulatory Commission as satisfying the provisions of 10 C.F.R. 71.101 through 71.137.

(3) The general license shall apply only when a package's contents:

(a) Contain less than a Type A quantity of radioactive material; and

(b) Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(4) The general license shall apply only to packages containing fissile material that are labeled with a Criticality Safety Index (CSI) that:

(a) Has been determined in accordance with subsection (5) of this section;

(b) Has a value less than or equal to ten (10); and

(c) For a shipment of multiple packages containing fissile material, the sum of the CSIs shall be less than or equal to fifty (50), for shipment on a nonexclusive use conveyance, and less than or equal to 100, for shipment on an exclusive use conveyance.

(5)(a) The value for the CSI shall be greater than or equal to the number calculated by the following equation:

$$\left(\frac{\text{grams of U-235}}{X} \pm \frac{\text{grams of U-233}}{Y} \pm \frac{\text{grams of Pu}}{Z} \right)$$

CSI = 10

(b) The calculated CSI shall be rounded up to the first decimal place;

(c) The values of X, Y, and Z used in the CSI equation shall be taken from 10 C.F.R. Tables 71 – 1 or 71 – 2[~~71 Appendix A, Table A-1 or A-2~~], as appropriate;

(d) If 10 C.F.R. Table 71 - 2[~~Table A-2~~] is used to obtain the value of X, then the values of the terms in the equation for uranium-233 and plutonium shall be assumed to be zero (0); and

(e) 10 C.F.R. Table 71 – 1[~~Table A-4~~] values for X, Y, and X shall be used to determine the CSI if:

1. Uranium-233 is present in the package;
2. The mass of plutonium exceeds one (1) percent of the mass of uranium-235;
3. The uranium is of unknown uranium-235 enrichment or greater than twenty-four (24) percent enrichment; or
4. Substances having a moderating effectiveness (an average hydrogen density greater than water), such as, certain hydrocarbons oils or plastics, are present in any form, except as polyethylene used for packaging or wrapping.

Section 16. General License: Plutonium-beryllium Special Form Material. (1) A general license is issued to any licensee of the cabinet 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 of this administrative regulation. This material need not be contained in a package which meets the standards of 10 C.F.R. 71.41 through 71.65 and 71.71 through 71.77, however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of 49 C.F.R. 173.417(a).

(2) The general license shall apply only to a licensee who has a quality assurance program approved by the U.S. Nuclear Regulatory Commission as satisfying the provisions of 10 C.F.R. 71 Subpart H.

(3) The general licensee applies only if a package's contents:

(a) Contain less than a Type A quantity of radioactive material; and

(b) Contain less than 1000 grams of plutonium, provided that plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 grams of the total quantity of plutonium in the package.

(4) The general license applies only to packages labeled with a CSI that:

(a) Have been determined in accordance with subsection (5) of this section;

(b) Have a value less than or equal to 100; and

(c) For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs shall be less than or equal to fifty (50), for shipment on a nonexclusive use conveyance and less than or equal to 100, for shipment on an exclusive use conveyance.

(5)(a) The value for the CSI shall be greater than or equal to the number calculated by the following equation:

$$\left(\frac{\text{Grams of Pu-239} + \text{grams of Pu-241}}{24} \right)$$

CSI = 10 and:

(b) The calculated CSI shall be rounded up to the first decimal place.

Section 17. External Radiation Standards for all Packages. (1) Except as provided in subsection (2) of this section, a package of radioactive materials offered for transporta-

tion shall be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level shall not exceed 200 millirem/hour (mrem/h) (2 milliserviets/h) (2 mSv/h) at any point on the external surface of the package, and the transport index shall not exceed ten (10).

(2) A package that exceeds the radiation level limits specified in subsection (1) of this section shall be transported by exclusive use shipment only, and the radiation levels for the shipment shall not exceed the following during transportation:

(a) 200 mrem/h (2 mSv/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 1000 mrem/h (10 mSv/h);

1. The shipment is made in a closed transport vehicle;

2. The package is secured within the vehicle so that its position remains fixed during transportation; and

3. There are no loading or unloading operations between the beginning and end of the transportation;

(b) 200 mrem/h (2 mSv/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle, or in 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

(c) 1. Ten (10) mrem/h (0.1 mSv/h) at any point eighty (80) inches (2 meters) from the outer lateral surface of the vehicle, excluding the top and underside of the vehicle; or

2. In the case of a flat-bed style vehicle, at any point six and six tenths (6.6) feet (2 meters) from the vertical planes projected by the outer edges of the vehicle, excluding

1 the top and underside of vehicle; and

2 (d) Two (2) mrem/h (0.02 mSv/h) in any normally occupied space, except that this
3 provision shall not apply to private carriers, if exposed personnel under their control
4 wear radiation dosimetry devices as required by 902 KAR 100:019, Section 13.

5 (3) For shipments made under the provisions of subsection (2) of this section, the
6 shipper shall provide specific written instructions to the carrier for maintenance of the
7 exclusive use shipment controls. The instructions shall be included with the shipping
8 paper information.

9 (4) The written instructions required for exclusive use shipments shall be sufficient so
10 that, when followed, they will cause the carrier to avoid actions that will unnecessarily
11 delay delivery or unnecessarily result in increased radiation levels or radiation exposure
12 to transport workers or members of the general public.

13 Section 18. Assumption as to Unknown Properties. If the isotopic abundance, mass,
14 concentration, degree of moderation, or other pertinent property of fissile material in any
15 package is not known, the licensee shall package the fissile material as if the unknown
16 properties have credible values that will cause the maximum neutron multiplication.

17 Section 19. Opening Instructions. Before delivery of a package to a carrier for trans-
18 port, the licensee shall ensure that any special instructions needed to safely open the
19 package have been sent to, or otherwise made available to, the consignee for the con-
20 signee's use in accordance with 902 KAR 100:019, Section 28(5).

21 Section 20. Quality Assurance Requirements. (1) The requirements in Sections 20
22 through 28 shall apply to design, purchase, fabrication, handling, shipping, storing,
23 cleaning, assembly, inspection, testing, operation, maintenance, repair, and modifica-

tion of components of packaging important to safety. As used in this administrative regulation, quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service.

(2) 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.

(3) 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.

(4) A licensee is responsible for the quality assurance provision that applies to its use of a packaging for the shipment of licensed material subject to this administrative regulation.

(5) A licensee, certificate holder, and applicant for a CoC shall:

1. Establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 10 C.F.R. 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging; and

2. Execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(6) A licensee shall, before the use of a package for the shipment of licensed material subject to this administrative regulation, obtain U.S. Nuclear Regulatory Commission approval of its quality assurance program. Using an appropriate method listed in 10

1 C.F.R. 71.1(a), a licensee shall file a description of its quality assurance program, in-
2 cluding a discussion of which requirements of this administrative regulation are applica-
3 ble and how they will be satisfied, by submitting the description to: Attention: Document
4 Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and
5 Safeguards.

6 (7) A program for transport container inspection and maintenance limited to radio-
7 graphic exposure devices, source changers, or packages transporting these devices
8 and meeting the requirements of 902 KAR 100:100, Section 9(3) is deemed to satisfy
9 the requirements of Section 6(2)(a) and subsection (5) of this section.

10 Section 21. Quality Assurance Organization. (1) The licensee, certificate holder, and
11 applicant for a Certificate of Compliance (CoC) shall be responsible for the establish-
12 ment and execution of the quality assurance program. The licensee, certificate holder,
13 and applicant for a CoC may delegate to others, such as contractors, agents, or consul-
14 tants, the work of establishing and executing the quality assurance program, or any part
15 of the quality assurance program, but shall retain responsibility for the program. These
16 activities include performing the functions associated with attaining quality objectives
17 and the quality assurance functions.

18 (2) The quality assurance functions are:

19 (a) Assuring an appropriate quality assurance program is established and effectively
20 executed; and

21 (b) Verifying, by procedures such as checking, auditing, and inspection, that activities
22 affecting the functions that are important to safety have been correctly performed.

23 (3) The persons and organizations performing quality assurance functions shall have

1 sufficient authority and organizational freedom to:

2 (a) Identify quality problems;

3 (b) Initiate, recommend, or provide solutions; and

4 (c) Verify implementation of solutions.

5 (4) While the term "licensee" is used, the requirements in this section shall be appli-
6 cable to whatever design, fabrication, assembly, and testing of the package is accom-
7 plished with respect to a package before the time a package approval is issued.

8 Section 22. Quality Assurance Program. (1) The licensee, certificate holder, and ap-
9 plicant for a Certificate of Compliance (CoC) shall establish, at the earliest practicable
10 time consistent with the schedule for accomplishing the activities, a quality assurance
11 program that complies with the requirements of 10 C.F.R. 71.101 through 71.137. The
12 licensee, certificate holder, and applicant for a CoC shall document the quality assur-
13 ance program by written procedures or instructions and shall carry out the program in
14 accordance with those procedures throughout the period during which the packaging is
15 used. The licensee, certificate holder, and applicant for a CoC shall identify the material
16 and components to be covered by the quality assurance program, the major organiza-
17 tions participating in the program and the designated functions of these organizations.

18 (2) The licensee, certificate holder, and applicant for a CoC, through its quality assur-
19 ance program, shall provide control over activities affecting the quality of the identified
20 materials and components to an extent consistent with their importance to safety, and
21 as necessary to assure conformance to the approved design of each individual package
22 used for the shipment of radioactive material. The licensee, certificate holder, and appli-
23 cant for a CoC shall assure that activities affecting quality are accomplished under suit-

ably 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. 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.

(3) The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following conditions concerning the complexity and proposed use of the package and its components:

- (a) The impact of malfunction or failure of the item to safety;
- (b) The design and fabrication complexity or uniqueness of the item;
- (c) The need for special controls and surveillance over processes and equipment;
- (d) The degree to which functional compliance can be demonstrated by inspection or test; and
- (e) The quality history and degree of standardization of the item.

(4) The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary, to assure that suitable proficiency is achieved and maintained.

(5) The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

1 Section 23. Handling, Storage, and Shipping Control. The licensee, certificate holder,
2 and applicant for a CoC shall establish measures to control, in accordance with instruc-
3 tions, the handling, storage, shipping, cleaning, and preservation of materials and
4 equipment to be used in packaging to prevent damage or deterioration. If necessary for
5 particular products, special protective environments, such as inert gas atmosphere, and
6 specific moisture content and temperature levels shall be specified and provided.

7 Section 24. Inspection, Test and Operating Status. (1) The licensee, certificate hold-
8 er, and applicant for a CoC shall establish measures to indicate, by the use of markings
9 such as stamps, tags, labels, routing cards, or other suitable means, the status of in-
10 spections and tests performed upon individual items of the packaging. These measures
11 shall provide for the identification of items that have satisfactorily passed required in-
12 spections and tests, where necessary to preclude inadvertent by passing of the inspec-
13 tions and tests.

14 (2) The licensee shall establish measures to identify the operating status of compo-
15 nents of the packaging, such as tagging valves and switches, to prevent inadvertent op-
16 eration.

17 Section 25. Nonconforming Materials, Parts, or Components. The licensee, certificate
18 holder, and applicant for a CoC shall establish measures to control materials, parts, or
19 components that do not conform to the licensee's requirements to prevent their inadver-
20 tent use or installation. These measures shall include, as appropriate, procedures for
21 identification, documentation, segregation, disposition, and notification to affected or-
22 ganizations. Nonconforming items shall be reviewed and accepted, rejected, repaired,
23 or reworked in accordance with documented procedures.

1 Section 26. Corrective Action. The licensee, certificate holder, and applicant for a
2 CoC shall establish measures to assure that conditions adverse to quality, such as defi-
3 ciencies, deviations, defective material and equipment, and nonconformances, are
4 promptly identified and corrected. In the case of a significant condition adverse to quali-
5 ty, the measures shall assure that the cause of the condition is determined and correc-
6 tive action taken to preclude repetition. The identification of the significant condition ad-
7 verse to quality, the cause of the condition, and the corrective action taken shall be do-
8 cumented and reported to appropriate levels of management.

9 Section 27. Quality Assurance Records. (1) The licensee, certificate holder, and ap-
10 plicant for a CoC shall maintain sufficient written records to describe the activities affect-
11 ing quality. The records shall include the instructions, procedures, and drawings re-
12 quired by 10 C.F.R. 71.111 to prescribe quality assurance activities and shall include
13 closely related specifications such as required qualifications of personnel, procedures,
14 and equipment.

15 (2) The records shall include the instructions or procedures that establish a records
16 retention program that is consistent with applicable regulations and designates factors
17 such as duration, location, and assigned responsibility.

18 (3) The licensee, certificate holder, and applicant for a CoC shall retain these records
19 for three (3) years beyond the date when the licensee, certificate holder, applicant for a
20 CoC last engage in the activity for which the quality assurance program was developed.
21 If any portion of the written procedures or instructions is superseded, the licensee, cer-
22 tificate holder, and applicant for CoC shall retain the superseded material for three (3)
23 years after it is superseded.

1 Section 28. Audits. (1) The licensee, certificate holder, and applicant for a CoC shall
2 carry out a comprehensive system of planned and periodic audits to verify compliance
3 with all aspects of the quality assurance program and to determine the effectiveness of
4 the program.

5 (2) The audits shall be performed in accordance with written procedures or checklists
6 by appropriately trained personnel not having direct responsibilities in the areas being
7 audited.

8 (3) Audited records shall be documented and reviewed by management having re-
9 sponsibility in the area audited.

10 (4) Follow-up action, including reaudit of deficient areas, shall be taken as indicated.

11 Section 29. Determination of A_1 and A_2 . (1) Values of A_1 and A_2 shall be determined
12 as described in 10 C.F.R. 71 Appendix A.

902 KAR 100:070 Transportation of radioactive material.

REVIEWED:

Date

Steve Davis, MD
Acting Commissioner
Department for Public Health

APPROVED:

Date

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

A public hearing of this administrative regulation shall, if requested, be held on September 21, 2012, at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by September 14, 2012, five (5) work-days prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business October 1, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502/564-7905, Fax: 502/564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 902 KAR 100:070

Contact Person: Matt McKinley (502) 564-3700 extension 3701

(1) Provide a brief summary of:

(a) What this administrative regulation does: This regulation establishes guidelines for the use of radionuclides in the health arts.

(b) The necessity of this administrative regulation: The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:070 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How this administrative regulation conforms to the content of the authorizing statutes: The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KAR 194A.030, 194A:050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

(d) How this administrative radiation currently assists or will assist in the effective administration of the statutes: By updating the Kentucky Administrative Regulations to be consistent with the Code of Federal Regulations thereby ensuring that Kentucky licensees are bound by the same requirements as their counterparts across the country.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: It updates 902 KAR 100:070 to add exemptions for naturally occurring material in certain activity concentrations, create Quality Assurance (QA) program requirements for the use of Nuclear Regulatory Commission approved packages, expands on requirements for transportation of fissile material, updates requirements for ex-

tensive QA programs for manufacturers of transport packages and removes A1/A2 table and adds reference to 10 C.F.R. 71 Appendix A.

(b) The necessity of the amendment to this administrative regulation: This will ensure compliance with the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How the amendment conforms to the content of the authorizing statutes: The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. That authority includes ensuring compliance with federal regulations.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will create conformance with federal regulations. This will ensure compliance is uniform between the two regulating bodies.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will assist all 430 radioactive material licensees by making Kentucky Administrative Regulations consistent with the Code of Federal Regulations.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Knowledge of its compliance with federal regulations is all that is required. Because radioactive material licensees must currently conform to federal regulations. This amendment will not require additional action.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No cost associated with uniformity of compliance.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The 430 radioactive material licensees will have the benefit of uniformity of compliance between state and federal regulations.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional cost will be incurred as a result of amending this administrative regulation.

(b) On a continuing basis: No additional cost will be incurred as a result of amending this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No additional cost will be required to implement this regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change if it is an amendment: An increase in fees or funding will not be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: No fees directly or indirectly increased as a result of this regulation.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 902 KAR 100:070

Contact Person: Matt McKinley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No

2. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? All that have a radioactive licensee in it.
3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by this administrative regulation.

The U.S. Nuclear Regulatory Commission has amended their regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:070 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

The statutory authority for the promulgation of an administrative regulation related to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. No local expenditure or revenue will be impacted by this regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts)

for the first year? No revenue will be generated for state or local governments by this regulation.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenue will be generated for state or local governments by this regulation.

(c) How much will it cost to administer this program for the first year? No additional cost will be incurred to administer this program the first year.

(d) How much will it cost to administer this program for subsequent years? No additional cost will be incurred to administer this program in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 DEPARTMENT FOR PUBLIC HEALTH

3 PUBLIC HEALTH PROTECTION AND SAFETY

4 RADIATION HEALTH BRANCH

5 902 KAR 100:072. Use of radionuclides in the health arts.

6 RELATES TO: KRS 211.842 to 211.852, 211.990(4), 10 C.F.R. 35, 45 C.F.R. 46

7 STATUTORY AUTHORITY: KRS 194A.050, 211.090, 211.844, 10 C.F.R. 35

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet for
9 Health and Family Services to promulgate administrative regulations for the registration
10 and licensing of the possession or use of sources of ionizing or electronic product
11 radiation and the handling and disposal of radioactive waste. This administrative
12 regulation establishes requirements and provisions for the use of radioactive material in
13 the healing arts, for issuance of licenses authorizing the medical use of radioactive
14 material and for specific licensees to possess, use, and transfer radioactive material for
15 medical uses.

16 Section 1. Implementation. (1) A licensee shall implement the provisions in this
17 administrative regulation on or before October 24, 2005, with the exception of the
18 requirements listed in subsection (2) of this section.

19 (2) A licensee shall implement the training requirements in Sections 63, 64, 65,
20 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, and 77 of this administrative regulation on or
21 before October 25, 2007.

1 (3) Prior to October 25, 2007, a licensee shall satisfy the training
2 requirements of this administrative regulation for a Radiation Safety Officer, an
3 authorized medical physicist, an authorized nuclear pharmacist, or an authorized user
4 by complying with either:

5 (a) The appropriate training requirements in Sections 63, 64, 65, 66, 67, 68, 69,
6 70, 71, 72, 73, 74, 75, 76, and 77 of this administrative regulation; or

7 (b) The appropriate training requirements in Section 78 of this administrative
8 regulation.

9 (4) If a license condition exempted a licensee from a provision of this
10 administrative regulation on October 24, 2005, then the license condition continues to
11 exempt the licensee from the provision of 902 KAR 100:072.

12 (5) If a requirement in this administrative regulation differs from the requirement
13 in an existing license condition, the requirement in this administrative regulation shall
14 govern.

15 (6) A licensee shall continue to comply with any license condition that requires it
16 to implement procedures required by Sections 49, 55, 56, and 57 of this administrative
17 regulation until there is a license amendment or renewal that modifies the license
18 condition.

19 Section 2. License Required. (1) A person may manufacture, produce, acquire,
20 receive, possess, prepare, use, or transfer radioactive material for medical use only in
21 accordance with a specific license issued by the cabinet, the U.S. Nuclear Regulatory
22 Commission, or another agreement state, or as allowed in subsection (2)(a) or (b) of
23 this section.

1 (2) A specific license is not required for an individual who:

2 (a) Receives, possesses, uses, or transfers radioactive material in accordance
3 with the administrative regulations in this chapter under the supervision of an authorized
4 user as provided in Section 12 of this administrative regulation unless prohibited by
5 license condition; or

6 (b) Prepares unsealed radioactive material for medical use in accordance with
7 the administrative regulations in this chapter under the supervision of an authorized
8 nuclear pharmacist or authorized user as provided in Section 12 of this administrative
9 regulation unless prohibited by license condition.

10 Section 3. Maintenance of Records. Each record required by this administrative
11 regulation shall be legible throughout the retention period specified by each section. The
12 record shall be the original or a reproduced copy or a microform if the copy or microform
13 is authenticated by authorized personnel and the microform is capable of producing a
14 clear copy throughout the required retention period. The record may also be stored in
15 electronic media with the capability for producing legible, accurate, and complete
16 records during the required retention period. Records such as letters, drawings, and
17 specifications shall include all pertinent information such as stamps, initials, and
18 signatures. The licensee shall maintain adequate safeguards against tampering with
19 and loss of records.

20 Section 4. Application for License, Amendment, or Renewal. (1) An application
21 shall be signed by the applicant's or licensee's management.

22 (2) An application for a license for medical use of radioactive material as
23 described in Sections 30, 31, 33, 37, 45, 46 and 62 of this administrative regulation and

1 shall be made by:

2 (a) Filing an original and one (1) copy of Form RPS-7, Application for Radioactive
3 Material License, that includes the facility diagram, equipment, and training and
4 experience qualifications of the Radiation Safety Officer, authorized user, authorized
5 medical physicist, and authorized nuclear pharmacist; and

6 (b) Submitting procedures required by Sections 49, 55, 56, and 57, of this
7 administrative regulation as applicable.

8 (3) A request for a license amendment or renewal shall be made by:

9 (a) Submitting an original and one (1) copy of either:

10 1. Form RPS-7, Application for Radioactive Material License; or

11 2. A letter requesting the amendment or renewal; and

12 (b) Submitting procedures required by Sections 49, 55, 56, and 57 of this
13 administrative regulation as applicable.

14 (4) In addition to the requirements in subsections (2) and (3) of this section, an
15 application for a license or amendment for medical use of radioactive material as
16 described in Section 62 of this administrative regulation shall also include information
17 regarding any radiation safety aspects of the medical use of the material that is unique
18 to the evolving technology.

19 (a) The applicant shall also provide specific information on:

20 1. Radiation safety precautions and instructions;

21 2. Methodology for measurement of dosages or doses to be administered to
22 patients or human research subjects; and

23 3. Calibration, maintenance, and repair of instruments and equipment necessary

for radiation safety.

(b) The applicant or licensee shall provide information requested by the cabinet as necessary to complete its review of the application.

(5) An applicant that satisfies the requirements specified in 902 KAR 100:052 of this chapter may apply for a Type A specific license of broad scope.

Section 5. License Amendments. A licensee shall apply for and receive a license amendment:

(1) Before the licensee receives, prepares, or uses radioactive material for a type of use that is permitted under this chapter, but that is not authorized on the licensee's current license issued under this chapter;

(2) Before the licensee permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except:

(a) For an authorized user, an individual who meets the requirements in Sections 63, 68(1), 69(1), 70(1), 71(1), 72(1), 74(1), 76(1), 77(1), 78(2)(a), 78(3)(a), 78(4)(a), 78(7)(a), 78(9)(a), and 78(10)(a) of this administrative regulation;

(b) For an authorized nuclear pharmacist, an individual who meets the requirements in Sections 63 and 66(1) or 78(12)(a);

(c) For an authorized medical physicist, an individual who meets the requirements in Sections 63 and 65(1) or 78(11)(a) or (b) of this administrative regulation;

(d) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist:

1. On a cabinet, an agreement state or U.S. Nuclear Regulatory Commission

1 license or other equivalent permit or license recognized by the cabinet that authorizes
2 the use of radioactive material in medical use or in the practice of nuclear pharmacy;

3 2. On a permit issued by the cabinet, an agreement state or U.S. Nuclear
4 Regulatory Commission specific license of broad scope that is authorized to permit the
5 use of radioactive material in medical use or in the practice of nuclear pharmacy;

6 3. On a permit issued by a U.S. Nuclear Regulatory Commission master material
7 licensee that is authorized to permit the use of radioactive material in medical use or in
8 the practice of nuclear pharmacy; or

9 4. By a commercial nuclear pharmacy that has been authorized to identify
10 authorized nuclear pharmacists.

11 (3) Before it changes Radiation Safety Officers, except as provided in Section
12 10(3) of this administrative regulation;

13 (4) Before it receives radioactive material in excess of the amount or in a different
14 form, or receives a different radionuclide than is authorized on the license;

15 (5) Before it adds to or changes the areas of use identified in the application or
16 on the license, except for areas of use where radioactive material is used only in
17 accordance with either Section 30 or 31 of this administrative regulation;

18 (6) Before it changes the address of use identified in the application or on the
19 license; or

20 (7) Before it revises procedures required by Sections 49, 55, 56 and 57 of this
21 administrative regulation as applicable, where the revision reduces radiation safety; and

22 (8) Before conducting research involving human research subjects using
23 radioactive material.

Section 6. Notifications. (1) A licensee shall provide the cabinet a copy of the board certification, the cabinet, U.S. Nuclear Regulatory Commission or agreement state license, the permit issued by a U.S. Nuclear Regulatory Commission master material licensee, the permit issued by a cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state licensee of broad scope, or the permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee for each individual no later than thirty (30) days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist under Section 5(2)(a) through (d) of this administrative regulation.

(2) A licensee shall notify the cabinet by letter no later than thirty (30) days after:

(a) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(b) The licensee's mailing address changes;

(c) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 902 KAR 100:040, Section 6(2) of this chapter; or

(d) The licensee has added to or changed the areas of use identified in the application or on the license if radioactive material is used in accordance with either Section 30 or 31 of this administrative regulation.

(3) The licensee shall mail the documents required in this section to the Cabinet for Health and Family Services, Radiation Health Branch, Manager, 275 East Main

1 Street, Mailstop HS1C-A, Frankfort, Kentucky 40621.

2 Section 7. Exemptions Regarding Type A Specific Licenses of Broad Scope. A
3 licensee possessing a Type A specific license of broad scope for medical use, issued
4 under 902 KAR 100:052 of this chapter, is exempt from:

5 (1) Section 4(4) of this administrative regulation regarding the need to file an
6 amendment to the license for medical use of radioactive material, as described in
7 Section 62 of this administrative regulation;

8 (2) The provisions of Section 5(2) of this administrative regulation;

9 (3) The provisions of Section 5(5) of this administrative regulation regarding
10 additions to or changes in the areas of use at the addresses identified in the application
11 or on the license;

12 (4) The provisions of Section 6(1) of this administrative regulation;

13 (5) The provisions of Section 6(2)(a) of this administrative regulation for an
14 authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

15 (6) The provisions of Section 6(2)(d) of this administrative regulation regarding
16 additions to or changes in the areas of use identified in the application or on the license
17 if radioactive material is used in accordance with either Section 30 or 31 of this
18 administrative regulation; and

19 (7) The provisions of Section 36(1) of this administrative regulation.

20 Section 8. License Issuance. (1) The cabinet shall issue a license for the medical
21 use of radioactive material if:

22 (a) The applicant has filed RPS-7 Application for Radioactive Material License in
23 accordance with the instructions in Section 4 of this administrative regulation;

(b) The applicant has paid any applicable fee as provided in 902 KAR 100:012 of this chapter;

(c) The cabinet finds the applicant equipped and committed to observe the safety standards established by the cabinet in this Chapter for the protection of the public health and safety; and

(d) The applicant meets the requirements of 902 KAR 100:040, 902 KAR 100:041, 100:042, and 100:045 of this chapter.

(2) The cabinet shall issue a license for mobile medical service if the applicant:

(a) Meets the requirements in subsection (1) of this section; and

(b) Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with Section 27 of this administrative regulation.

Section 9. Specific Exemptions. The cabinet may, as established in 10 C.F.R. 35.19, upon application of any interested person or upon its own initiative, grant exemptions from the administrative regulations in this chapter that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Section 10. Authority and Responsibilities for the Radiation Protection Program.

(1) In addition to the radiation protection program requirements of 902 KAR 100:019 of this administrative regulation, a licensee's management shall approve in writing:

(a) Requests for a license application, renewal, or amendment before submittal

1 to the cabinet;

2 (b) Any individual before allowing that individual to work as an authorized user,
3 authorized nuclear pharmacist, or authorized medical physicist; and

4 (c) Radiation protection program changes that do not require a license
5 amendment and are permitted in under Section 11 of this administrative regulation.

6 (2) A licensee's management shall appoint a Radiation Safety Officer, who
7 agrees, in writing, to be responsible for implementing the radiation protection program.
8 The licensee, through the Radiation Safety Officer, shall ensure that radiation safety
9 activities are being performed in accordance with licensee-approved procedures and
10 regulatory requirements.

11 (3) For up to sixty (60) days each year, a licensee may permit an authorized user
12 or an individual qualified to be a Radiation Safety Officer, under Sections 63 and 64, of
13 this administrative regulation to function as a temporary radiation safety officer and to
14 perform the functions of a Radiation Safety Officer, as provided in subsection (7) of this
15 section, if the licensee takes the actions required in subsections (2), (5), (7), and (8) of
16 this section and notifies the cabinet in accordance with Section 6 of this administrative
17 regulation.

18 (4) A licensee may simultaneously appoint more than one (1) temporary radiation
19 safety officer in accordance with subsection (3) of this section, if needed to ensure that
20 the licensee has a temporary radiation safety officer that satisfies the requirements to
21 be a Radiation Safety Officer for each of the different types of uses of radioactive
22 material permitted by the license.

23 (5) A licensee shall establish the authority, duties, and responsibilities of the

1 Radiation Safety Officer in writing.

2 (6) A licensee authorized for two (2) or more different types of uses of radioactive
3 material under Sections 33, 37, and 46 of this administrative regulation or two (2) or
4 more types of units under Section 46 of this administrative regulation shall establish a
5 Radiation Safety Committee to oversee all uses of radioactive material permitted by the
6 license. The committee shall include an authorized user of each type of use permitted
7 by the license, the Radiation Safety Officer, a representative of the nursing service, and
8 a representative of management who is neither an authorized user nor a Radiation
9 Safety Officer. The committee may include other members the licensee considers
10 appropriate.

11 (7) A licensee shall provide the radiation safety officer sufficient authority,
12 organizational freedom, time, resources, and management prerogative to:

- 13 (a) Identify radiation safety problems;
- 14 (b) Initiate, recommend, or provide corrective actions;
- 15 (c) Stop unsafe operations; and
- 16 (d) Verify implementation of corrective actions.

17 (8) A licensee shall retain a record of actions taken under subsections (1), (2),
18 and (5) of this section as follows:

19 (a) A licensee shall retain a record of actions taken by the licensee's
20 management in accordance with subsection (1) of this section, for five (5) years. The
21 record shall include a summary of the actions taken and a signature of licensee
22 management.

23 (b) The licensee shall retain a copy of both authority, duties, and responsibilities

1 of the Radiation Safety Officer, as required in subsection (5) of this section, and a
2 signed copy of each Radiation Safety Officer's agreement to be responsible for
3 implementing the radiation safety program, as required in subsection (5) of this section,
4 for the duration of the license. The records shall include the signature of the
5 radiation safety officer and licensee management.

6 Section 11. Radiation Protection Program Changes. (1) A licensee may revise its
7 radiation protection program without cabinet approval if:

8 (a) The revision does not require a license amendment under Section 5 of this
9 administrative regulation;

10 (b) The revision is in compliance with 902 KAR Chapter 100 and the license;

11 (c) The revision has been reviewed and approved by the radiation safety officer
12 and licensee management; and

13 (d) The affected individuals are instructed on the revised program before the
14 changes are implemented.

15 (2) A licensee shall retain a record of each radiation protection program change
16 made in accordance with subsection (1) of this section for five (5) years. The record
17 shall include a copy of the old and new procedures, the effective date of the change,
18 and the signature of the licensee management that reviewed and approved the change.

19 Section 12. Supervision. (1) A licensee that permits the receipt, possession, use,
20 or transfer of radioactive material by an individual under the supervision of an
21 authorized user, as allowed by Section 2(2)(a) of this administrative regulation shall:

22 (a) In addition to the requirements in 902 KAR 100:165, instruct the supervised
23 individual in the licensee's written radiation protection procedures, written directive

1 procedures, administrative regulations of this chapter, and license conditions with
2 respect to the use of radioactive material; and

3 (b) Require the supervised individual to follow the instructions of the supervising
4 authorized user for medical uses of radioactive material, written radiation protection
5 procedures established by the licensee, written directive procedures, administrative
6 regulations of this chapter, and license conditions with respect to the medical use of
7 radioactive material.

8 (2) A licensee that permits the preparation of radioactive material for medical use
9 by an individual under the supervision of an authorized nuclear pharmacist or physician
10 who is an authorized user, as allowed by Section 2(2)(b) of this administrative regulation
11 shall:

12 (a) In addition to the requirements in 902 KAR 100:165, instruct the supervised
13 individual in the preparation of radioactive material for medical use, as appropriate to
14 that individual's involvement with radioactive material; and

15 (b) Require the supervised individual to follow the instructions of the supervising
16 authorized user or authorized nuclear pharmacist regarding the preparation of
17 radioactive material for medical use, written radiation protection procedures established
18 by the licensee, the administrative regulations of this chapter, and license conditions.

19 (3) A licensee that permits supervised activities under subsections (1) and (2) of
20 this section is responsible for the acts and omissions of the supervised individual.

21 Section 13. Written Directives. (1) A written directive shall be dated and signed
22 by an authorized user before the administration of I-131 sodium iodide greater than 1.11
23 Megabecquerels (MBq) (Thirty (30) microcuries (μCi)), any therapeutic dosage of

1 unsealed radioactive material or any therapeutic dose of radiation from radioactive
2 material.

3 (a) If, because of the emergent nature of the patient's condition, a delay in order
4 to provide a written directive would jeopardize the patient's health, an oral directive shall
5 be acceptable. The information contained in the oral directive shall be documented as
6 soon as possible in writing in the patient's record.

7 (b) A written directive shall be prepared within forty-eight (48) hours of the oral
8 directive.

9 (2) The written directive shall contain the patient or human research subject's
10 name and the following information:

11 (a) For any administration of quantities greater than 1.11 MBq (30 µCi) of sodium
12 iodide I-131: the dosage;

13 (b) For an administration of a therapeutic dosage of unsealed radioactive
14 material other than sodium iodide I-131: the radioactive drug, dosage, and route of
15 administration;

16 (c) For gamma stereotactic radiosurgery: the total dose, treatment site, and
17 values for the target coordinate settings per treatment for each anatomically distinct
18 treatment site;

19 (d) For teletherapy: the total dose, dose per fraction, number of fractions, and
20 treatment site;

21 (e) For high dose-rate remote afterloading brachytherapy: the radionuclide,
22 treatment site, dose per fraction, number of fractions, and total dose; or

23 (f) For all other brachytherapy, including low, medium, and pulsed dose rate

remote afterloaders:

1. Before implantation: treatment site, the radionuclide, and dose; and

2. After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(3) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(a) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable. The oral revision shall be documented as soon as possible in the patient's record.

(b) A revised written directive shall be signed by the authorized user within forty-eight (48) hours of the oral revision.

(4) The licensee shall retain a copy of the written directive as required by this section for three (3) years.

Section 14. Procedures for Administrations Requiring a Written Directive. (1) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(a) The patient's or human research subject's identity is verified before each administration; and

(b) Each administration is in accordance with the written directive.

(2) At a minimum, the procedures required by subsection (1) of this section shall address the following items that are applicable to the licensee's use of radioactive material:

(a) Verifying the identity of the patient or human research subject;

(b) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(c) Checking both manual and computer-generated dose calculations; and

(d) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Section 46 or 62 of this administrative regulation.

(3) A licensee shall retain a copy of the procedures required under subsection (1) for the duration of the license.

Section 15. Report and Notification of Medical Events. (1) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

(a) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, five-tenths (0.5) Sv (50 rem) to an organ or tissue, or five-tenths (0.5) Sv (50 rem) shallow dose equivalent to the skin; and

1. The total dose delivered differs from the prescribed dose by twenty (20) percent or more;

2. The total dosage delivered differs from the prescribed dosage by twenty (20) percent or more or falls outside the prescribed dosage range; or

1 3. The fractionated dose delivered differs from the prescribed dose, for a single
2 fraction, by fifty (50) percent or more.

3 (b) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, five-tenths
4 (0.5) Sv (50 rem) to an organ or tissue, or five-tenths (0.5) Sv (50 rem) shallow dose
5 equivalent to the skin from any of the following:

6 1. An administration of a wrong radioactive drug containing radioactive material;

7 2. An administration of a radioactive drug containing radioactive material by the
8 wrong route of administration;

9 3. An administration of a dose or dosage to the wrong individual or human
10 research subject;

11 4. An administration of a dose or dosage delivered by the wrong mode of
12 treatment; or

13 5. A leaking sealed source.

14 (c) A dose to the skin or an organ or tissue other than the treatment site that
15 exceeds by five-tenths (0.5) Sv (fifty (50) rem) to an organ or tissue and fifty (50)
16 percent or more of the dose expected from the administration defined in the written
17 directive (excluding, for permanent implants, seeds that were implanted in the correct
18 site but migrated outside the treatment site).

19 (2) A licensee shall report any event resulting from intervention of a patient or
20 human research subject in which the administration of radioactive material or radiation
21 from radioactive material results or will result in unintended permanent functional
22 damage to an organ or a physiological system, as determined by a physician.

23 (3) The licensee shall notify the cabinet by telephone no later than the next

1 calendar day after discovery of the medical event. The commercial telephone number of
2 the Cabinet for Health and Family Services, Radiation Health Branch is (502) 564-3700.
3 The twenty-four (24) hour emergency number is (800) 255-2587.

4 (4) The licensee shall submit a written report to the Cabinet for Health and Family
5 Services, Radiation Health Branch, Manager,
6 275 East Main Street, Mailstop HS1C-A, Frankfort, Kentucky 40621, within fifteen (15)
7 days after discovery of the medical event.

8 (a) The written report shall include:

- 9 1. The licensee's name;
10 2. The name of the prescribing physician;
11 3. A brief description of the event;
12 4. Why the event occurred;
13 5. The effect, if any, on the individual who received the administration;
14 6. What actions, if any, have been taken or are planned to prevent recurrence;
15 and
16 7. Certification that the licensee notified the individual (or the individual's
17 responsible relative or guardian), and if not, why not.

18 (b) The report shall not contain the individual's name or any other information that
19 could lead to identification of the individual.

20 (5) The licensee shall provide notification of the event to the referring physician
21 and also notify the individual who is the subject of the medical event no later than
22 twenty-four (24) hours after its discovery, unless the referring physician personally
23 informs the licensee either that he or she will inform the individual or that, based on

1 medical judgment, telling the individual would be harmful. The licensee shall not be
2 required to notify the individual without first consulting the referring physician. If the
3 referring physician or the affected individual cannot be reached within twenty-four (24)
4 hours, the licensee shall notify the individual as soon as possible thereafter. The
5 licensee shall not delay any appropriate medical care for the individual, including any
6 necessary remedial care as a result of the medical event, because of any delay in
7 notification. To meet the requirements of this subsection, the notification of the
8 individual who is the subject of the medical event may be made instead to that
9 individual's responsible relative or guardian. If a verbal notification is made, the licensee
10 shall inform the individual, or appropriate responsible relative or guardian, that a written
11 description of the event can be obtained from the licensee upon request. The licensee
12 shall provide this written description if requested.

13 (6) Aside from the notification requirement, nothing in this section shall affect any
14 rights or duties of licensees and physicians in relation to each other, to individuals
15 affected by the medical event, or to that individual's responsible relatives or guardians.

16 (7) A licensee shall:

17 (a) Annotate a copy of the report provided to the cabinet with the:

18 1. Name of the individual who is the subject of the event; and

19 2. Social Security number or other identification number, if one (1) has been
20 assigned, of the individual who is the subject of the event; and

21 (b) Provide a copy of the annotated report to the referring physician, if other than
22 the licensee, no later than fifteen (15) days after the discovery of the event.

23 Section 16. Report and Notification of a Dose to an Embryo/fetus or a Nursing

Child. (1) A licensee shall report any dose to an embryo/fetus that is greater than fifty (50) mSv (five (5) rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

(a) Is greater than fifty (50) mSv (five (5) rem) total effective dose equivalent; or

(b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify the cabinet by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsections (1) or (2) of this section. The commercial telephone number of the Cabinet for Health and Family Services, Radiation Health Branch is (502) 564-3700. The twenty-four (24) hour emergency number is (800) 255-2587.

(4) The licensee shall submit a written report to the Cabinet for Health and Family Services, Radiation Health Branch, Manager, 275 East Main Street, Mailstop HS1C-A, Frankfort, Kentucky 40621, within fifteen (15) days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsections (1) or (2) in this section.

(a) The written report shall include:

1. The licensee's name;

2. The name of the prescribing physician;

1 3. A brief description of the event;
2 4. Why the event occurred;
3 5. The effect, if any, on the embryo or fetus or the nursing child;
4 6. What actions, if any, have been taken or are planned to prevent recurrence;
5 and
6 7. Certification that the licensee notified the pregnant individual or mother (or the
7 mother's or child's responsible relative or guardian), and if not, why not.
8 (b) The report shall not contain the individual's or child's name or any other
9 information that could lead to identification of the individual or child.
10 (5) The licensee shall provide notification of the event to the referring physician
11 and also notify the pregnant individual or mother, both hereafter referred to as the
12 mother, no later than twenty-four (24) hours after discovery of an event that would
13 require reporting under subsection (1) or (2) of this section, unless the referring
14 physician personally informs the licensee either that he or she will inform the mother or
15 that, based on medical judgment, telling the mother would be harmful. The licensee
16 shall not be required to notify the mother without first consulting with the referring
17 physician. If the referring physician or mother cannot be reached within twenty-four (24)
18 hours, the licensee shall make the appropriate notifications as soon as possible
19 thereafter. The licensee shall not delay any appropriate medical care for the embryo or
20 fetus or for the nursing child, including any necessary remedial care as a result of the
21 event, because of any delay in notification. To meet the requirements of this paragraph,
22 the notification may be made to the mother's or child's responsible relative or guardian
23 instead of the mother. If a verbal notification is made, the licensee shall inform the

1 mother, or the mother's or child's responsible relative or guardian, that a written
2 description of the event can be obtained from the licensee upon request. The licensee
3 shall provide this written description if requested.

4 (6) A licensee shall:

5 (a) Annotate a copy of the report provided to the cabinet with the:

6 1. Name of the pregnant individual or the nursing child who is the subject of the
7 event; and

8 2. Social Security number or other identification number, if one (1) has been
9 assigned, of the pregnant individual or the nursing child who is the subject of the event;
10 and

11 (b) Provide a copy of the annotated report to the referring physician, if other than
12 the licensee, no later than fifteen (15) days after the discovery of the event.

13 Section 17. Provisions for the Protection of Human Research Subjects. (1) A
14 licensee may conduct research involving human research subjects only if it uses the
15 radioactive materials specified on its license for the uses authorized on its license.

16 (2) If the research is conducted, funded, supported, or regulated by another
17 federal agency that has implemented the Federal Policy for the Protection of Human
18 Subjects, 45 C.F.R. Part 46, the licensee shall, before conducting research:

19 (a) Obtain review and approval of the research from an Institutional Review
20 Board, as defined and described in the Federal Policy for the Protection of Human
21 Subjects, 45 C.F.R. Part 46; and

22 (b) Obtain informed consent, as defined and described in the Federal Policy for
23 the Protection of Human Subjects, 45 C.F.R. Part 46, from the human research subject.

1 (3) If the research will not be conducted, funded, supported, or regulated by
2 another federal agency that has implemented the Federal Policy, the licensee, shall
3 before conducting research, apply for and receive a specific amendment to its cabinet
4 medical use license. The amendment request shall include a written commitment that
5 the licensee shall, before conducting research:

6 (a) Obtain review and approval of the research from an Institutional Review
7 Board, as defined and described in the Federal Policy for the Protection of Human
8 Subjects, 45 C.F.R. Part 46; and

9 (b) Obtain "informed consent", as defined and described in the Federal Policy,
10 form the human research subject.

11 (4) Nothing in this section relieves the licensees from complying with the other
12 requirements in this administrative regulation.

13 Section 18. Report of a Leaking Source. A licensee shall file a report within five
14 (5) days if a leak test required by Section 24, of this administrative regulation reveals
15 the presence of 185 Bq (0.005 μ Ci) or more of removable contamination. The report
16 shall be filed with the Cabinet for Health and Family Services, Radiation Health Branch,
17 Manager, 275 East Main Street, Frankfort, Kentucky 40621. The written report shall
18 include the model number and serial number, if assigned, of the leaking source; the
19 radionuclide and its estimated activity; the results of the test; the date of the test; and
20 the action taken.

21 Section 19. Quality Control of Diagnostic Equipment. A licensee shall establish
22 written quality control procedures for diagnostic equipment used for radionuclide
23 studies.

(1) As a minimum, the procedures shall include:

(a) Quality control procedures recommended by equipment manufacturers; or

(b) Procedures approved by the cabinet.

(2) The licensee shall conduct quality control procedures in accordance with written procedures.

Section 20. Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material. (1) For direct measurements performed in accordance with Section 22, of this administrative regulation a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

(2) A licensee shall calibrate the instrumentation required in subsection (1) of this section in accordance with nationally-recognized standards or the manufacturer's instructions.

(3) A licensee shall maintain a record of instrument calibrations, required by this section, for three (3) years. The records shall include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Section 21. Calibration of Survey Instruments. (1) A licensee shall calibrate the survey instruments used to show compliance with this administrative regulation and 902 KAR 100:019 before first use, annually, and following a repair that affects the calibration. A licensee shall:

(a) Calibrate all scales with readings up to ten (10) mSv (1000 mrem) per hour with a radiation source;

1 (b) Calibrate two (2) separated readings on each scale or decade that will be
2 used to show compliance; and

3 (c) Conspicuously note on the instrument the apparent dose rate from a
4 dedicated check source as determined at the time of calibration, and the date of
5 calibration.

6 (2) A licensee shall not use survey instruments if the difference between the
7 indicated exposure rate and the calculated exposure rate is more than twenty (20)
8 percent.

9 (3) A licensee shall maintain a record of each radiation survey instrument
10 calibrations for three (3) years. The record shall include the model and serial number of
11 the instrument, the date of the calibration, the results of the calibration, and the name of
12 the individual who performed the calibration.

13 Section 22. Determination of Dosages of Unsealed Radioactive Material for
14 Medical Use. (1) A licensee shall determine and record the activity of each dosage
15 before medical use.

16 (2) For a unit dosage, this determination shall be made by:

17 (a) Direct measurement of radioactivity; or

18 (b) A decay correction, based on the activity or activity concentration determined
19 by:

20 1. A manufacturer or preparer licensed pursuant to 902 KAR 100:040 and 902
21 KAR 100:058, U.S. Nuclear Regulatory Commission, or equivalent agreement state
22 requirements; or

23 2. A cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement

1 state license for use in research in accordance with a Radioactive Drug Research
2 Committee-approved protocol or an Investigational New Drug (IND) protocol accepted
3 by FDA;

4 (3) For other than unit dosages, this determination shall be made by:

5 (a) Direct measurement of radioactivity;

6 (b) Combination of measurement of radioactivity and mathematical calculations;

7 or

8 (c) Combination of volumetric measurements and mathematical calculations,
9 based on the measurement made by a manufacturer or preparer licensed pursuant to
10 902 KAR 100:040 and 902 KAR 100:058, U.S. Nuclear Regulatory Commission, or
11 equivalent agreement state requirements. [~~requirements; or~~]

12 (4) Unless otherwise directed by the authorized user, a licensee shall not use a
13 dosage if the dosage does not fall within the prescribed dosage range or if the dosage
14 differs from the prescribed dosage by more than twenty (20) percent.

15 (5) A licensee shall retain a record of the dosage determination, required by this
16 section, for three (3) years. The record shall contain:

17 (a) The radiopharmaceutical;

18 (b) The patient's or human research subject's name, or identification number if
19 one (1) has been assigned;

20 (c) The prescribed dosage, the determined dosage, or a notation that the total
21 activity is less than 1.11 MBq (30 μ Ci);

22 (d) The date and time of the dosage determination; and

23 (e) The name of the individual who determined the dosage.

1 Section 23. Authorization for Calibration, Transmission, and Reference Sources.

2 Any person authorized by Section 2 of this administrative regulation for medical use of
3 radioactive material may receive, possess, and use any of the following radioactive
4 material for check, calibration, transmission, and reference use.

5 (1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and
6 distributed by a person licensed pursuant to 902 KAR 100:040 and 902 KAR 100:058,
7 U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements.

8 (2) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a
9 licensee authorized to redistribute the sealed sources manufactured and distributed by
10 a person licensed pursuant to 902 KAR 100:040 and 902 KAR 100:058, U.S. Nuclear
11 Regulatory Commission, or equivalent agreement state requirements, providing the
12 redistributed sealed sources are in the original packaging and
13 shielding and are accompanied by the manufacturer's approved instructions.

14 (3) Any radioactive material with a half-life not longer than 120 days in individual
15 amounts not to exceed 0.56 GBq (15 mCi).

16 (4) Any radioactive material with a half-life longer than 120 days in individual
17 amounts not to exceed the smaller of 7.4 MBq (200 µCi) or 1000 times the quantities in
18 902 KAR 100:030.

19 (5) Technetium-99m in amounts as needed.

20 Section 24. Requirements for Possession of Sealed Sources and Brachytherapy
21 Sources. (1) A licensee in possession of any sealed source or brachytherapy source
22 shall follow the radiation safety and handling instructions supplied by the manufacturer.

23 (2) A licensee in possession of a sealed source shall:

1 (a) Test the source for leakage before its first use unless the licensee has a
2 certificate from the supplier indicating that the source was tested within six (6) months
3 before transfer to the licensee; and

4 (b) Test the source for leakage at intervals not to exceed six (6) months or at
5 other intervals approved by the cabinet, U.S. Nuclear Regulatory Commission, or
6 equivalent agreement state in the Sealed Source and Device Registry.

7 (3) To satisfy the leak test requirements of this section, the licensee shall
8 measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μ Ci)
9 of radioactive material in the sample.

10 (4) A licensee shall retain leak test records in accordance with subsection (8)(a)
11 of this section.

12 (5) If the leak test reveals the presence of 185 Bq (0.005 μ Ci) or more of
13 removable contamination, the licensee shall:

14 (a) Immediately withdraw the sealed source from use and store, dispose, or
15 cause it to be repaired in accordance with the requirements in 902 KAR 100:019,
16 100:021, 100:040, and 100:058; and

17 (b) File a report within five (5) days of the leak test in accordance with 902 KAR
18 100:072, Section 18.

19 (6) A licensee need not perform a leak test on the following sources:

20 (a) Sources containing only radioactive material with a half-life of less than thirty
21 (30) days;

22 (b) Sources containing only radioactive material as a gas;

23 (c) Sources containing 3.7 MBq (100 μ Ci) or less of beta or gamma-emitting

1 material or 0.37 MBq (10 µCi) or less of alpha-emitting material;

2 (d) Seeds of iridium-192 encased in nylon ribbon; and

3 (e) Sources stored and not being used. However, the licensee shall test each
4 source for leakage before any use or transfer unless it has been leak tested within six
5 (6) months before the date of use or transfer.

6 (7) A licensee in possession of sealed sources or brachytherapy sources, except
7 for gamma stereotactic radiosurgery sources, shall conduct a semiannual physical
8 inventory of all these sources in its possession. The licensee shall retain each inventory
9 record in accordance with subsection (8)(b) of this section.

10 (8) A licensee shall keep records of leaks tests and inventory of sealed sources
11 and brachytherapy sources as follows:

12 (a) A licensee shall retain records of leak tests for three (3) years. The records
13 shall include the model number and serial number, if one (1) has been assigned, of
14 each source tested; the identity of each source by radionuclide and its estimated
15 activity; the results of the test; the date of the test; and the name of the individual who
16 performed the test.

17 (b) A licensee shall retain records of the semiannual physical inventory of sealed
18 sources and brachytherapy sources for three (3) years. The inventory records shall
19 contain the model number of each source, and serial number if one (1) has been
20 assigned, the identity of each source by radionuclide and its nominal activity, the
21 location of each source, and the name of the individual who performed the inventory.

22 Section 25. Labeling of Vials and Syringes. Each syringe and vial that contains
23 unsealed radioactive material shall be labeled to identify the radioactive drug. Each

1 syringe shield and vial shield shall also be labeled unless the label on the syringe or vial
2 is visible when shielded.

3 Section 26. Surveys of Ambient Radiation Exposure Rate. (1) In addition to the
4 surveys required by 902 KAR 100:019, a licensee shall survey with a radiation detection
5 survey instrument at the end of each day of use. A licensee shall survey all areas where
6 unsealed radioactive material requiring a written directive was prepared for use or
7 administered.

8 (2) A licensee is not required to perform the surveys required by subsection (1) of
9 this section in an area where patients or human research subjects are confined when
10 they cannot be released under Section 27 of this administrative regulation.

11 (3) A licensee shall retain a record of each survey for three (3) years. The record
12 shall include the date of the survey, the results of the survey, the instrument used to
13 conduct the survey, and the name of the individual who performed the survey.

14 Section 27. Release of Individuals Containing Unsealed Radioactive Material or
15 Implants Containing Radioactive Material. (1) A licensee may authorize the release from
16 its control of any individual who has been administered unsealed radioactive material or
17 implants containing radioactive material if the total effective dose equivalent to any other
18 individual from exposure to the released individual is not likely to exceed five (5) mSv
19 (fife-tenths (0.5) rem). NUREG-1556, Vol. 9, "Consolidated Guidance About Materials
20 Licenses: Program-Specific Guidance About Medical Licenses," describes methods for
21 calculating doses to other individuals and contains tables of activities not likely to cause
22 doses exceeding five (5) mSv (0.5 rem).

23 (2) A licensee shall provide the released individual, or the individual's parent or

guardian, with instructions, including 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 one (1) mSv (one-tenth (0.1) rem). If the total effective dose equivalent to a nursing infant or child could exceed one (1) mSv (one-tenth (0.1) rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and

2. Information on the potential consequences, if any, of failure to follow the guidance.

(3) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with this section, if the total effective dose equivalent is calculated by:

(a) Using the retained activity rather than the activity administered;

(b) Using an occupancy factor less than 0.25 at one (1) meter;

(c) Using the biological or effective half-life; or

(d) Considering the shielding by tissue.

(4) A licensee shall retain a record that the instructions, required by this section, were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five (5) mSv (five-tenths (0.5) rem).

(5) The records required by subsections (3), and (4) of this section shall be retained for three (3) years after the date of release of the individual.

(6) A report shall be filed in accordance with Section 15 of this chapter and

submitted to the cabinet if a dose greater than 50 mSv (5 rem) is received by an individual from a patient released under this section.

Section 28. Provision of Mobile Medical Service. (1) A licensee providing mobile medical service shall:

(a) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(b) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph shall include a constancy check;

(c) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(d) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in 902 KAR 100:019.

(2) A mobile medical service shall not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(3) A licensee providing mobile medical services shall retain the letter required in subsection (1)(a) and the record of each survey required in subsection (1)(d) of this section respectively:

(a) A licensee shall retain a copy of each letter required in subsection (1)(a) that

permits the use of radioactive material at a client's address. Each letter shall clearly delineate the authority and responsibility of the licensee and the client and shall be retained for three (3) years after the last provision of service.

(b) A licensee shall retain the record of each survey required by subsection (1)(d) for three (3) years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(4) The cabinet shall license mobile medicine services in accordance with this administrative regulation and applicable requirements of 902 KAR 100:012, 100:015, 100:019, 100:021, 100:040, 100:050, 100:060, 100:070, and 100:165.

Section 29. Decay-in-storage. (1) 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;

(a) Holds radioactive material for decay a minimum of ten (10) half-lives;

(b) Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(c) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(2) A licensee shall retain a record of each disposal for three (3) years. The record shall include the:

- 1 (a) Date of the disposal;
- 2 (b) Date on which the radioactive material was placed in storage;
- 3 (c) Radionuclides disposed;
- 4 (d) Model and serial number of the survey instrument used;
- 5 (e) Background dose rate;
- 6 (f) Radiation dose rate measured at the surface of each waste container; and
- 7 (g) Name of the individual who performed the disposal.

8 Section 30. Use of Unsealed Radioactive Material for Uptake, Dilution, and
9 Excretion Studies for Which a Written Directive is Not Required. Except for quantities
10 that require a written directive under Section 13(2), of this administrative regulation a
11 licensee may use any unsealed radioactive material prepared for medical use for
12 uptake, dilution, or excretion studies that is:

13 (1) Obtained from a manufacturer or preparer licensed under 902 KAR 100:040
14 and 902 KAR 100:058 of this chapter, U.S. Nuclear Regulatory Commission, or
15 equivalent agreement state requirements;

16 (2) Prepared by:

- 17 (a) An authorized nuclear pharmacist;
- 18 (b) A physician who is an authorized user and who meets the requirements
19 specified in Section 69 or 70 and Section 69(3)(a)2.g of this administrative regulation; or
- 20 (c) An individual under the supervision of either as specified in Section 12 of this
21 administrative regulation; or

22 (3) Obtained from and prepared by a licensee of the cabinet, U.S. Nuclear
23 Regulatory Commission, or equivalent agreement state for use in research in

1 accordance with a Radioactive Drug Research Committee-approved protocol or an
2 Investigational New Drug (IND) protocol accepted by FDA; or

3 (4) Prepared by the licensee for use in research in accordance with a
4 Radioactive Drug Research Committee-approved application or an Investigational New
5 Drug (IND) protocol accepted by FDA.

6 Section 31. Use of Unsealed Radioactive Material for Imaging and Localization
7 Studies for Which a Written Directive is Not Required. Except for quantities that require
8 a written directive under Section 13(2) of this administrative regulation a licensee may
9 use any unsealed radioactive material prepared for medical use for imaging and
10 localization studies that is:

11 (1) Obtained from a manufacturer or preparer licensed under 902 KAR 100:040
12 or 100:058 of this chapter, U.S. Nuclear Regulatory Commission, or equivalent
13 agreement state requirements;

14 (2) Prepared by:

15 (a) An authorized nuclear pharmacist;

16 (b) A physician who is an authorized user and who meets the requirements
17 specified in Sections 69 or 70 and Section 69(3)(a)2.g. of this administrative regulation;
18 or

19 (c) An individual under the supervision, as specified in Section 12 of this
20 administrative regulation;

21 (3) Obtained from and prepared by a cabinet, U.S. Nuclear Regulatory
22 Commission, or equivalent agreement state licensee for use in research in accordance
23 with a Radioactive Drug Research Committee-approved protocol or an Investigational

1 New Drug (IND) protocol accepted by FDA; or

2 (4) Prepared by the licensee for use in research in accordance with a
3 Radioactive Drug Research Committee-approved application or an Investigational New
4 Drug (IND) protocol accepted by FDA.

5 Section 32. Permissible Radionuclide Contaminant Concentration. (1) A licensee
6 shall not administer to humans a radiopharmaceutical containing more than:

7 (a) 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m
8 (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

9 (b) 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride
10 injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or

11 (c) 0.02 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride
12 injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82
13 chloride);

14 (2) A licensee preparing radiopharmaceuticals from radionuclide generators shall
15 measure the concentration of radionuclide contaminant of the first eluate after receipt of
16 a generator to demonstrate compliance with limits specified in subsection (1) of this
17 section.

18 (3) A licensee required to measure radionuclide contaminant concentration, in
19 this section, shall retain a record of each measurement for three (3) years;

20 (a) The record shall include, for each elution or extraction tested, the:

21 1. Measured activity of the radiopharmaceutical expressed in millicuries;

22 2. Measured activity of contaminant expressed in microcuries;

23 3. Ratio of the measurements in subsection (1)(a), (b), and (c) of this section

expressed as microcuries of contaminant per millicurie of radiopharmaceutical;

4. Date of the test; and

5. Initials of the individual who performed the test.

(b) A licensee shall report immediately to the cabinet each occurrence of contaminant concentration exceeding the limits specified in this section.

Section 33. Use of Unsealed Radioactive Material for Which a Written Directive is Required. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

(1) Obtained from a manufacturer or preparer licensed under 902 KAR 100:040 or 902 KAR 100:058 of this chapter, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements;

(2) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in Section 69 or 70 of this administrative regulation, or an individual under the supervision, as specified in Section 12 of this administrative regulation;

(3) Obtained from and prepared by a cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(4) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

Section 34. Safety Instruction. (1) In addition to 902 KAR 100:165, a licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for the patient or the human research subjects receiving radiopharmaceutical

1 therapy and hospitalized for compliance with Section 27 of this administrative
2 regulation. To satisfy this requirement, the instruction shall describe the licensee's
3 procedures for:

4 (a) Patient or human research subject control;

5 (b) Visitor control:

6 1. Routine visitation to hospitalized individuals in accordance with 902 KAR
7 100:019, Section 10(1)(a) of this chapter; and

8 2. Visitation authorized in accordance with 902 KAR 100:019, Section 10(6) of
9 this chapter;

10 (c) Contamination control;

11 (d) Waste control; and

12 (e) Notification of the Radiation Safety Officer, or his or her designee, and the
13 authorized user if the patient or the human research subject has a medical emergency
14 or dies.

15 (2) A licensee shall retain a record of individuals receiving safety instructions for
16 three (3) years. The record shall include a list of the topics covered, the date of the
17 instruction, the name of the attendee(s), and the name(s) of the individual(s) who
18 provided the instruction.

19 Section 35. Safety Precautions. (1) For each patient or human research subject
20 who cannot be released under Section 27 of this administrative regulation a licensee
21 shall:

22 (a) Quarter the patient or the human research subject either in:

23 1. A private room with a private sanitary facility; or

1 2. A room, with a private sanitary facility, with another individual who also has
2 received therapy with unsealed radioactive material and who also cannot be released
3 under Section 27 of this administrative regulation;

4 (b) Visibly post the patient's or the human research subject's room with a
5 "Radioactive Materials" sign:

6 (c) Note on the door or in the patient's or human research subject's chart where
7 and how long visitors may stay in the patient's or the human research subject's room;
8 and

9 (d) Either monitor material and items removed from the patient's or the human
10 research subject's room to determine that their radioactivity cannot be distinguished
11 from the natural background radiation level with a radiation detection survey instrument
12 set on its most sensitive scale and with no interposed shielding, or handle the material
13 and items as radioactive waste.

14 (2) A licensee shall notify the radiation safety officer, or his or her designee, and
15 the authorized user as soon as possible if the patient or human research subject has a
16 medical emergency or dies.

17 Section 36. Suppliers for Sealed Sources or Devices for Medical Use. For
18 medical use, a licensee shall only use:

19 (1) Sealed sources or devices manufactured, labeled, packaged, and distributed
20 in accordance with a license issued by the cabinet, U.S. Nuclear Regulatory
21 Commission, or equivalent agreement state;

22 (2) Sealed sources or devices noncommercially transferred from a 902 KAR
23 100:072 license, U.S. Nuclear Regulatory Commission, or equivalent State Medical

1 License; or

2 (3) Teletherapy sources manufactured and distributed in accordance with a
3 license issued by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent
4 agreement state.

5 Section 37. Use of Sources for Manual Brachytherapy. A licensee shall use only
6 brachytherapy sources for therapeutic medical uses:

7 (1) As approved in the Sealed Source and Device Registry; or

8 (2) In research in accordance with an active Investigational Device Exemption
9 (IDE) application accepted by the FDA if the requirements of Section 36(1) of this
10 administrative regulation are met.

11 Section 38. Surveys After Source Implant and Removal. (1) Immediately after
12 implanting sources in a patient or a human research subject, the licensee shall make a
13 survey to locate and account for all sources that have not been implanted.

14 (2) Immediately after removing the last temporary implant source from a patient
15 or a human research subject, the licensee shall make a survey of the patient or the
16 human research subject with a radiation detection survey instrument to confirm that all
17 sources have been removed.

18 (3) A licensee shall retain a record of the surveys required by subsections (1) and
19 (2) of this section for three (3) years. Each record shall include the date and results of
20 the survey, the survey instrument used, and the name of the individual who made the
21 survey.

22 Section 39. Brachytherapy Sources Accountability. (1) A licensee shall maintain
23 accountability at all times for all brachytherapy sources in storage or use.

1 (2) As soon as possible after removing sources from a patient or a human
2 research subject, a licensee shall return brachytherapy sources to a secure storage
3 area.

4 (3) A licensee shall maintain a record of the brachytherapy source accountability
5 for three (3) years for:

6 (a) Temporary implants, the record shall include:

7 1. The number and activity of sources removed from storage, the time and date
8 they were removed from storage, the name of the individual who removed them from
9 storage, and the location of use; and

10 2. The number and activity of sources returned to storage, the time and date they
11 were returned to storage, and the name of the individual who returned them to storage.

12 (b) Permanent implants, the record shall include:

13 1. The number and activity of sources removed from storage, the date they were
14 removed from storage, and the name of the individual who removed them from storage;

15 2. The number and activity of sources not implanted, the date they were returned
16 to storage, and the name of the individual who returned them to storage; and

17 3. The number and activity of sources permanently implanted in the patient or
18 human research subject.

19 Section 40. Safety Instruction. In addition to the requirements of 902 KAR
20 100:165 of this chapter. (1) The licensee shall provide radiation safety instruction,
21 initially and at least annually, to personnel caring for patients or human research
22 subjects who are receiving brachytherapy and cannot be released under Section 27 of
23 this administrative regulation. To satisfy this requirement, the instruction shall be

1 commensurate with the duties of the personnel and shall include the:

2 (a) Size and appearance of the brachytherapy sources;

3 (b) Safe handling and shielding instructions;

4 (c) Patient or human research subject control;

5 (d) Visitor control, including both:

6 1. Routine visitation of hospitalized individuals in accordance with 902 KAR
7 100:019, Section 10(1)(a) of this chapter; and

8 2. Visitation authorized in accordance with 902 KAR 100:019, Section 10(6) of
9 this chapter; and

10 (e) Notification of the Radiation Safety Officer, or his or her designee, and an
11 authorized user if the patient or the human research subject has a medical emergency
12 or dies.

13 (2) A licensee shall retain a record of individuals receiving instruction for three (3)
14 years. The record shall include a list of the topics covered, the date of the instruction,
15 the name of the attendee, and the name of the individual who provided the instruction.

16 Section 41. Safety Precautions. (1) For each patient or human research subject
17 who is receiving brachytherapy and cannot be released under Section 27 of this
18 administrative regulation a licensee shall:

19 (a) Not quarter the patient or the human research subject in the same room as an
20 individual who is not receiving brachytherapy;

21 (b) Visibly post the patient's or human research subject's room with a
22 "Radioactive Materials" sign; and

23 (c) Note on the door or in the patient's or human research subject's chart where

1 and how long visitors may stay in the patient's or human research subject's room.

2 (2) A licensee shall have applicable emergency response equipment available
3 near each treatment room to respond to a source:

4 (a) Dislodged from the patient; and

5 (b) Lodged within the patient following removal of the source applicators.

6 (3) A licensee shall notify the Radiation Safety Officer, or his or her designee,
7 and an authorized user as soon as possible if the patient or human research subject
8 has a medical emergency or dies.

9 Section 42. Calibration Measurements of Brachytherapy Sources. (1) Before the
10 first medical use of a brachytherapy source on or after October 24, 2005, a licensee
11 shall have:

12 (a) Determined the source output or activity using a dosimetry system that meets
13 the requirements of Section 51(1) of this administrative regulation;

14 (b) Determined source positioning accuracy within applicators; and

15 (c) Used published protocols currently accepted by nationally recognized bodies
16 to meet the requirements of subsection (1)(a) and (b) of this section.

17 (2) A licensee may use measurements provided by the source manufacturer or
18 by a calibration laboratory accredited by the American Association of Physicists in
19 Medicine that are made in accordance with subsection (1) of this section.

20 (3) A licensee shall mathematically correct the outputs or activities determined in
21 subsection (1) of this section for physical decay at intervals consistent with one (1)
22 percent physical decay.

23 (4) A licensee shall retain a record of each calibration of brachytherapy sources

required by this section for three (3) years after the last use of the source. The record shall include:

- (a) The date of the calibration;
- (b) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;
- (c) The source output or activity;
- (d) The source positioning accuracy within the applicators; and
- (e) The name of the individual, source manufacturer, or the calibration laboratory that performed the calibration.

Section 43. Decay of strontium-90 sources for ophthalmic treatments. (1) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under Section 42 of this administrative regulation.

(2) A licensee shall retain a record of the activity of each strontium-90 source for the life of the source. The record shall include:

- (a) The date and initial activity of the source as determined under Section 42 of this administrative regulation; and
- (b) For each decay calculation, the date and the source activity as determined under subsection (1) of this section.

Section 44. Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally-recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification

1 of:

2 (1) The source-specific input parameters required by the dose calculation
3 algorithm;

4 (2) The accuracy of dose, dwell time, and treatment time calculations at
5 representative points;

6 (3) The accuracy of isodose plots and graphic displays; and

7 (4) The accuracy of the software used to determine sealed source positions from
8 radiographic images.

9 Section 45. Use of Sealed Sources for Diagnosis. A licensee shall use only
10 sealed sources for diagnostic medical uses as approved in the Sealed Source and
11 Device Registry.

12 Section 46. Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy
13 Unit, or Gamma Stereotactic Radiosurgery Unit. A licensee shall use sealed sources in
14 photon emitting remote afterloader units, teletherapy units, or gamma stereotactic
15 radiosurgery units for therapeutic medical uses:

16 (1) As approved in the Sealed Source and Device Registry; or

17 (2) In research in accordance with an active Investigational Device Exemption
18 (IDE) application accepted by the FDA provided the requirements of Section 36(1) of
19 this administrative regulation are met.

20 Section 47. Surveys of Patients and Human Research Subjects Treated with a
21 Remote Afterloader Unit. (1) Before releasing a patient or a human research subject
22 from licensee control, a licensee shall survey the patient or the human research subject
23 and the remote afterloader unit with a portable radiation detection survey instrument to

confirm that the source has been removed from the patient or human research subject and returned to the safe shielded position.

(2) A licensee shall retain a record of the surveys for three (3) years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Section 48. Installation, Maintenance, Adjustment, and Repair. (1) Only a person specifically licensed by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source contained in the unit.

(4) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic

1 radiosurgery units for three (3) years. For each installation, maintenance, adjustment
2 and repair, the record shall include the date, description of the service, and name of the
3 individual who performed the work.

4 Section 49. Safety Procedures and instructions for Remote Afterloader Units,
5 Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. (1) A licensee shall:

6 (a) Secure the unit, the console, the console keys, and the treatment room when
7 not in use or unattended;

8 (b) Permit only individuals approved by the authorized user, Radiation Safety
9 Officer, or authorized medical physicist to be present in the treatment room during
10 treatment with the source;

11 (c) Prevent dual operation of more than one (1) radiation producing device in a
12 treatment room if applicable; and

13 (d) Develop, implement, and maintain written procedures for responding to an
14 abnormal situation if the operator is unable to place the source in the shielded position,
15 or remove the patient or human research subject from the radiation field with controls
16 from outside the treatment room. These procedures shall include:

17 1. Instructions for responding to equipment failures and the names of the
18 individuals responsible for implementing corrective actions;

19 2. The process for restricting access to and posting of the treatment area to
20 minimize the risk of inadvertent exposure; and

21 3. The names and telephone numbers of the authorized users, the authorized
22 medical physicist, and the radiation safety officer to be contacted if the unit or console
23 operates abnormally.

1 (2) A copy of the procedures required by subsection (1)(d) of this section shall be
2 physically located at the unit console.

3 (3) A licensee shall post instructions at the unit console to inform the operator of:

4 (a) The location of the procedures required by subsection (1)(d) of this section;
5 and

6 (b) The names and telephone numbers of the authorized users, the authorized
7 medical physicist, and the radiation safety officer to be contacted if the unit or console
8 operates abnormally.

9 (4) A licensee shall provide instruction, initially and at least annually, to all
10 individuals who operate the unit, as appropriate to the individual's assigned duties, in:

11 (a) The procedures identified in paragraph (1)(d) of this section; and

12 (b) The operating procedures for the unit.

13 (5) A licensee shall ensure that operators, authorized medical physicists, and
14 authorized users participate in drills of the emergency procedures, initially and at least
15 annually.

16 (6) A licensee shall retain a record of individuals receiving instructions for three
17 (3) years. The record shall include a list of the topics covered, the date of the
18 instruction, the name of the attendee, and the name of the individual who provided the
19 instruction.

20 (7) A licensee shall retain a copy of the procedures until the licensee no longer
21 possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery
22 unit.

23 Section 50. Safety Precautions for Remote Afterloader Units, Teletherapy Units,

1 and Gamma Stereotactic Radiosurgery Units. (1) A licensee shall control access to the
2 treatment room by a door at each entrance.

3 (2) A licensee shall equip each entrance to the treatment room with an electrical
4 interlock system that shall:

5 (a) Prevent the operator from initiating the treatment cycle unless each treatment
6 room entrance door is closed;

7 (b) Cause the source to be shielded when an entrance door is opened; and

8 (c) Prevent the source from being exposed following an interlock interruption until
9 all treatment room entrance doors are closed and the source on-off control is reset at
10 the console.

11 (3) A licensee shall require any individual entering the treatment room to assure,
12 through the use of appropriate radiation monitors, that radiation levels have returned to
13 ambient levels.

14 (a) Each radiation monitor shall be equipped with a backup power supply
15 separate from the power supply to the unit. This backup power supply may be a battery
16 system.

17 (b) If the radiation monitor is inoperable, the licensee shall require any individual
18 entering the treatment room to use a survey instrument or audible alarm personal
19 dosimeter to monitor for any malfunction of the source exposure mechanism that may
20 result in an exposed or partially exposed source. The instrument or dosimeter shall be
21 checked with a dedicated check source for proper operation at the beginning of each
22 day of use. The licensee shall keep a record as described in this section.

23 (c) A licensee shall promptly repair or replace the radiation monitor if it is

1 inoperable.

2 (4) Except for low-dose remote afterloader units, a licensee shall construct or
3 equip each treatment room with viewing and intercom systems to permit continuous
4 observation of the patient or the human research subject from the treatment console
5 during irradiation.

6 (5) For licensed activities in which a source is placed within the patient's or
7 human research subject's body, a licensee shall only conduct treatments that allow for
8 expeditious removal of a decoupled or jammed source.

9 (6) In addition to the requirements specified in subsections (1) through (5) of this
10 section, a licensee shall:

11 (a) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

12 1. An authorized medical physicist and either an authorized user or a physician,
13 under the supervision of an authorized user, who has been trained in the operation and
14 emergency response for the unit to be physically present during the initiation of all
15 patient treatments involving the unit; and

16 2. An authorized medical physicist and either an authorized user or an individual,
17 under the supervision of an authorized user, who has been trained to remove the
18 source applicator in the event of an emergency involving the unit, to be immediately
19 available during continuation of all patient treatments involving the unit.

20 (b) For high dose-rate remote afterloader units, require:

21 1. An authorized user and an authorized medical physicist to be physically
22 present during the initiation of all patient treatments involving the unit; and

23 2. An authorized medical physicist and either an authorized user or a physician,

1 under the supervision of an authorized user, who has been trained in the operation and
2 emergency response for the unit, to be physically present during continuation of all
3 patient treatments involving the unit.

4 (c) For gamma stereotactic radiosurgery units, require an authorized user and an
5 authorized medical physicist to be physically present throughout all patient treatments
6 involving the unit.

7 (d) Notify the Radiation Safety Officer, or his or her designee, and an authorized
8 user as soon as possible if the patient or human research subject has a medical
9 emergency or dies.

10 (7) A licensee shall have applicable emergency response equipment available
11 near each treatment room to respond to a source:

12 (a) Remaining in the unshielded position; or

13 (b) Lodged within the patient following completion of the treatment.

14 Section 51. Dosimetry Equipment. (1) Except for low dose-rate remote
15 afterloader sources in which the source output or activity is determined by the
16 manufacturer, a licensee shall have a calibrated dosimetry system available for use. To
17 satisfy this requirement, one (1) of the following two (2) conditions shall be met:

18 (a) The system shall have been calibrated using a system or source traceable to
19 the National Institute of Science and Technology (NIST) and published protocols
20 accepted by nationally recognized bodies or by a calibration laboratory accredited by
21 the American Association of Physicists in Medicine (AAPM). The calibration shall have
22 been performed within the previous two (2) years and after any servicing that may have
23 affected system calibration; or

(b) The system shall have been calibrated within the previous four (4) years. Eighteen (18) to thirty (30) months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past twenty-four (24) months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall indicate that the calibration factor of the licensee's system had not changed by more than two (2) percent. The licensee shall not use the intercomparison result to change the calibration factor. If intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall 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.

(2) The licensee shall have a dosimetry system available for use 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 subsection (1) of this section. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subsection (1) of this section.

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with this section for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:

(a) The date;

(b) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subsections (1) and (2) of this section;

1 (c) The correction factor that was determined from the calibration or comparison
2 or the apparent correction factor that was determined from an intercomparison; and

3 (d) The names of the individuals who performed the calibration, intercomparison,
4 or comparison.

5 Section 52. Full Calibration Measurements on Teletherapy Units. (1) A licensee
6 authorized to use a teletherapy unit for medical use shall perform full calibration
7 measurements on each teletherapy unit:

8 (a) Before the first medical use of the unit;

9 (b) Before medical use under the following conditions:

10 1. If spot-check measurements indicate that the output differs by more than five
11 (5) percent from the output obtained at the last full calibration corrected mathematically
12 for radioactive decay;

13 2. Following replacement of the source or following reinstallation of the
14 teletherapy unit in a new location; or

15 3. Following any repair of the teletherapy unit that includes removal of the source
16 or major repair of the components associated with the source exposure assembly; and

17 (c) At intervals not exceeding one (1) year.

18 (2) To satisfy the requirement of subsection (1) of this section, full calibration
19 measurements shall include determination of:

20 (a) The output within +/- three (3) percent for the range of field sizes and for the
21 distance or range of distances used for medical use;

22 (b) The coincidence of the radiation field and the field indicated by the light beam
23 localizing device;

1 (c) The uniformity of the radiation field and its dependence on the orientation of
2 the useful beam;

3 (d) Timer accuracy and linearity over the range of use;

4 (e) On-off error; and

5 (f) The accuracy of all distance measuring and localization devices in medical
6 use.

7 (3) A licensee shall use the dosimetry system described in Section 51(1) of this
8 administrative regulation to measure the output for one (1) set of exposure conditions.
9 The remaining radiation measurements required in subsection (2)(a) of this section may
10 be made using a dosimetry system that indicates relative dose rates.

11 (4) A licensee shall make full calibration measurements required by subsection
12 (1) of this section in accordance with published protocols accepted by nationally-
13 recognized bodies.

14 (5) A licensee shall mathematically correct the outputs determined in subsection
15 (2)(a) of this section for physical decay for intervals not exceeding one (1) month for
16 cobalt-60, six (6) months for cesium-137, or at intervals consistent with one (1) percent
17 decay for all other nuclides.

18 (6) Full calibration measurements required by subsection (1) of this section and
19 physical decay corrections required by subsection (5) of this section shall be performed
20 by the authorized medical physicist.

21 (7) A licensee shall retain a record of each calibration for three (3) years. The
22 record shall include:

23 (a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source, and the instruments used to calibrate the unit;

(c) The results and an assessment of the full calibrations;

(d) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(e) The signature of the authorized medical physicist who performed the full calibration.

Section 53. Full calibration measurements on remote afterloader units. (1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

1. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

2. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;

(c) At intervals not exceeding one (1) quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds seventy-five (75) days; and

(d) At intervals not exceeding one (1) year for low dose-rate remote afterloader units.

(2) To satisfy the requirement of subsection (1) of this section, full calibration

1 measurements shall include, as applicable, determination of:

2 (a) The output within \pm five (5) percent;

3 (b) Source positioning accuracy to within \pm one (1) millimeter;

4 (c) Source retraction with backup battery upon power failure;

5 (d) Length of the source transfer tubes;

6 (e) Timer accuracy and linearity over the typical range of use;

7 (f) Length of the applicators; and

8 (g) Function of the source transfer tubes, applicators, and transfer tube-applicator
9 interfaces.

10 (3) A licensee shall use the dosimetry system described in Section 51(1) of this
11 administrative regulation to measure the output.

12 (4) A licensee shall make full calibration measurements required by subsection
13 (1) of this section in accordance with published protocols accepted by nationally-
14 recognized bodies.

15 (5) In addition to the requirements for full calibrations for low dose-rate remote
16 afterloader units in subsection (2) of this section, a licensee shall perform an
17 autoradiograph of the source to verify inventory and source arrangement at intervals not
18 exceeding one (1) quarter.

19 (6) For low dose-rate remote afterloader units, a licensee may use
20 measurements provided by the source manufacturer that are made in accordance with
21 subsections (1) through (5) of this section.

22 (7) A licensee shall mathematically correct the outputs determined in subsection
23 (2)(a) of this section for physical decay at intervals consistent with one (1) percent

1 physical decay.

2 (8) Full calibration measurements required by subsection (1) of this section and
3 physical decay corrections required by subsection (7) of this section shall be performed
4 by the authorized medical physicist.

5 (9) A licensee shall retain a record of each calibration for three (3) years. The
6 record shall include:

7 (a) The date of the calibration;

8 (b) The manufacturer's name, model number, and serial number of the
9 teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source,
10 and the instruments used to calibrate the unit;

11 (c) The results and an assessment of the full calibrations;

12 (d) The results of the autoradiograph required for low dose-rate remote
13 afterloader units; and

14 (e) The signature of the authorized medical physicist who performed the full
15 calibration.

16 Section 54. Full calibration measurements on gamma stereotactic radiosurgery
17 units (1) A licensee authorized to use a gamma stereotactic radiosurgery unit for
18 medical use shall perform full calibration measurements on each unit:

19 (a) Before the first medical use of the unit;

20 (b) Before medical use under the following conditions:

21 1. Whenever spot-check measurements indicate that the output differs by more
22 than five (5) percent from the output obtained at the last full calibration corrected.

23 2. Following replacement of the sources or following reinstallation of the gamma

1 mathematically for radioactive decay, stereotactic radiosurgery unit in a new location,
2 and

3 3. Following any repair of the gamma stereotactic radiosurgery unit that includes
4 removal of the sources or major repair of the components associated with the source
5 assembly; and

6 (c) At intervals not exceeding one (1) year, with the exception that relative helmet
7 factors need only be determined before the first medical use of a helmet and following
8 any damage to a helmet.

9 (2) To satisfy the requirement of subsection (1) of this section, full calibration
10 measurements shall include determination of:

- 11 (a) The output within \pm three (3) percent;
- 12 (b) Relative helmet factors;
- 13 (c) Isocenter coincidence;
- 14 (d) Timer accuracy and linearity over the range of use;
- 15 (e) On-off error;
- 16 (f) Trunnion centricity;
- 17 (g) Treatment table retraction mechanism, using backup battery power or
18 hydraulic backups with the unit off;
- 19 (h) Helmet microswitches;
- 20 (i) Emergency timing circuits; and
- 21 (j) Stereotactic frames and localizing devices (trunnions).

22 (3) A licensee shall use the dosimetry system described in Section 51(1) of this
23 administrative regulation to measure the output for one (1) set of exposure conditions.

1 The remaining radiation measurements required in subsection (2)(a) of this section may
2 be made using a dosimetry system that indicates relative dose rates.

3 (4) A licensee shall make full calibration measurements required by subsection
4 (1) of this section in accordance with published protocols accepted by nationally
5 recognized bodies.

6 (5) A licensee shall mathematically correct the outputs determined in subsection
7 (2)(a) of this section at intervals not exceeding one (1) month for cobalt-60 and at
8 intervals consistent with one (1) percent physical decay for all other radionuclides.

9 (6) Full calibration measurements required by subsection (1) of this section and
10 physical decay corrections required by subsection (5) of this section shall be performed
11 by the authorized medical physicist.

12 (7) A licensee shall retain a record of each calibration for three (3) years. The
13 record shall include:

14 (a) The date of the calibration;

15 (b) The manufacturer's name, model number, and serial number of the
16 teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source,
17 and the instruments used to calibrate the unit;

18 (c) The results and an assessment of the full calibrations;

19 (d) The results of the autoradiograph required for low dose-rate remote
20 afterloader units; and

21 (e) The signature of the authorized medical physicist who performed the full
22 calibration.

23 Section 55. Periodic Spot-checks for Teletherapy Units. (1) A licensee authorized

1 to use teletherapy units for medical use shall perform output spot-checks on each
2 teletherapy unit once in each calendar month that shall include determination of:

3 (a) Timer accuracy, and timer linearity over the range of use;

4 (b) On-off error;

5 (c) The coincidence of the radiation field and the field indicated by the light beam
6 localizing device;

7 (d) The accuracy of all distance measuring and localization devices used for
8 medical use;

9 (e) The output for one (1) typical set of operating conditions measured with the
10 dosimetry system described in Section 51(2) of this administrative regulation; and

11 (f) The difference between the measurement made in subsection (1)(e) of this
12 section and the anticipated output, expressed as a percentage of the anticipated output
13 (i.e., the value obtained at last full calibration corrected mathematically for physical
14 decay).

15 (2) A licensee shall perform measurements required by subsection (1) of this
16 section in accordance with written procedures established by the authorized medical
17 physicist. That individual shall not be required to actually perform the spot-check
18 measurements.

19 (3) A licensee shall have the authorized medical physicist review the results of
20 each spot-check within fifteen (15) days. The authorized medical physicist shall notify
21 the licensee as soon as possible in writing of the results of each spot-check.

22 (4) A licensee authorized to use a teletherapy unit for medical use shall perform
23 safety spot-checks of each teletherapy facility once in each calendar month and after

1 each source installation to assure proper operation of:

2 (a) Electrical interlocks at each teletherapy room entrance;

3 (b) Electrical or mechanical stops installed for the purpose of limiting use of the
4 primary beam of radiation (restriction of source housing angulation or elevation, carriage
5 or stand travel and operation of the beam on-off mechanism);

6 (c) Source exposure indicator lights on the teletherapy unit, on the control
7 console, and in the facility;

8 (d) Viewing and intercom systems;

9 (e) Treatment room doors from inside and outside the treatment room; and

10 (f) Electrically assisted treatment room doors with the teletherapy unit electrical
11 power turned off.

12 (5) If the results of the checks required in subsection (4) of this section indicate
13 the malfunction of any system, a licensee shall lock the control console in the off
14 position and shall not use the unit except as may be necessary to repair, replace, or
15 check the malfunctioning system.

16 (6) A licensee shall retain a record of each spot-check for teletherapy units for
17 three (3) years. The record shall include:

18 (a) The date of the spot-check;

19 (b) The manufacturer's name, model number, and serial number of the
20 teletherapy unit, source and instrument used to measure the output of the teletherapy
21 unit;

22 (c) An assessment of timer linearity and constancy;

23 (d) The calculated on-off error;

1 (e) A determination of the coincidence of the radiation field and the field indicated
2 by the light beam localizing device;

3 (f) The determined accuracy of each distance measuring and localization device;

4 (g) The difference between the anticipated output and the measured output;

5 (h) Notations indicating the operability of each entrance door electrical interlock,
6 each electrical or mechanical stop, each source exposure indicator light, and the
7 viewing and intercom system and doors; and

8 (i) The name of the individual who performed the periodic spot-check and the
9 signature of the authorized medical physicist who reviewed the record of the spot-
10 check.

11 (7) A licensee shall retain a copy of the procedures required by subsection (2) of
12 this section until the licensee no longer possesses the teletherapy unit.

13 Section 56. Periodic Spot-checks for Remote Afterloader Units. (1) A licensee
14 authorized to use a remote afterloader unit for medical use shall perform spot-checks of
15 each remote afterloader facility and on each unit:

16 (a) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-
17 rate remote afterloader unit on a given day;

18 (b) Before each patient treatment with a low dose-rate remote afterloader unit;
19 and

20 (c) After each source installation.

21 (2) A licensee shall perform the measurements required by subsection (1) of this
22 section in accordance with written procedures established by the authorized medical
23 physicist. That individual shall not be required to actually perform the spot check

1 measurements.

2 (3) A licensee shall have the authorized medical physicist review the results of
3 each spot-check within fifteen (15) days. The authorized medical physicist shall notify
4 the licensee as soon as possible in writing of the results of each spot-check.

5 (4) To satisfy the requirements of subsection (1) of this section, spot-checks
6 shall, at a minimum, assure proper operation of:

7 (a) Electrical interlocks at each remote afterloader unit room entrance;

8 (b) Source exposure indicator lights on the remote afterloader unit, on the control
9 console, and in the facility;

10 (c) Viewing and intercom systems in each high dose-rate, medium dose-rate, and
11 pulsed dose-rate remote afterloader facility;

12 (d) Emergency response equipment;

13 (e) Radiation monitors used to indicate the source position;

14 (f) Timer accuracy;

15 (g) Clock (date and time) in the unit's computer; and

16 (h) Decayed source activity in the unit's computer.

17 (5) If the results of the checks required in subsection (4) of this section indicate
18 the malfunction of any system, a licensee shall lock the control console in the off
19 position and shall not use the unit except as may be necessary to repair, replace, or
20 check the malfunctioning system.

21 (6) A licensee shall retain a record of each spot-check for remote afterloader
22 units for three (3) years. The record shall include, as applicable:

23 (a) The date of the spot-check;

1 (b) The manufacturer's name, model number, and serial number for the remote
2 afterloader unit and source;

3 (c) An assessment of timer accuracy;

4 (d) Notations indicating the operability of each entrance door electrical interlock,
5 radiation monitors, source exposure indicator lights, viewing and intercom systems, and
6 clock and decayed source activity in the unit's computer; and

7 (e) The name of the individual who performed the periodic spot-check and the
8 signature of the authorized medical physicist who reviewed the record of the spot-
9 check.

10 (7) A licensee shall retain a copy of the procedures required by subsection (2) of
11 this section until the licensee no longer possesses the remote afterloader unit.

12 Section 57. Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

13 (1) A licensee authorized to use a gamma stereotactic radiosurgery unit for
14 medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility
15 and on each unit:

16 (a) Monthly;

17 (b) Before the first use of the unit on a given day; and

18 (c) After each source installation.

19 (2) A licensee shall:

20 (a) Perform the measurements required by subsection (1) of this section in
21 accordance with written procedures established by the authorized medical physicist.

22 That individual shall not be required to actually perform the spot check measurements.

23 (b) Have the authorized medical physicist review the results of each spot-check

1 within fifteen (15) days. The authorized medical physicist shall notify the licensee as
2 soon as possible in writing of the results of each spot-check.

3 (3) To satisfy the requirements of subsection (1)(a) of this section, spot-checks
4 shall, at a minimum:

5 (a) Assure proper operation of:

6 1. Treatment table retraction mechanism, using backup battery power or
7 hydraulic backups with the unit off;

8 2. Helmet microswitches;

9 3. Emergency timing circuits; and

10 4. Stereotactic frames and localizing devices (trunnions).

11 (b) Determine:

12 1. The output for one (1) typical set of operating conditions measured with the
13 dosimetry system described in Section 51(2) of this administrative regulation;

14 2. The difference between the measurement made in subsection (3)(b)1. of this
15 section and the anticipated output, expressed as a percentage of the anticipated output
16 (the value obtained at last full calibration corrected mathematically for physical decay);

17 3. Source output against computer calculation;

18 4. Timer accuracy and linearity over the range of use;

19 5. On-off error; and

20 6. Trunnion centricity.

21 (4) To satisfy the requirements of subsection (1)(b) and (c) of this section, spot-
22 checks shall assure proper operation of:

23 (a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

1 (b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit,
2 on the control console, and in the facility;

3 (c) Viewing and intercom systems;

4 (d) Timer termination;

5 (e) Radiation monitors used to indicate room exposures; and

6 (f) Emergency off buttons.

7 (5) A licensee shall arrange for the repair of any system identified in subsection
8 (3) of this section that is not operating properly as soon as possible.

9 (6) If the results of the checks required in subsection (4) of this section indicate
10 the malfunction of any system, a licensee shall lock the control console in the off
11 position and shall not use the unit except as may be necessary to repair, replace, or
12 check the malfunctioning system.

13 (7) A licensee shall retain a record of each spot-check for gamma stereotactic
14 radiosurgery units required by this section for three (3) years. The record shall include:

15 (a) The date of the spot-check;

16 (b) The manufacturer's name, model number, and serial number for the gamma
17 stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

18 (c) An assessment of timer linearity and accuracy;

19 (d) The calculated on-off error;

20 (e) A determination of trunnion centricity;

21 (f) The difference between the anticipated output and the measured output;

22 (g) An assessment of source output against computer calculations;

23 (h) Notations indicating the operability of radiation monitors, helmet

1 microswitches, emergency timing circuits, emergency off buttons, electrical interlocks,
2 source exposure indicator lights, viewing and intercom systems, timer termination,
3 treatment table retraction mechanism, and stereotactic frames and localizing devices
4 (trunnions); and

5 (i) The name of the individual who performed the periodic spot-check and the
6 signature of the authorized medical physicist who reviewed the record of the spot-
7 check.

8 (8) A licensee shall retain a copy of the procedures required by subsection (2) of
9 this section until the licensee no longer possesses the gamma stereotactic radiosurgery
10 unit.

11 Section 58. Additional Technical Requirements for Mobile Remote Afterloader
12 Units. (1) A licensee providing mobile remote afterloader service shall:

13 (a) Check survey instruments before medical use at each address of use or on
14 each day of use, whichever is more frequent; and

15 (b) Account for all sources before departure from a client's address of use.

16 (2) In addition to the periodic spot-checks required by Section 56 of this
17 administrative regulation a licensee authorized to use mobile afterloaders for medical
18 use shall perform checks on each remote afterloader unit before use at each address of
19 use. At a minimum, checks shall be made to verify the operation of:

20 (a) Electrical interlocks on treatment area access points;

21 (b) Source exposure indicator lights on the remote afterloader unit, on the control
22 console, and in the facility;

23 (c) Viewing and intercom systems;

1 (d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;
2 (e) Radiation monitors used to indicate room exposures;
3 (f) Source positioning (accuracy); and
4 (g) Radiation monitors used to indicate whether the source has returned to a safe
5 shielded position.

6 (3) In addition to the requirements for checks in subsection (2) of this section, a
7 licensee shall ensure overall proper operation of the remote afterloader unit by
8 conducting a simulated cycle of treatment before use at each address of use.

9 (4) If the results of the checks required in subsection (2) of this section indicate
10 the malfunction of any system, a licensee shall lock the control console in the off
11 position and shall not use the unit except as may be necessary to repair, replace, or
12 check the malfunctioning system.

13 (5) A licensee shall retain a record of each check for mobile remote afterloader
14 units for three (3) years. The record shall include:

- 15 (a) The date of the check;
- 16 (b) The manufacturer's name, model number, and serial number of the remote
17 afterloader unit;
- 18 (c) Notations accounting for all sources before the licensee departs from a
19 facility;
- 20 (d) Notations indicating the operability of each entrance door electrical interlock,
21 radiation monitors, source exposure indicator lights, viewing and intercom system,
22 applicators, source transfer tubes, and transfer tube applicator interfaces, and source
23 positioning accuracy; and

1 (e) The signature of the individual who performed the check.

2 Section 59. Radiation Surveys. (1) In addition to the survey requirement in 902
3 KAR 100:019, Section 12, a person licensed under this administrative regulation shall
4 conduct surveys to ensure that the maximum radiation levels and average radiation
5 levels from the surface of the main source safe with the source in the shielded position
6 do not exceed the levels stated in the Sealed Source and Device Registry.

7 (2) The licensee shall conduct the survey required by subsection (1) of this
8 section at installation of a new source and following repairs to the source shielding, the
9 source driving unit, or other electronic or mechanical component that could expose the
10 source, reduce the shielding around the source, or compromise the radiation safety of
11 the unit or the source.

12 (3) A licensee shall maintain a record of radiation surveys of treatment units for
13 the duration of use of the unit. The record shall include:

14 (a) The date of the measurements;

15 (b) The manufacturer's name, model number and serial number of the treatment
16 unit, source, and instrument used to measure radiation levels;

17 (c) Each dose rate measured around the source while the unit is in the off
18 position and the average of all measurements; and

19 (d) The signature of the individual who performed the test.

20 Section 60. Five (5) year Inspection for Teletherapy and Gamma Stereotactic
21 Radiosurgery Units. (1) A licensee shall have each teletherapy unit and gamma
22 stereotactic radiosurgery unit fully inspected and serviced during source replacement or
23 at intervals not to exceed five (5) years, whichever comes first, to assure proper

functioning of the source exposure mechanism.

(2) This inspection and servicing may only be performed by persons specifically licensed to do so by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state.

(3) A licensee shall maintain a record of the five (5) year inspections for teletherapy and gamma stereotactic radiosurgery units for the duration of use of the unit. The record shall contain:

(a) The inspector's radioactive materials license number;

(b) The date of inspection;

(c) The manufacturer's name and model number and serial number of both the treatment unit and source;

(d) A list of components inspected and serviced, and the type of service; and

(e) The signature of the inspector.

Section 61. Therapy-related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

(1) The source-specific input parameters required by the dose calculation algorithm;

(2) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) The accuracy of isodose plots and graphic displays;

1 (4) The accuracy of the software used to determine sealed source positions from
2 radiographic images; and

3 (5) The accuracy of electronic transfer of the treatment delivery parameters to the
4 treatment delivery unit from the treatment planning system.

5 Section 62. Other Medical Uses of Radioactive Material or Radiation from
6 Radioactive Material. A licensee may use radioactive material or a radiation source
7 approved for medical use which is not specifically addressed in Sections 30, 31, 33, 37,
8 45, and 46 of this administrative regulation if:

9 (1) The applicant or licensee has submitted the information required by Section
10 4(2) through (4) of this administrative regulation; and

11 (2) The applicant or licensee has received written approval from the cabinet in a
12 license or license amendment and uses the material in accordance with the
13 administrative regulations and specific conditions the cabinet considers necessary for
14 the medical use of the material.

15 Section 63. Recentness of Training. The training and experience specified in
16 Sections 64 through 77 of this administrative regulation shall have been obtained within
17 the seven (7) years preceding the date of application or the individual shall have had
18 related continuing education and experience since the required training and experience
19 was completed.

20 Section 64. Training for Radiation Safety Officer. Except as provided in Section
21 67 of this administrative regulation, the licensee shall require an individual fulfilling the
22 responsibilities of the radiation safety officer as provided in 902 KAR 100:072, Section
23 10 to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an ~~[equivalent]~~ agreement state and who meets the requirements in subsections (4) and (5) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a)1. 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 twenty (20) college credits in physical science;

2. Have five (5) or more years of professional experience in health physics (graduate training may be substituted for no more than two (2) years of the required experience) including at least three (3) years in applied health physics; and

3. 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 measurements of radioactivity, radiation biology, and radiation dosimetry; or

(b)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;

2. Have two (2) years of full-time practical training, two (2) years of supervised experience, or two (2) years of a combination of full-time practical training and supervised experience in medical physics;

a. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the cabinet, U.S. Nuclear Regulatory Commission,

1 or an ~~equivalent~~ agreement state; or

2 b. In clinical nuclear medicine facilities providing diagnostic or therapeutic
3 services under the direction of physicians who meet the requirements for authorized
4 users in 902 KAR 100:072, Sections 67, 69, or 70 of this administrative regulation;

5 3. Pass an examination, administered by diplomats of the specialty board, that
6 assesses knowledge and competence in clinical diagnostic radiological or nuclear
7 medicine physics and in radiation safety; or

8 (2)(a) Has completed a structured educational program consisting of both:

9 1. 200 hours of classroom and laboratory training in the following areas:

10 a. Radiation physics and instrumentation;

11 b. Radiation protection;

12 c. Mathematics pertaining to the use and measurement of radioactivity;

13 d. Radiation biology; and

14 e. Radiation dosimetry; and

15 2. One (1) year of full-time radiation safety experience under the supervision of
16 the individual identified as the radiation safety officer on a cabinet, U.S. Nuclear
17 Regulatory Commission, or ~~equivalent~~ agreement state license or permit issued by a
18 Commission master material licensee that authorizes similar type of use of radioactive
19 material involving the following:

20 a. Shipping, receiving, and performing related radiation surveys;

21 b. Using and performing checks for proper operation of instruments used to
22 determine the activity of dosages, survey meters, and instruments used to measure
23 radionuclides;

- c. Securing and controlling radioactive material;
- d. Using administrative controls to avoid mistakes in the administration of radioactive material;
- e. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- f. Using emergency procedures to control radioactive material; and
- g. Disposing of radioactive material: or

(3)(a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an [equivalent] agreement state pursuant to ~~[under]~~ 902 KAR 100:072, Section 65(1), 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 requirements in subsections (4) and (5) of this section; or

(b) 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

(4) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsections (5) and in (1)(a)1 and 2 or (1)(b)1 and 2 or (2)(a) or (3)(a) or (3)(b) 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

1 (5) Has training in the radiation safety, regulatory issues, and emergency
2 procedures for the types of use for which a licensee seeks approval. This training
3 requirement may be satisfied by completing training that is supervised by a radiation
4 safety officer, authorized medical physicist, authorized nuclear pharmacist, or
5 authorized user, as appropriate, who is authorized for the type of use for which the
6 licensee is seeking approval.

7 Section 65. Training for an Authorized Medical Physicist. Except as provided in
8 Section 67 of this administrative regulation the licensee shall require the authorized
9 medical physicist to be an individual who:

10 (1) Is certified by a specialty board whose certification process has been
11 recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an ~~[equivalent]~~
12 agreement state and who meets the requirements in subsection (2)(b) and (3) of this
13 section. To have its certification process recognized, a specialty board shall require all
14 candidates for certification to:

15 (a) Hold a master's or doctor's degree in physics, medical physics, other physical
16 science, engineering, or applied mathematics from an accredited college or university;

17 (b) Have ~~[a]~~ two (2) years of full-time practical training, two (2) years of
18 supervised experience, or two (2) years of a combination of full-time practical training
19 and supervised experience in medical physics:

20 1. Under the supervision of a medical physicist who is certified in medical physics
21 by a specialty board recognized by the cabinet, U.S. Nuclear Regulatory Commission,
22 or an ~~[equivalent]~~ agreement state; or

23 2. In clinical radiation facilities providing high-energy, external beam therapy

(photons and electrons with energies greater than or equal to one (1) million electron volts) and brachytherapy services under the direction of physicians who meet the requirements ~~[of authorized users]~~ in Section 67, 74, or 77 of this administrative regulation, and

(c) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2)(a) 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 (1) year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provides high-energy, external beam therapy (photons and electrons with energies greater than or equal to one (1) million electron volts) and brachytherapy services and shall include:

1. Performing sealed source leak test and inventories;
2. Performing decay corrections;
3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (3), and (1)(a) and (b), or subsection (2)(a) and (3) 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 shall be signed by a preceptor authorized medical physicist who meets the requirements in Sections 65 or 67 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or [~~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

(3) Has training for the type of use for which authorization is sought that includes hands-on device operation, safety operations, clinical use, and the operation of a treatment planning system. This training requirement shall 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 of use for which the individual is seeking authorization.

Section 66. Training for an Authorized Nuclear Pharmacist. Except as provided in Section 67 of this administrative regulation the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified by a specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an [~~equivalent~~] agreement state and who meets the requirements in subsection (2)(b) of this section. To have its certification process recognized, a specialty board shall require all

1 candidates for certification to:

2 (a) Have graduated from a pharmacy program accredited by the American
3 Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy
4 Graduate Examination Committee (FPGEC) examination;

5 (b) Hold a current, active license to practice pharmacy;

6 (c) Provide evidence of having acquired at least 4,000 hours of training and
7 experience in nuclear pharmacy practice. Academic training may be substituted for no
8 more than 2,000 hours of the required training and experience; and

9 (d) Pass an examination in nuclear pharmacy administered by diplomats of the
10 specialty board, that assesses knowledge and competency in procurement,
11 compounding, quality assurance, dispensing, distribution, health and safety, radiation
12 safety, provision of information and consultation, monitoring patient outcomes, research
13 and development; or

14 (2)(a) Has completed 700 hours in a structured educational program consisting of
15 both:

16 1. 200 hours of classroom and laboratory training in the following areas:

17 a. Radiation physics and instrumentation;

18 b. Radiation protection;

19 c. Mathematics pertaining to the use and measurement of radioactivity;

20 d. Chemistry of radioactive material for medical use; and

21 e. Radiation biology; and

22 2. Supervised practical experience in a nuclear pharmacy involving:

23 a. Shipping, receiving, and performing related radiation surveys;

1 b. Using and performing checks for proper operation of instruments used to
2 determine the activity of dosages, survey meters, and, if appropriate, instruments used
3 to measure alpha- or beta-emitting radionuclides;

4 c. Calculating, assaying, and safely preparing dosages for patients or human
5 research subjects;

6 d. Using administrative controls to avoid medical events in the administration of
7 radioactive material; and

8 e. Using procedures to prevent or minimize radioactive contamination and using
9 proper decontamination procedures; and

10 (b) Has obtained written attestation, signed by a preceptor authorized nuclear
11 pharmacist, that the individual has satisfactorily completed the requirements in
12 subsections (1)(a), (1)(b) and (1)(c) or (2)(a) of this section and has achieved a level of
13 competency sufficient to function independently as an authorized nuclear pharmacist.

14 Section 67. Training for Experienced Radiation Safety Officer, Teletherapy or
15 Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist
16 and Authorized Nuclear Pharmacist.

17 (1)(a) An individual identified as a Radiation Safety Officer, a teletherapy or
18 medical physicist, or a nuclear pharmacist on a cabinet, U.S. Nuclear Regulatory
19 Commission, or ~~[equivalent]~~ agreement state license or a permit issued by the cabinet,
20 U.S. Nuclear Regulatory Commission, or an ~~[equivalent]~~ agreement state broad scope
21 licensee or master material license permit or by a master material license permittee of
22 broad scope before October 24, 2005 shall not be required to comply with the training
23 requirements of Section 64, 65, or 66, of this administrative regulation respectively:

1 (b) An individual identified as a radiation safety officer, an authorized medical
2 physicist, or an authorized nuclear pharmacist on a cabinet, U.S. Nuclear Regulatory
3 Commission, or ~~[equivalent]~~ agreement state license or a permit issued by the cabinet,
4 U.S. Nuclear Regulatory Commission, or an agreement state broad scope licensee or
5 master material license permit or master material licensee permittee of broad scope
6 between October 24, 2002 and April 29, 2005 is not required to comply with the training
7 requirements of Section 64, 65, or 66 of this administration regulation respectively.

8 (2)(a) Physicians, dentists, or podiatrists identified as authorized users for the
9 medical use of radioactive material on a license issued by the cabinet, U.S. Nuclear
10 Regulatory Commission, or an ~~[equivalent]~~ agreement state, a permit issued by a
11 Commission master material licensee, a permit issued by the cabinet, U.S. Nuclear
12 Regulatory Commission, or an ~~[equivalent]~~ agreement state broad scope licensee, or a
13 permit issued by a Commission master material license broad scope permittee before
14 October 24, 2002 who perform only those medical uses for which they were authorized
15 on that date shall not be required to comply with the training requirements of 902 KAR
16 100:072, Sections 68 through 77.

17 (b) Physicians, dentists, or podiatrists identified as authorized users for the
18 medical use of radioactive material on a license issued by the cabinet, U.S. Nuclear
19 Regulatory Commission, or an ~~[equivalent]~~ agreement state, a permit issued by a
20 Commission master material licensee, a permit issued by the cabinet, U.S. Nuclear
21 Regulatory Commission or an agreement state broad scope licensee or a permit issued
22 by a ~~[U.S. Nuclear Regulatory]~~ Commission master material license broad scope
23 permittee who performs only those medical uses for which they were authorized

1 between October 24, 2002 and April 29, 2005 shall not be required to comply with the
2 training requirements of 902 KAR 100:072, Sections 68 through 77.

3 Section 68. Training for Uptake, Dilution, and Excretion Studies. Except as
4 provided in Section 67 of this administrative regulation the licensee shall require an
5 authorized user of unsealed radioactive material for the uses authorized pursuant to
6 ~~[under]~~ Section 30 of this administrative regulation to be a physician who:

7 (1)(a) Is certified by a medical specialty board whose certification process
8 ~~[includes all of the requirements in subsection (3)(b) of this section and who]~~ has been
9 recognized by the cabinet, U.S. Nuclear Regulatory Commission or an ~~[equivalent]~~
10 agreement state and who meets the requirements in subsection (3)(b) of this section.
11 To have its certification process recognized, a specialty board shall require all
12 candidates for certification to:

13 1. Complete sixty (60) hours of training and experience in basic radionuclide
14 handling techniques and radiation safety applicable to the medical use of unsealed
15 radioactive material for uptake, dilution, and excretion studies as described in
16 subsection (3)(a)1 through 3(a)2 of this section; and

17 2. Pass an examination, administered by diplomats of the specialty board, that
18 assesses knowledge and competence in radiation safety, radionuclide handling, and
19 quality control; or

20 (2) Is an authorized user under Section 69 or 70 ~~[70;]~~ of this administrative
21 regulation, ~~[regulation]~~ or equivalent U.S. Nuclear Regulatory Commission or
22 ~~[equivalent]~~ agreement state requirements; or

23 (3)(a) Has completed sixty (60) hours of training and experience, including a

1 minimum of eight (8) hours of classroom and laboratory training, in basic radionuclide
2 handling techniques applicable to the medical use of unsealed radioactive material for
3 uptake, dilution, and excretion studies. The training and experience shall include:

4 1. Classroom and laboratory training, in the following areas;

5 a. Radiation physics and instrumentation;

6 b. Radiation protection;

7 c. Mathematics pertaining to the use and measurement of radioactivity;

8 d. Chemistry of radioactive material for medical use; and

9 e. Radiation biology; and

10 2. Work experience, under the supervision of an authorized user who meets the
11 requirements in Section 67, 68, 69, or 70, of this administrative regulation, or equivalent
12 U.S. Nuclear Regulatory Commission or [~~or equivalent~~] agreement state requirements,
13 involving:

14 a. Ordering, receiving, and unpacking radioactive materials safely and performing
15 the related radiation surveys;

16 b. Performing quality control procedures on instruments used to determine the
17 activity of dosages and performing checks for proper operation of survey meters;

18 c. Calculating, measuring, and safely preparing patient or human research
19 subject dosages;

20 d. Using administrative controls to prevent a medical event involving the use of
21 unsealed radioactive material;

22 e. Using procedures to contain spilled radioactive material safely and using
23 proper decontamination procedures; and

1 f. Administering dosages of radioactive drugs to patients or human research
2 subjects; and

3 (b) Has obtained written attestation, signed by a preceptor authorized user who
4 meets the requirements in Section 67, 68, 69, or 70 of this administrative regulation, or
5 equivalent U.S. Nuclear Regulatory Commission or [~~or equivalent~~] agreement state
6 requirements, that the individual has satisfactorily completed the requirements in
7 subsection (1)(a) or (3)(a) of this section and has achieved a level of competency
8 sufficient to function independently as an authorized user for the medical uses
9 authorized pursuant to [~~under~~] Section 30 of this administrative regulation.

10 Section 69. Training for Imaging and Localization Studies. Except as provided in
11 Section 67 of this administrative regulation the licensee shall require an authorized user
12 of unsealed radioactive material for the uses authorized pursuant to [~~under~~] Section 31
13 of this administrative regulation to be a physician who:

14 (1) Is certified by a medical specialty board whose certification process has been
15 recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an [~~equivalent~~]
16 agreement state and who meets the requirements in subsection (3)(b) of this section.
17 To have its certification process recognized, a specialty board shall require all
18 candidates for certification to:

19 (a) Complete 700 hours of training and experience in basis radionuclide handling
20 techniques and radiation safety applicable to the medical use of unsealed radioactive
21 material for imaging and localization studies that includes the topics listed in subsection
22 (3)(a)1 through (3)(a)2 of this section; and

23 (b) Pass an examination, administered by diplomats of the specialty board, which

assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) Is an authorized user pursuant to ~~[under]~~ Section 70 of this administrative regulation and meets the requirements in subsection (3)(a)2.g of this section, or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state requirements; or

(3) (a) Has completed 700 hours of training and experience, including a minimum of eighty (80) hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include, at a minimum:

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

2. Work experience, under the supervision of an authorized user, who meets the requirements in Section 67, 69 or 70 and Section 69(3)(a)2.g of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state requirements, involving:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the

activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

f. Administering dosages of radioactive drugs to patients or human research subjects; and

g. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(b) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Sections 67, 69, or 70 and ~~[or]~~ Section 69(3)(a)2.g of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[or equivalent]~~ agreement state requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or (3)(a) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized pursuant to ~~[under]~~ Sections 30 and 31 of this administrative regulation.

Section 70. Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required. Except as provided in Section 67 of this administrative

1 regulation the licensee shall require an authorized user of unsealed radioactive material
2 for the uses authorized pursuant to ~~[under]~~ Section 33 of this administrative regulation
3 to be a physician who:

4 (1) Is certified by a medical specialty board whose certification process has been
5 recognized by the cabinet, U.S. Nuclear Regulatory Commission or an ~~[equivalent]~~
6 agreement state, and who meets the requirements in subsection (2)(a)2.f and (b) of this
7 section. To be recognized, a specialty board shall require all candidates for certification
8 to:

9 (a) Successfully complete residency training in a radiation therapy or nuclear
10 medicine training program or a program in a related medical specialty. These residency
11 training programs shall include 700 hours of training and experience as described in
12 subsection (2)(a)1 through 2.e of this section. Eligible training programs shall be
13 approved by:

14 1. Residency Review Committee of the Accreditation Council for Graduate
15 Medical Education;

16 2. Royal College of Physicians and Surgeons of Canada; or

17 3. Committee on Post-Graduate Training of the American Osteopathic
18 Association; and

19 (b) Pass an examination, administered by the diplomats of the specialty board,
20 which tests knowledge and competence in radiation safety, radionuclide handling,
21 quality assurance, and clinical use of unsealed radioactive material for which a written
22 directive is required; or

23 (2)(a) Has completed 700 hours of training and experience, including a minimum

1 ~~of~~ [or] 200 hours of classroom and laboratory training, in basic radionuclide handling
2 techniques applicable to the medical use of unsealed radioactive material requiring a
3 written directive. The training and experience shall include:

4 1. Classroom and laboratory training in the following areas:

5 a. Radiation physics and instrumentation;

6 b. Radiation protection;

7 c. Mathematics pertaining to the use and measurement of radioactivity;

8 d. Chemistry of radioactive material for medical use; and

9 e. Radiation biology; and

10 2. Work experience, under the supervision of an authorized user who meets the
11 requirements in this section, or Section 67 [~~of Sections 67 and 70~~] of this administrative
12 regulation, or equivalent U.S. Nuclear Regulatory Commission or [~~or equivalent~~]
13 agreement state requirements. A supervising authorized user, who meets the
14 requirements in Section 70(2) of this administrative regulation, shall have experience in
15 administering dosages in the same dosage category or categories (Section 70(2)(a)2.f)
16 of this administrative regulation as the individual requesting authorized user status. The
17 work experience shall involve:

18 a. Ordering, receiving, and unpacking radioactive materials safely and performing
19 the related radiation surveys;

20 b. Performing quality control procedures on instruments used to determine the
21 activity of dosages, and performing checks for proper operation of survey meters;

22 c. Calculating, measuring, and safely preparing patient or human research
23 subject dosages;

1 d. Using administrative controls to prevent a medical event involving the use of
2 unsealed radioactive material;

3 e. Using procedures to contain spilled radioactive material safely and using
4 proper decontamination procedures;

5 f. Administering dosages of radioactive drugs to patients or human research
6 subjects involving a minimum of three (3) cases in each of the following categories for
7 which the individual is requesting authorized user status:

8 (i) Oral administration of less than or equal to 1.22 Gigabecquerels (33
9 millicuries) of sodium iodide I-131, for which a written directive is required;

10 (ii) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of
11 sodium iodide I-131;

12 (iii) Parenteral administration of any beta emitter or a photon-emitting
13 radionuclide with a photon energy less than 150 keV, for which a written directive is
14 required; or

15 (iv) Parenteral administration of any other radionuclide, for which a written
16 directive is required; and

17 (b) Has obtained written attestation that the individual has satisfactorily
18 completed the requirements in subsection (1)(a) and (2)(a)2.f or (2)(a) of this section,
19 and has achieved a level of competency sufficient to function independently as an
20 authorized user for the medical uses authorized pursuant to ~~[under]~~ Section 33 of this
21 administrative regulation. The written attestation shall be signed by a preceptor
22 authorized user who meets the requirements of this section, and section 67 of this
23 administrative regulation, or equivalent ~~[regulation—or]~~ U.S. Nuclear Regulatory

Commission or [~~or equivalent~~] agreement state requirements. The preceptor authorized user, who meets the requirements in subsection (2) of this section, shall have experience in administering dosages in the same dosage category or categories (Section 70(2)(a)2.f) of this administrative regulation as the individual requesting authorized user status.

Section 71. 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). Except as provided in Section 67 of this administrative regulation, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3)(a) and (b) of this section and whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an [~~equivalent~~] agreement state and who meets the requirements in subsection (3)(c) of this section;

(2) Is an authorized user pursuant to [~~under~~] Section 70 of this administrative regulation for uses listed in Section 70(2)(a)2.f.(i) [~~70(2)(a)2.f.(i);~~] or (ii), or Section 72 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or [~~or equivalent~~] agreement state requirements; or

(3) (a) Has successfully completed eighty (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 shall include:

- 1 1. Radiation physics and instrumentation;
- 2 2. Radiation protection;
- 3 3. Mathematics pertaining to the use and measurement of radioactivity;
- 4 4. Chemistry of radioactive material for medical use; and
- 5 5. Radiation biology; and

6 (b) Has work experience, under the supervision of an authorized user who meets
7 the requirements in Section 67, 70, 71,, or 72 of this administrative regulation, or
8 equivalent U.S. Nuclear Regulatory Commission or [~~or equivalent~~] agreement state
9 requirements. A supervising authorized user who meets the requirements in Section 70
10 (2)(a) of this administrative regulation shall have experience in administering dosages
11 as specified in Section 70(2)(a)2.f.(i) or (ii) of this administrative regulation. The work
12 experience shall involve:

13 1. Ordering, receiving, and unpacking radioactive materials safely and performing
14 the related radiation surveys;

15 2. Performing quality control procedures on instruments used to determine the
16 activity of dosages and performing checks for proper operation for survey meters;

17 3. Calculating, measuring, and safely preparing patient or human research
18 subject dosages;

19 4. Using administrative controls to prevent a medical event involving the use of
20 radioactive material;

21 5. Using procedures to contain spilled radioactive material safely and using
22 proper decontamination procedures; and

23 6. Administering dosages to patients or human research subjects, that includes

1 at least three (3) cases involving the oral administration of less than or equal to 1.22
2 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

3 (c) Has obtained written attestation that the individual has satisfactorily
4 completed the requirements in subsection (3)(a) and (b) of this section and has
5 achieved a level of competency sufficient to function independently as an authorized
6 user for medical uses authorized pursuant to ~~[under]~~ Section 33 of this administrative
7 regulation. The written attestation shall be signed by a preceptor authorized user who
8 meets the requirements in Section 67, 70, 71, or 72 of this administrative regulation, or
9 equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state
10 requirements. A preceptor authorized user, who meets the requirement in Section 70(2)
11 of this administrative regulation shall also have experience in administering dosages as
12 specified in Section 70(2)(a)2.f.(i) or (ii) of this administrative regulation.

13 Section 72. Training for the oral administration of sodium iodide I-131 requiring a
14 written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries). Except
15 as provided in Section 67 of this administrative regulation the licensee shall require an
16 authorized user for the oral administration of sodium iodide I-131 requiring a written
17 directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a
18 physician who:

19 (1) Is certified by a medical specialty board whose certification process includes
20 all of the requirements in subsection (3)(a) and (b) of this section, and whose
21 certification has been recognized by the cabinet, U.S. Nuclear Regulatory Commission,
22 or an ~~[equivalent]~~ agreement state and who meets the requirements in subsection of
23 (3)(c) of this section; or

(2) Is an authorized user pursuant to ~~[under]~~ Section 70 of this administrative regulation for uses listed in Section 70(2)(a)2.f.(ii) of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state requirements; or

(3)(a) Has successfully completed eighty (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 shall include:

1. Radiation physics and instrumentation;
2. Radiation protection; and
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology;

(b) Has work experience, under the supervision of an authorized user who meets the requirements in Section 67, 70, or ~~[and]~~ 72 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state requirements. A supervising authorized user, who meets the requirements in Section 70(2) of this administrative regulation, shall also have experience in administering dosages as specified in Section 70(2)(a)2.f.(ii) of this administrative regulation. The work experience shall involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

1 3. Calculating, measuring, and safely preparing patient or human research
2 subject dosages;

3 4. Using administrative controls to prevent a medical event involving the use of
4 radioactive material;

5 5. Using procedures to contain spilled radioactive material safely and using
6 proper decontamination procedures; and

7 6. Administering dosages to patients or human research subjects, that includes
8 at least three (3) cases involving the oral administration of greater than 1.22
9 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

10 (c) Has obtained written attestation that the individual has satisfactorily
11 completed the requirements in subsection (3)(a) and (b) of this section and has
12 achieved a level of competency sufficient to function independently as an authorized
13 user for medical uses authorized pursuant to ~~[under]~~ Section 33 of this administrative
14 regulation. The written attestation shall be signed by a preceptor authorized user who
15 meets the requirements in Section 67, 70 or 72 of this administrative regulation, or
16 equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state
17 requirements. A preceptor authorized user, who meets the requirements in Section
18 70(2) of this administrative regulation, shall have experience in administering dosages
19 as specified in Section 70(2)(a)2.f.(ii).

20 Section 73. Training for the Parenteral Administration of Unsealed Radioactive
21 Material Requiring a Written Directive. Except as provided in Section 67 of this
22 administrative regulation, the licensee shall require an authorized user for the parenteral
23 administration requiring a written directive, to be a physician who:

(1) Is an authorized user pursuant to ~~[under]~~ Section 70 for uses listed in Section 70(2)(a)2.f.(iii) or Section 70(2)(a)2.f.(iv) ~~[or]~~ of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state requirements ~~[regulations]~~; or

(2)(a)1. Is an authorized user pursuant to ~~[under]~~ Sections 74 or 77 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state and who meets the requirements in paragraph (b) of this subsection ~~[(4) of this section]~~; or

2.~~[(3)]~~ Is certified by a medical specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an ~~[equivalent]~~ agreement state pursuant to ~~[under]~~ Sections 74 or 77 of this administrative regulation; and who meets the requirements in paragraph (b) of this subsection ~~[(4) of this section]~~; and ~~[or]~~

(b)1.~~[(4)(a)]~~ Has successfully completed eighty (80) hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of a ~~[any]~~ beta emitter or a ~~[any]~~ photon-emitting radionuclide with a photon energy less than ~~[that]~~ 150 keV, or ~~[and/or]~~ parenteral administration of other radionuclides ~~[any other radionuclide]~~ for which a written directive is required. The training shall include:

a.~~[1.]~~ Radiation physics and instrumentation;

b.~~[2.]~~ Radiation protection;

c.~~[3.]~~ Mathematics pertaining to the use and measurement of radioactivity;

d.~~[4.]~~ Chemistry of radioactive material for medical use; and

1 e.~~[5-]~~ Radiation biology; ~~and~~

2 2.~~[(b)]~~ Has work experience, under the supervision of an authorized user who
3 meets the requirements in Sections 67, 70, or ~~[and]~~ 73 of this administrative regulation,
4 or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state
5 requirements, in the parenteral administration, for which a written directive is required,
6 of a ~~[any]~~ beta emitter, or a ~~[any]~~ photon-emitting radionuclide with a photon energy less
7 than 150 keV, or ~~[and/or]~~ parenteral administration of other radionuclides ~~[any other~~
8 ~~radionuclide]~~ for which a written directive is required. A supervising authorized user who
9 meets the requirements in Section 70 of this administrative regulation shall have
10 experience in administering dosages as specified in Section 70(2)(a)2.f.(iii) or (iv) of this
11 administrative regulation or both ~~[and/or Section 70(2)(a)2.f.(iv)]~~. The work experience
12 shall involve:

13 a.~~[4-]~~ Ordering, receiving, and unpacking radioactive materials safely, and
14 performing the related radiation surveys;

15 b.~~[2-]~~ Performing quality control procedures on instruments used to determine the
16 activity of dosages, and performing checks for proper operation of survey meters;

17 c.~~[3-]~~ Calculating, measuring, and safely preparing patient or human research
18 subjects dosages;

19 d.~~[4-]~~ Using administrative controls to prevent a medical event involving the use
20 of unsealed radioactive material;

21 e.~~[5-]~~ Using procedures to contain spilled radioactive material safely, and using
22 proper decontamination procedures; and

23 f.~~[6-]~~ Administering dosages to patients or human research subjects, that include

1 at least three (3) cases involving the parenteral administration, for which a written
2 directive is required, of a ~~[any]~~ beta emitter, or photon-emitting radionuclide with a
3 photon energy less than 150 keV , or a minimum of~~[and/or at least]~~ three (3) cases
4 involving the parenteral administration of other radionuclides~~[any other radionuclide]~~, for
5 which a written directive is required, or both; and

6 3.[(e)] Has obtained written attestation that the individual has satisfactorily
7 completed the requirements in paragraph (a)1. or 2. of this subsection~~[subsection (2)-or~~
8 ~~(3)-of this section]~~, and has achieved a level of competency sufficient to function
9 independently as an authorized user for the parenteral administration of unsealed
10 radioactive material requiring a written directive. The written attestation shall be signed
11 by a preceptor authorized user who meets the requirements in Sections 67, 70, or 73 of
12 this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent
13 agreement state requirements. A preceptor authorized user, who meets the
14 requirements in Section 70 of this administrative regulation, shall have experience in
15 administering dosages as specified in Section 70(2)(a)2.f.(iii) or (iv)~~[and/or Section~~
16 ~~70(2)(a)2.f.(iv)]~~ of this administrative regulation or both.

17 Section 74. Training for Use of Manual Brachytherapy Sources. Except as
18 provided in Section 67 of this administrative regulation, the licensee shall require an
19 authorized user of a manual brachytherapy source for the uses authorized pursuant to
20 ~~[under]~~ Section 37 of this administrative regulation to be a physician who:

21 (1) Is certified by a medical specialty board whose certification process has been
22 recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an ~~[equivalent]~~
23 agreement state and who meets the requirements in (2)(c) of this section. To have its

certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three (3) years of residency training in a radiation oncology program approved by the:

1. Residency Review Committee of the Accreditation Council for Graduate Medical Education; or

2. Royal College of Physicians and Surgeons of Canada; or

3. Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) 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 of manual brachytherapy; or

(2)(a) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

1. 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this section, or Section 67 [~~Sections 67 and 74~~] of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or [~~or~~

~~equivalent~~] agreement state requirements at a medical institution, involving:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Checking survey meters for proper operation;

c. Preparing, implanting, and removing brachytherapy sources;

d. Maintaining running inventories of material on hand;

e. Using administrative controls to prevent a medical event involving the use of radioactive material;

f. Using emergency procedures to control radioactive material; and

(b) Has completed three (3) years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this section, or Section 67 ~~[in sections 67 and 74]~~ of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[, 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 subsection (2)(a)2. of this section; and

(c) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in ~~[of]~~ this section , or Section 67 ~~[and Sections 67 and 74]~~ of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state requirements, that the individual has satisfactorily

completed the requirements in subsection (1)(a) or (2)(a) and (b) 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 pursuant to ~~[under]~~ Section 37 of this administrative regulation.

Section 75. Training for Ophthalmic Use of Strontium-90. Except as provided in Section 67 of this administrative regulation the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is an authorized user pursuant to ~~[under]~~ Section 74 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state requirements; or

(2)(a) Has completed twenty-four (24) hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; and

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five (5) individuals. This supervised clinical training shall involve:

1. Examination of each individual to be treated;
2. Calculation of the dose to be administered;

1 3. Administration of the dose; and

2 4. Follow up and review of each individual's case history; and

3 (c) Has obtained written attestation, signed by a preceptor authorized user who
4 meets the requirements in Sections 67, 74, ~~and or~~ or 75 of this administrative regulation,
5 or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state
6 requirements, that the individual has satisfactorily completed the requirements in
7 subsection (2) of this section and has achieved a level of competency sufficient to
8 function independently as an authorized user of strontium-90 for ophthalmic use.

9 Section 76. Training for use of sealed sources for diagnosis. Except as provided
10 in Section 67 of this administrative regulation, the licensee shall require the authorized
11 user of a diagnostic sealed source for use in a device authorized pursuant to ~~[under]~~
12 Section 45 of this administrative regulation to be a physician, dentist, or podiatrist who:

13 (1) Is certified by a specialty board whose certification process includes all of the
14 requirements in subsection (2) and (3) of this section and whose certification has been
15 recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an ~~[equivalent]~~
16 agreement state; or

17 (2) Has completed eight (8) hours of classroom and laboratory training in basic
18 radionuclide handling techniques specifically applicable to the use of the device. The
19 training shall include:

20 (a) Radiation physics and instrumentation;

21 (b) Radiation protection;

22 (c) Mathematics pertaining to the use and measurement of radioactivity; and

23 (d) Radiation biology; and

1 (3) Has completed training in the use of the device for the uses requested.

2 Section 77. Training for Use of Remote Afterloader Units, Teletherapy Units, and
3 Gamma Stereotactic Radiosurgery Units. Except as provided in Section 67 of this
4 administrative regulation, the licensee shall require an authorized user of a sealed
5 source for a use authorized pursuant to ~~[under]~~ Section 46 of this administrative
6 regulation to be a physician who:

7 (1) Is certified by a medical specialty board whose certification process has been
8 recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an ~~[equivalent]~~
9 agreement state and who meets the requirements in (2)(c) and (3) of this section. To
10 have its certification recognized, a specialty board shall require all candidates for
11 certification to:

12 (a) Successfully complete a minimum of three (3) years of residency training in a
13 radiation therapy program approved by the:

14 1. Residency Review Committee of the Accreditation Council for Graduate
15 Medical Education;

16 2. Royal College of Physicians and Surgeons of Canada; or

17 3. Committee on Post-Graduate Training of the American Osteopathic
18 Association; and

19 (b) Pass an examination, administered by diplomats of the specialty board, which
20 tests knowledge and competence in radiation safety, radionuclide handling, treatment
21 planning, quality assurance, and clinical use of stereotactic radiosurgery, remote
22 afterloaders and external beam therapy; or

23 (2)(a) 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:

1. 200 hours of classroom and laboratory training in the following areas:

- a. Radiation physics and instrumentation;
- b. Radiation protection;
- c. Mathematics pertaining to the use and measurement of radioactivity; and
- d. Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this section, or Section 67 ~~[Sections 67 and 77]~~ of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state requirements at a medical institution, involving:

- a. Reviewing full calibration measurements and periodic spot-checks;
- b. Preparing treatment plans and calculating treatment doses and times;
- c. Using administrative controls to prevent a medical event involving the use of radioactive material;
- d. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
- e. Checking and using survey meters; and
- f. Selecting the proper dose and how it is to be administered; and

(b) Has completed three (3) years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this section, or Section 67 ~~[Sections 67 and 77]~~ of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or ~~[, or equivalent]~~ agreement state requirements, as

1 part of a formal training program approved by the Residency Review Committee for
2 Radiation Oncology of the Accreditation Council for Graduate Medical Education or the
3 Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral
4 Training of the American Osteopathic Association. This experience may be obtained
5 concurrently with the supervised work experience required by subsection (2)(a)2 of this
6 section; and

7 (c) Has obtained written attestation that the individual has satisfactorily
8 completed the requirements in subsection (1)(a) or (2)(a) and (b), and (3) of this section,
9 and has achieved a level of competency sufficient to function independently as an
10 authorized user of each type of therapeutic medical unit for which the individual is
11 requesting authorized user status. The written attestation shall be signed by a preceptor
12 authorized user who meets the requirements in this section, or Section 67 ~~[Sections 67~~
13 ~~and 77]~~ of this administrative regulation, or equivalent U.S. Nuclear Regulatory
14 Commission or ~~[, or equivalent]~~ agreement state requirements for an authorized user for
15 each type of therapeutic medical unit for which the individual is requesting authorized
16 user status; and

17 (3) Has received training in device operation, safety procedures, and clinical use
18 for the type of use for which authorization is sought, This training requirement may be
19 satisfied by satisfactory completion of a training program provided by the vendor for new
20 users or by receiving training supervised by an authorized user or authorized medical
21 physicist, as appropriate, who is authorized for the type of use for which the individual is
22 seeking authorization.

23 Section 78. Alternative Training. During a two (2) year period after the effective

1 date of October 24, 2005, alternative training and experience requirements shall be
2 available. Licensees shall have the option of complying with either the training
3 requirements of Section 78 of this administrative regulation or the new requirements in
4 Sections 65 through 77 of this administrative regulation. After October 24, 2007,
5 licensee shall not have the option of using Section 78 of this administrative regulation.
6 Except as provided in Section 67 of this administrative regulation, the licensee shall
7 require for:

8 (1) A Radiation Safety Officer, an individual fulfilling the responsibilities of the
9 radiation safety officer as provided in Section 10 of this administrative regulation to be
10 an individual who:

11 (a) Is certified by the:

- 12 1. American Board of Health Physics in Comprehensive Health Physics;
- 13 2. American Board of Radiology;
- 14 3. American Board of Nuclear Medicine;
- 15 4. American Board of Science in Nuclear Medicine;
- 16 5. Board of Pharmaceutical Specialties in Nuclear Pharmacy;
- 17 6. American Board of Medical Physics in radiation oncology physics;
- 18 7 Royal College of Physicians and Surgeons of Canada in nuclear medicine;
- 19 8. American Osteopathic Board of Radiology; or
- 20 9. American Osteopathic Board of Nuclear Medicine;

21 (b) Has had classroom and laboratory training and experience as follows:

- 22 1. 200 hours of classroom and laboratory training that includes:
 - 23 a. Radiation physics and instrumentation;

1 b. Radiation protection;

2 c. Mathematics pertaining to the use and measurement of radioactivity;

3 d. Radiation biology; and

4 e. Radiopharmaceutical chemistry; and

5 2. One (1) year of full time experience as a radiation safety technologist at a
6 medical institution under the supervision of the individual identified as the radiation
7 safety officer on a cabinet, U.S. Nuclear Regulatory Commission, or equivalent
8 agreement state license that authorizes the medical use of radioactive material; or

9 (c) Is an authorized user identified on the licensee's license.

10 (2) Authorized user of a radiopharmaceutical for uptake, dilution, and excretion in
11 Section 30(1) of this administrative regulation to be a physician who:

12 (a) Is certified in:

13 1. Nuclear medicine by the American Board of Nuclear Medicine;

14 2. Diagnostic radiology by the American Board of Radiology;

15 3. Diagnostic radiology or radiology by the American Osteopathic Board of
16 Radiology;

17 4. Nuclear medicine by the Royal College of Physicians and Surgeons of
18 Canada; or

19 5. American Osteopathic Board of Nuclear Medicine in nuclear medicine;

20 (b) Has had classroom and laboratory training in basic radioisotope handling
21 techniques applicable to the use of prepared radiopharmaceuticals, and supervised
22 clinical experience as follows:

23 1. Forty (40) hours of classroom and laboratory training that includes:

1 a. Radiation physics and instrumentation;

2 b. Radiation protection;

3 c. Mathematics pertaining to the use and measurement of radioactivity;

4 d. Radiation biology; and

5 e. Radiopharmaceutical chemistry; and

6 2. Twenty (20) hours of supervised clinical experience under the supervision of
7 an authorized user and that includes:

8 a. Examining patients or human research subjects and reviewing their case
9 histories to determine their suitability for radioisotope diagnosis, limitations, or
10 contraindications;

11 b. Selecting the suitable radiopharmaceuticals and calculating and measuring the
12 dosages;

13 c. Administering dosages to patients or human research subjects and using
14 syringe radiation shields;

15 d. Collaborating with the authorized user in the interpretation of radioisotope test
16 results; and

17 e. Patient or human research subject follow up; or

18 (c) Has successfully completed a six (6) month training program in nuclear
19 medicine as part of a training program that has been approved by the Accreditation
20 Council for Graduate Medical Education and that included classroom and laboratory
21 training, work experience, and supervised clinical experience in all the topics identified
22 in paragraph (b) of this section.

23 (3) Authorized user for imaging and localization studies using a

radiopharmaceutical, generator, or reagent kit in Section 31(1) of this administrative regulation to be a physician who:

(a) Is certified in:

1. Nuclear medicine by the American Board of Nuclear Medicine;

2. Diagnostic radiology by the American Board of Radiology;

3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

5. American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(c) 1. 200 hours of classroom and laboratory training that includes:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiopharmaceutical chemistry; and

e. Radiation biology;

2. 500 hours of supervised work experience under the supervision of an authorized user that includes:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

1 b. Calibrating dose calibrators and diagnostic instruments and performing checks
2 for proper operation of survey meters;

3 c. Calculating and safely preparing patient or human research subject dosages;

4 d. Using administrative controls to prevent the medical event of radioactive
5 material;

6 e. Using procedures to contain spilled radioactive material safely and using
7 proper decontamination procedures; and

8 f. Eluting technetium-99m from generator systems, measuring and testing the
9 eluate for molybdenum-99 and alumina contamination, and processing the eluate with
10 reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

11 3. 500 hours of supervised clinical experience under the supervision of an
12 authorized user that includes:

13 a. Examining patients or human research subjects and reviewing their case
14 histories to determine their suitability for radioisotope diagnosis, limitations, or
15 contraindications;

16 b. Selecting the suitable radiopharmaceuticals and calculating and measuring the
17 dosages;

18 c. Administering dosages to patients or human research subjects and using
19 syringe radiation shields;

20 d. Collaborating with the authorized user in the interpretation of radioisotope test
21 results; and

22 e. Patient or human research subject follow up; or

23 (c) Has successfully completed a six (6) month training program in nuclear

1 medicine that has been approved by the Accreditation Council for Graduate Medical
2 Education and that included classroom and laboratory training, work experience, and
3 supervised clinical experience in all the topics identified in paragraph (b) of this section.

4 (4) The authorized user of radiopharmaceuticals for therapeutic use in Section 33
5 of this administrative regulation to be a physician who:

6 (a) Is certified by:

7 1. The American Board of Nuclear Medicine;

8 2. The American Board of Radiology in radiology, therapeutic radiology, or
9 radiation oncology;

10 3. The Royal College of Physicians and Surgeons of Canada in nuclear
11 medicine; or

12 4. The American Osteopathic Board of Radiology after 1984; or

13 (b) Has had classroom and laboratory training in basic radioisotope handling
14 techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised
15 clinical experience as follows:

16 1. Eighty (80) hours of classroom and laboratory training that includes:

17 a. Radiation physics and instrumentation;

18 b. Radiation protection;

19 c. Mathematics pertaining to the use and measurement of radioactivity; and

20 d. Radiation biology; and

21 2. Supervised clinical experience under the supervision of an authorized user at
22 a medical institution that includes:

23 a. Use of iodine-131 for diagnosis of thyroid function and the treatment of

1 hyperthyroidism or cardiac dysfunction in ten (10) individuals; and

2 b. Use of iodine-131 for treatment of thyroid carcinoma in three (3) individuals.

3 (5) The authorized user of only iodine-131 for the treatment of hyperthyroidism to
4 be a physician with special experience in thyroid disease who has had classroom and
5 laboratory training in basic radioisotope handling techniques applicable to the use of
6 iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

7 (a) Eighty (80) hours of classroom and laboratory training that includes:

8 1. Radiation physics and instrumentation;

9 2. Radiation protection;

10 3. Mathematics pertaining to the use and measurement of radioactivity; and

11 4. Radiation biology; and

12 (b) Supervised clinical experience under the supervision of an authorized user
13 that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of
14 hyperthyroidism in ten (10) individuals.

15 (6) The authorized user of only iodine-131 for the treatment of thyroid carcinoma
16 to be a physician with special experience in thyroid disease who has had classroom and
17 laboratory training in basic radioisotope handling techniques applicable to the use of
18 iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

19 (a) Eighty (80) hours of classroom and laboratory training that includes:

20 1. Radiation physics and instrumentation;

21 2. Radiation protection;

22 3. Mathematics pertaining to the use and measurement of radioactivity; and

23 4. Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in three (3) individuals.

(7) The authorized user of a brachytherapy source in Section 36 of this administrative regulation for therapy to be a physician who:

(a) Is certified in:

1. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

2. Radiation oncology by the American Osteopathic Board of Radiology;

3. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

1. 200 hours of classroom and laboratory training that includes:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology;

2. 500 hours of supervised work experience under the supervision of an

1 authorized user at a medical institution that includes:

2 a. Ordering, receiving, and unpacking radioactive materials safely and performing
3 the related radiation surveys;

4 b. Checking survey meters for proper operation;

5 c. Preparing, implanting, and removing sealed sources;

6 d. Maintaining running inventories of material on hand;

7 e. Using administrative controls to prevent a medical event involving radioactive
8 material; and

9 f. Using emergency procedures to control radioactive material; and

10 3. Three (3) years of supervised clinical experience that includes one (1) year in
11 a formal training program approved by the Residency Review Committee for Radiology
12 of the Accreditation Council for Graduate Medical Education or the Committee on
13 Postdoctoral Training of the American Osteopathic Association, and an additional two
14 (2) years of clinical experience in therapeutic radiology under the supervision of an
15 authorized user at a medical institution that includes:

16 a. Examining individuals and reviewing their case histories to determine their
17 suitability for brachytherapy treatment, and any limitations or contraindications;

18 b. Selecting the proper brachytherapy sources and dose and method of
19 administration;

20 c. Calculating the dose; and

21 d. Post-administration follow-up and review of case histories in collaboration with
22 the authorized user.

23 (8) The authorized user of only strontium-90 for ophthalmic radiotherapy to be a

1 physician who is in the active practice of therapeutic radiology or ophthalmology, and
2 has had classroom and laboratory training in basic radioisotope handling techniques
3 applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of
4 supervised clinical training in ophthalmic radiotherapy as follows:

5 (a) Twenty-four (24) hours of classroom and laboratory training that includes:

- 6 1. Radiation physics and instrumentation;
- 7 2. Radiation protection;
- 8 3. Mathematics pertaining to the use and measurement of radioactivity; and
- 9 4. Radiation biology; and

10 (b) Supervised clinical training in ophthalmic radiotherapy under the supervision
11 of an authorized user at a medical institution that includes the use of strontium-90 for
12 the ophthalmic treatment of five individuals that includes:

- 13 1. Examination of each individual to be treated;
- 14 2. Calculation of the dose to be administered;
- 15 3. Administration of the dose; and
- 16 4. Follow up and review of each individual's case history.

17 (9) The authorized user of a sealed source for diagnosis in a device listed in
18 Section 45 of this administrative regulation to be a physician, dentist, or podiatrist who:

19 (a) Is certified in:

- 20 1. Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by
21 the American Board of Radiology;
- 22 2. Nuclear medicine by the American Board of Nuclear Medicine;
- 23 3. Diagnostic radiology or radiology by the American Osteopathic Board of

1 Radiology; or

2 4. Nuclear medicine by the Royal College of Physicians and Surgeons of
3 Canada; or

4 (b) Has had eight (8) hours of classroom and laboratory training in basic
5 radioisotope handling techniques specifically applicable to the use of the device that
6 includes:

7 1. Radiation physics, mathematics pertaining to the use and measurement of
8 radioactivity, and instrumentation;

9 2. Radiation biology;

10 3. Radiation protection; and

11 4. Training in the use of the device for the uses requested.

12 (10) The authorized user of a sealed source for therapeutic medical devices
13 listed in Section 46 of this administrative regulation to be a physician who:

14 (a) Is certified in:

15 1. Radiology, therapeutic radiology, or radiation oncology by the American Board
16 of Radiology;

17 2. Radiation oncology by the American Osteopathic Board of Radiology;

18 3. Radiology, with specialization in radiotherapy, as a British "Fellow of the
19 Faculty of Radiology" or "Fellow of the Royal College of Radiology";

20 4. Therapeutic radiology by the Canadian Royal College of Physicians and
21 Surgeons; or

22 (b) Is in the active practice of therapeutic radiology, and has had classroom and
23 laboratory training in basic radioisotope techniques applicable to the use of a sealed

source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows:

1. 200 hours of classroom and laboratory training that includes:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology;

2. 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

a. Review of the full calibration measurements and periodic spot-checks;

b. Preparing treatment plans and calculating treatment times;

c. Using administrative controls to prevent medical events;

d. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and

e. Checking and using survey meters; and

3. Three (3) years of supervised clinical experience that includes one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

a. Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery

1 treatment, and any limitations or contraindications;

2 b. Selecting the proper dose and how it is to be administered;

3 c. Calculating the doses and collaborating with the authorized user in the review
4 of patients' or human research subjects' progress and consideration of the need to
5 modify originally prescribed doses as warranted by patients' or human research
6 subjects' reaction to radiation; and

7 d. Postadministration follow up and review of case histories.

8 (11) The authorized medical physicist shall be an individual who:

9 (a) Is certified by the American Board of Radiology in:

10 1. Therapeutic radiological physics;

11 2. Roentgen ray and gamma ray physics;

12 3. X-ray and radium physics; or

13 4. Radiological physics; or

14 (b) Is certified by the American Board of Medical Physics in radiation oncology
15 physics; or

16 (c) Holds a master's or doctor's degree in physics, biophysics, radiological
17 physics, or health physics, and has completed one (1) year of full time training in
18 therapeutic radiological physics and an additional year of full time work experience
19 under the supervision of a medical physicist at a medical institution that includes the
20 tasks listed in Sections 24, 52, 53, 54, 55, 56, 57 and 58 of this administrative regulation
21 as applicable.

22 (12) The authorized nuclear pharmacist to be a pharmacist who:

23 (a) Has current board certification as a nuclear pharmacist by the Board of

1 Pharmaceutical Specialties; or

2 (b)1. Has completed 700 hours in a structured educational program consisting of
3 both:

4 a. Didactic training in the following areas:

5 (i) Radiation physics and instrumentation;

6 (ii) Radiation protection;

7 (iii) Mathematics pertaining to the use and measurement of radioactivity;

8 (iv) Chemistry of radioactive material for medical use; and

9 (v) Radiation biology; and

10 b. Supervised experience in a nuclear pharmacy involving the following:

11 (i) Shipping, receiving, and performing related radiation surveys;

12 (ii) Using and performing checks for proper operation of dose calibrators, survey
13 meters, and, if appropriate, instruments used to measure alpha- or beta-emitting
14 radionuclides;

15 (iii) Calculating, assaying, and safely preparing dosages for patients or human
16 research subjects;

17 (iv) Using administrative controls to avoid mistakes in the administration of
18 radioactive material;

19 (v) Using procedures to prevent or minimize contamination and using proper
20 decontamination procedures; and

21 2. Has obtained written certification, signed by a preceptor authorized nuclear
22 pharmacist, that the above training has been satisfactorily completed and that the
23 individual has achieved a level of competency sufficient to independently operate a

1 nuclear pharmacy.

2 (13) An authorized experienced nuclear pharmacist must be a pharmacist who
3 has completed a structured educational program as specified in subsection (12)(b)(1) of
4 this section before December 2, 1994, and who is working in a nuclear pharmacy would
5 qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist shall
6 not be required to comply with the requirements for a preceptor statement (subsection
7 (12)(b)(2) of this section) and recentness of training (Section 63 of this administrative
8 regulation) to qualify as an authorized nuclear pharmacist.

9 Section 79. Food and Drug Administration (FDA), Other Federal and State
10 Requirements. Nothing in this administrative regulation relieves the license from
11 complying with applicable FDA, other federal and state requirements governing
12 radioactive drugs or devices.

902 KAR 100:072 Use of radionuclides in the health arts.

REVIEWED:

Date

Steve Davis, MD
Acting Commissioner
Department for Public Health

APPROVED:

Date

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on September 9, 2012 at 9:00 a.m. in the Administrative Hearing Branch conference room, Health Services Building, 1st floor of the Cabinet for Health and Family Services, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by September 14, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business October 1, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 902 KAR 100:072

Contact Person: Matt McKinley (502) 564-3700 extension 3701

(1) Provide a brief summary of:

(a) What this administrative regulation does: This regulation establishes guidelines for the use of radionuclides in the health arts.

(b) The necessity of this administrative regulation: The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:073 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How this administrative regulation conforms to the content of the authorizing statutes: The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: By updating the Kentucky Administrative Regulations to be consistent with the Code of Federal Regulations thereby ensuring that Kentucky licensees are bound by the same requirements as their counterparts across the country.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: It updates 902 KAR 100:072 to recognize additional specialty boards for qualification of practitioners, removes the option to designate a practitioner as "visiting", and, removes the alternate training options which expired October 24, 2007.

(b) The necessity of the amendment to this administrative regulation: To ensure compliance with the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How the amendment conforms to the content of the authorizing statutes:

KRS 211.844 states the Cabinet for Health Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste. This amendment updates those regulations created to implement that statute.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will create conformance between state and federal regulations, thus reducing confusion between them.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will assist all 190 medical and radiopharmaceutical licensees in making Kentucky Administrative Regulations consistent with the Code of Federal Regulations.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Licensees will have to be aware of these changes but already are as they are already following federal regulations.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The regulation will have no cost associated with compliance

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The licenses will benefit from consistency between state and federal regulations.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional cost will be incurred as a result of amending this administrative regulation.

(b) On a continuing basis: No additional cost will be incurred as a result of amending this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No additional funding will be required to implement this regulation. The existing program is covered by General Funds appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change if it is an amendment: An increase in fees or funding will not be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This regulation establishes no fees directly or indirectly.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 902 KAR 100:072 Contact Person: Matt McKinley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No

2. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? All parts of the state and local governments are covered by the license holders impacted by this regulation amendment.

3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by this administrative regulation.

The U.S. Nuclear Regulatory Commission has amended their regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:010 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. This administrative regulation will have no effect on the revenues or expenditures of state or local governments.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No revenue will be produced by this regulation the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenue will be produced by this regulation in subsequent years.

(c) How much will it cost to administer this program for the first year?

There will be no additional cost to implement this regulation the first year.

(d) How much will it cost to administer this program for subsequent years?

There will be no cost to implement this regulation in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

1 **CABINET FOR HEALTH AND FAMILY SERVICES**

2 **Department of Public Health**

3 **Division of Public Health Protection and Safety**

4 **(Amendment)**

5 **902 KAR 100:100. Industrial radiography.**

6 RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. 34, 71, 21 C.F.R.
7 1020.40

8 STATUTORY AUTHORITY: KRS 194A.050(1), 211.090(3), 211.844

9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet for
10 Health and Family Services to provide by administrative regulation for the registration and
11 licensing of the possession or use of sources of ionizing or electronic product radiation
12 and the handling and disposal of radioactive waste. This administrative regulation estab-
13 lishes radiation safety requirements for industrial radiographic operations and shall apply
14 to licensees or registrants who use sources of radiation for industrial radiography.

15 Section 1. Specific License and Registration Requirements for Industrial Radiogra-
16 phy. (1) An Application for Radioactive Material License, incorporated by reference in
17 902 KAR 100:040, for a specific license or registration for the use of sources of radiation
18 in industrial radiography shall be approved if the applicant meets the following require-
19 ments:

20 (a) Except as provided in subsection 3(k) of this section, the applicant shall satisfy
21 the general requirements specified in 902 KAR

1 100:040, Section 4, or 100:110 and 100:145, and any specific requirements contained
2 in this administrative regulation.

3 (b) The applicant shall submit an adequate program for training a radiographer and a
4 radiographers' assistant that meets the requirements of Section 14 of this administrative
5 regulation.

6 1. After June 30, 2002, an applicant shall not describe the initial training and exami-
7 nation program for a radiographer in the subjects outlined in Section 14 of this adminis-
8 trative regulation.

9 2. From June 30, 2000, to June 30, 2002, an applicant shall affirm that an individual
10 acting as an industrial radiographer shall be certified in radiation safety by a certifying
11 entity as described in 10 C.F.R. Part 34, Appendix A, before commencing duty as a ra-
12 diographer. This affirmation shall substitute for a description of the initial training and
13 examination program for a radiographer in the subjects outlined in Section 14 of this
14 administrative regulation.

15 (c) The applicant shall submit procedures for verifying and documenting the certifica-
16 tion status of a radiographer and for ensuring that the certification of an individual acting
17 as a radiographer remains valid.

18 (d) The applicant shall submit written operating and emergency procedures as de-
19 scribed in Section 15 of this administrative regulation.

20 (e) The applicant shall submit a description of a program for inspections of the job
21 performance of a radiographer and a radiographers' assistant at intervals not to exceed
22 six (6) months as described in Section 14 of this administrative regulation.

23 (f) The applicant shall submit a description of the applicant's overall organization

1 structure as it applies to the radiation safety responsibilities in industrial radiography, in-
2 cluding specified delegation of authority and responsibility.

3 (g) The applicant shall identify and list the qualifications of the individual designated
4 as the radiation safety officer (RSO) and of the potential designees responsible for en-
5 suring that the licensee's radiation safety program is implemented in accordance with
6 approved procedures.

7 (h) If an applicant intends to perform leak testing of sealed sources or exposure de-
8 vices containing depleted uranium (DU) shielding, the applicant shall describe the pro-
9 cedures for performing and the qualifications of the person authorized to do the leak
10 testing.

11 (i) If the applicant intends to analyze the applicant's own wipe samples, the applica-
12 tion shall include a description of the procedures to be followed, which shall include:

- 13 1. Instruments to be used;
- 14 2. Methods of performing the analysis; and
- 15 3. Pertinent experience of the person analyzing the wipe samples.

16 (j) If the applicant intends to perform an "in-house" calibration of a survey instrument,
17 the applicant shall describe the method to be used and the relevant experience of the
18 person performing the calibration. A calibration shall be performed according to the pro-
19 cedures and at the intervals prescribed in Section 5 of this administrative regulation.

20 (k) The applicant shall identify and describe the location of each field station and
21 permanent radiographic installation.

22 (l) The applicant shall identify the location where records required by this and other
23 administrative regulations in 902 KAR Chapter 100 shall be maintained.

(2) A licensee shall maintain a copy of its license, documents incorporated by reference, and amendments to these items until superseded by new documents approved by the cabinet or until the cabinet terminates the license.

Section 2. Performance Provisions for Radiography Equipment. Equipment used in industrial radiographic operations shall meet the following criteria:

(1)(a) Except as provided in subsection (3)(k) of this section, a radiographic exposure device, source assembly, or sealed source and associated equipment shall meet the provisions specified in American National Standard Institute (ANSI) N432-1980, Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography; and

(b) Engineering analysis shall be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. If upon review, the cabinet determines that the engineering analysis demonstrates that actual testing of the component is not necessary, the engineering analysis shall be an acceptable alternative.

(2)(a) A radiographic exposure device shall have attached to it by the user, a durable, legible, clearly visible label bearing the:

1. Chemical symbol and mass number of the radionuclide in the device;
2. Activity and date on which this activity was last measured;
3. Model or product code and serial number of the sealed source;
4. Manufacturer of the sealed source; and
5. Name, address, and telephone number of the licensee or registrant.

(b) A radiographic exposure device intended for use as a Type B transport container

1 shall meet the applicable provisions of 10 C.F.R. 71.

2 (c) Modification of an exposure device, source changer, source assembly, or asso-
3 ciated equipment shall be prohibited, unless the design of a replacement component,
4 including source holder, source assembly, control, or guide tube, shall not compromise
5 the design safety features of the system.

6 (3) In addition to the provisions specified in subsections (1) and (2) of this section, the
7 following provisions shall apply to a radiographic exposure device, source assembly,
8 and associated equipment that allow the source to be moved out of the device for radi-
9 ographic operation or to a source changer:

10 (a) The coupling between the source assembly and the control cable shall be de-
11 signed in a manner so that the source assembly cannot:

- 12 1. Become disconnected if cranked outside the guide tube; and
13 2. Be unintentionally disconnected under normal and reasonably foreseeable abnor-
14 mal conditions.

15 (b) The device shall automatically secure the source assembly if it is cranked back in-
16 to the fully shielded position within the device. The securing system shall be released
17 only by a deliberate operation on the exposure device.

18 (c) Each outlet fitting, lock box, and drive cable fitting on a radiographic exposure de-
19 vice shall be equipped with a safety plug or cover, which shall be installed during sto-
20 rage and transportation to protect the source assembly from water, mud, sand, or other
21 foreign matter.

22 (d) A sealed source or source assembly shall have attached to it or engraved on it, a
23 durable, legible, visible label with the words: "DANGER-RADIOACTIVE." The label shall

not interfere with the safe operation of the exposure device or associated equipment.

(e) The guide tube shall have passed:

1. A crushing test that closely approximates the crushing forces likely to be encountered during use; and

2. A kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

(f) Guide tubes shall be used if moving the source out of the device.

(g) An exposure head or similar device designed to prevent the source assembly from passing out the end of the guide tube shall be attached to the outermost end of the guide tube during a radiographic operation.

(h) The guide tube exposure head connection shall withstand the tensile test for control units specified in ANSI N432-1980.

(i) A source changer shall provide a system for assuring that the source cannot be accidentally withdrawn from the changer if connecting or disconnecting the drive cable to or from a source assembly.

(j) A radiographic exposure device and associated equipment in use after January 10, 1996, shall comply with the provisions of this section.

(k) Equipment used in industrial radiography operations need not comply with paragraph 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiographic equipment can realistically exert on the lever or crankshaft of the drive mechanism.

Section 3. Limits on External Levels of Radiation for Radiographic Exposure Devices

and Storage Containers. The maximum exposure rate limits for storage containers and source changers shall be:

(1) 200 millirems (2 millisieverts) per hour at any exterior surface; and

(2) Ten (10) millirems (0.1 millisieverts) per hour at one (1) meter from any exterior surface, with the sealed source in the shielded position.

Section 4. Locking of Radiographic Exposure Devices, Storage Containers, and Source Containers. (1) A radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source from its shielded position.

(a) An exposure device or its container shall be kept locked, and if a keyed lock, with the key removed at all times except:

1. If under the direct surveillance of a radiographer or radiographer's assistant; or

2. As authorized by Section 19 of this administrative regulation.

(b) During radiographic operation the sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

(c) A sealed source storage container and source changer shall be:

1. Provided with a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position; and

2. Kept locked, and if a keyed lock, with the key removed at all times if containing sealed sources, except if under the direct surveillance of a radiographer or radiographer's assistant.

(2) The control panel of a radiation machine shall be:

(a) Equipped with a lock that prevents the unauthorized use of an x-ray system or the

1 accidental production of radiation; and

2 (b) Kept locked and the key removed at all times, except if under the direct visual
3 surveillance of a radiographer or radiographer's assistant.

4 Section 5. Radiation Survey Instruments. (1) A licensee or registrant shall maintain
5 sufficient calibrated and operable radiation survey instruments at a location where a
6 source of radiation is present in order to perform radiation surveys as required by this
7 administrative regulation and 902 KAR 100:019, Section 12(1).

8 (2) A radiation survey instrument shall be calibrated:

9 (a) At intervals not to exceed six (6) months;

10 (b) After an instrument servicing, except for battery changes;

11 (c)1. At two (2) points located approximately one-third ($1/3$) and two-thirds ($2/3$) of
12 full-scale for linear scale instruments;

13 2. Midrange of each decade, and at two (2) points of at least one (1) decade for loga-
14 rithmic scale instruments;

15 3. At three (3) points between two (2) and 1,000 millirems (90.02 and ten (10) milli-
16 sieverts) per hour for digital instruments; and

17 (d) So that an accuracy within plus or minus twenty (20) percent of the calibration
18 source can be demonstrated at the points checked.

19 (3) A record of each calibration shall be maintained for three (3) years after the cali-
20 bration date for inspection by the cabinet.

21 (4) Instrumentation required by this section shall have a range so that two (2) milli-
22 rems (0.02 millisieverts) per hour through one (1) rem (0.01 sievert) per hour may be
23 measured.

Section 6. Leak Testing and Replacement of Sealed Sources. (1) The replacement of a sealed source fastened to or contained in a radiographic exposure device, and leak testing, repairing, opening, or modification of a sealed source shall be performed by a person specifically authorized by the cabinet, the U.S. Nuclear Regulatory Commission, or an agreement state.

(2) A sealed source shall be tested for leakage:

(a) At intervals not to exceed six (6) months;

(b) Using a method approved by the cabinet, the U.S. Nuclear Regulatory Commission, or an agreement state; and

(c)1. By taking a wipe sample from the nearest accessible point to the sealed source where contamination might accumulate.

2. The wipe sample shall be analyzed for radioactive contamination.

3. The analysis shall be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample; and

4. The analysis shall be performed by a person specifically authorized by the cabinet, the U.S. Nuclear Regulatory Commission, or an agreement state to perform the analysis.

(3) A sealed source shall not be used by the licensee until tested for leakage, except if:

(a) The source is accompanied by a certificate from the transferor showing it to have been leak-tested within six (6) months preceding the transfer; or

(b) The source has been in storage and not in use for six (6) months or less.

(4) (a) A test conducted in accordance with subsections (1) and (2) of this section

1 that reveals the presence of 0.005 microcuries (185 Bq) or more of remov-
2 able material shall be considered evidence that the sealed source is leaking.

3 (b) The licensee shall immediately withdraw the equipment involved from use and
4 shall have it decontaminated and repaired or disposed of in accordance with 902 KAR
5 100:021.

6 (c) The licensee shall file a report with the Manager, Radiation Health Branch, De-
7 partment of Public Health, 275 East Main Street, Frankfort, Kentucky 40621, within five
8 (5) days of a test with results that exceed the threshold in this subsection.

9 (d) The report shall describe the equipment involved, the test results, and the correc-
10 tive action taken.

11 (5) An exposure device using depleted uranium (DU) shielding and an "S" tube confi-
12 guration shall be tested for DU contamination at intervals not to exceed twelve (12)
13 months.

14 (a) The analysis shall be:

15 1. Capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive
16 material on the test sample; and

17 2. Performed by a person specifically authorized by the cabinet, the U.S. Nuclear
18 Regulatory Commission, or an agreement state to perform the analysis.

19 (b) If testing reveals the presence of 0.005 microcuries (185 Bq) or more of remova-
20 ble DU contamination, the exposure device shall be removed from use until an evalua-
21 tion of the wear on the S-tube has been made.

22 (c) If the evaluation reveals that the S-tube is worn through, the device shall not be
23 used again.

(d) A DU shielded device shall:

1. Not require testing for DU contamination while in storage and not in use; and

2. Require testing before use or transfer if the interval of storage exceeded twelve (12) months.

(6) (a) A licensee shall maintain records of leak test results for each sealed source or device containing DU.

(b) The results shall be stated in units of microcuries (becquerels).

(c) The licensee shall retain a record for three (3) years after it is made or until the source in storage is removed.

Section 7. Quarterly Inventory. (1) A licensee or registrant shall conduct a quarterly physical inventory to account for each source of radiation and each device containing depleted uranium received or possessed in accordance with the license.

(2) Records of the inventories shall be maintained for three (3) years from the date of the inventory for inspection by the cabinet. The records of inventories shall include:

(a) Radionuclide;

(b) Number of curies (becquerels) or mass (for DU) in a device;

(c) Location of sealed sources and devices;

(d) Date of the inventory;

(e) Name of the individual making the inventory; and

(f) Manufacturer, model number, and serial number of each sealed source or device, as appropriate.

Section 8. Utilization Logs. A licensee or registrant shall maintain utilization logs, which shall be kept available for inspection by the cabinet for three (3) years from the

1 date of the recorded event, at the address specified in the license or on the registration,
2 showing for a source of radiation the following information:

3 (1) A description including make, model, and serial number of the exposure device,
4 radiation machine, or transport or storage container in which a sealed source is located;

5 (2) Identity and signature of the radiographer to whom assigned;

6 (3) Site or plant where used and dates of use;

7 (4) Date a source of radiation is removed from storage and returned to storage; and

8 (5) For permanent radiographic installations, the dates a radiation machine is ener-
9 gized.

10 Section 9. Inspection and Maintenance of Radiographic Exposure Devices, Radiation
11 Machines, Transport and Storage Containers, Associated Equipment, Source Changes,
12 and Survey Instruments. (1) A licensee or registrant shall perform:

13 (a) Visual and operability checks on survey meters, radiographic exposure devices,
14 radiation machines, transport and storage containers, associated equipment, and
15 source changers before use on a day the equipment is to be used to ensure that the:

16 1. Equipment is in good working condition;

17 2. Source is adequately shielded; and

18 3. Required labeling is present; and

19 (b) An operability check of survey instruments using check sources or other appropri-
20 ate means.

21 (2) If an equipment problem is found, the equipment shall be removed from service
22 until repaired.

23 (3) A licensee or registrant shall have written procedures for:

(a) Inspection and routine maintenance of radiographic exposure devices, radiation machines, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three (3) months, or before the first use in order to ensure the proper functioning of components important to safety;

(b) Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials; and

(c) Inspection and maintenance program to assure that a Type B package is shipped and maintained in accordance with the certificate of compliance, or other approval.

(4) A replacement component shall meet design specifications.

(5) If an equipment problem is found, the equipment shall be removed from service until repaired.

(6)(a) A record of equipment problems found in daily checks and quarterly inspections of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments and of any maintenance performed in accordance with subsections (1) through (3) of this section shall be kept for three (3) years for inspection by the cabinet.

(b)The record shall include:

1. The date of check or inspection;

2. Name of the inspector;

3. Equipment involved;

4. Problems found; and

5. What repair and maintenance was done.

Section 10. Permanent Radiographic Installations. (1) Permanent radiographic instal-

lations with an entrance used for personnel access to a high radiation area shall have:

(a) Entrance controls of the type described in 902 KAR 100:019, Section 14(1)(b) and (c) and Section 14(2) that reduce the radiation level upon entry into the area; or:

(b) Both visible and audible warning signals to warn of the presence of radiation.

1. The visible signal shall be activated by radiation if the source is exposed or the machine is energized.

2. The audible signal shall be activated if an attempt is made to enter the installation while the source is exposed or the machine is energized.

(2)(a) The alarm system shall be tested for proper operation with a radiation source at the beginning of each day before the installation is used for radiographic operations.

(b) The test shall include a check of the visible and audible signals.

(c) Each entrance control device that reduces the radiation level upon entry, as designated in subsection (1) of this section, shall be tested monthly.

(3)(a) If an entrance device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired within seven (7) calendar days.

(b) The facility may continue to be used during the seven (7) day repair period if the licensee:

1. Implements the continuous surveillance requirements of Section 19 of this administrative regulation; and

2. Uses an alarming ratemeter.

(4) Records of tests for entrance control and audible and visual alarms shall be maintained for inspection by the cabinet for three (3) years from the date of the test.

Section 11. Labeling, Storage, and Transportation. (1) A licensee shall not use a

1 source changer or a container to store radioactive material unless the source changer
2 or the storage container has securely attached to it a durable, legible, and clearly visible
3 label bearing the standard trefoil radiation caution symbol conventional colors (magenta,
4 purple or black on a yellow background, having a minimum diameter of twenty-five (25)
5 millimeters), and the following words:

6 (a)1. CAUTION*; or

7 2. DANGER;

8 (b) RADIOACTIVE MATERIAL; and

9 (c) NOTIFY:

10 1. CIVIL AUTHORITIES; or

11 2. NAME OF COMPANY.

12 (2) The licensee shall not transport radioactive material unless the material is pack-
13 aged, and the package is labeled, marked, and accompanied with appropriate shipping
14 papers in accordance with 10 C.F.R. Part 71.

15 (3) A locked radiographic exposure device, radiation machine, or storage container
16 shall be physically secured to prevent tampering or removal by unauthorized personnel.
17 The licensee shall store radioactive material in a manner that minimizes danger from
18 explosion or fire.

19 (4) The licensee shall lock and physically secure the transport package containing
20 radioactive material in the transporting vehicle to prevent accidental loss, tampering, or
21 unauthorized removal of the radioactive material from the vehicle.

22 Section 12. Conducting Industrial Radiographic Operations. (1)(a) If radiography is
23 performed at a location other than a permanent radiographic installation, the radio-

grapher shall be accompanied by at least one (1) other qualified radiographer or an individual who has met the requirements of Section 14 of this administrative regulation. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry.

(b) Radiography shall not be performed unless more than one (1) qualified individual is present.

(2) A radiographic operation conducted at a location of use authorized on the license shall be conducted in a permanent radiographic installation, unless specifically authorized by the cabinet.

(3) A licensee shall have one (1) year from the effective date of June 27, 1998 to meet the requirement for having two (2) qualified individuals present at a location other than a permanent radiographic installation, as specified in subsection (1) of this section.

Section 13. Radiation Safety Officer for Industrial Radiography. The radiation safety officer (RSO) shall ensure that radiation safety is being performed in the daily operation of the licensee's program in accordance with approved procedures and regulatory requirements.

(1) The minimum qualifications, training, and experience for RSOs for industrial radiography is as follows:

(a) Completion of the training and testing requirements of Section 14 of this administrative regulation;

(b) 2,000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

(c) Formal training in the establishment and maintenance of a radiation protection

1 program.

2 (2) The cabinet shall consider alternatives if the RSO has:

3 (a) Appropriate training or experience in the field of ionizing radiation; and

4 (b) Adequate formal training in establishing and maintaining a radiation safety protec-
5 tion program.

6 (3) The specific duties and authorities of the RSO shall include:

7 (a) Establishing and overseeing operating, emergency and ALARA procedures as re-
8 quired by 902 KAR 100:019, and reviewing them regularly to ensure that the procedures
9 in use conform to current 902 KAR 100:019 procedures, and conform to other require-
10 ments in 902 KAR Chapter 100 and to the license conditions.

11 (b) Overseeing and approving all phases of the training program for radiographic per-
12 sonnel, ensuring that appropriate and effective radiation protection is taught;

13 (c) Ensuring that:

14 1. Required radiation surveys and leak tests are performed and documented in ac-
15 cordance with 902 KAR Chapter 100, including corrective measures if levels of radiation
16 exceed established limits;

17 2. Personnel monitoring devices are calibrated and used properly by occupationally-
18 exposed personnel;

19 3. Records are kept of the monitoring results;

20 4. Timely notifications are made as required by 902 KAR 100:019, Section 40; and

21 5. Operations are conducted safely; and

22 (d) Assuming control for instituting corrective actions including stopping of operations,
23 if necessary.

(4) A licensee or registrant shall have two (2) years from the effective date of June 27, 1999 to meet the requirements of subsections (1) and (2) of this section.

Section 14. Training. (1) A licensee or registrant:

(a) Shall not permit an individual to act as a radiographer as defined in 902 KAR 100:010 until the individual has received:

1. Formal training in the subjects identified in subsection (4) of this section;
2. At least two (2) months of on-the-job training; and
3. Is certified through a radiographer certification program in accordance with the criteria specified in Section 1 of this administrative regulation; or

(b) May, until two (2) years from the effective date of June 27, 1999, allow an individual who has not met the requirements of this section, to act as a radiographer if the individual has:

1. Received training in the subjects identified in subsection (4) of this section; and
2. Demonstrated an understanding of the subjects by successful completion of a written examination previously submitted to and approved by the cabinet;

(c) Shall not permit an individual to act as a radiographer until the individual has:

1. Received copies of and instructions in the following:
 - a. Provisions contained in this administrative regulation;
 - b. Provisions of 902 KAR 100:019, 100:040, 100:070, and 100:165;
 - c. Conditions of the license or registration certificate issued by the cabinet; and
 - d. The licensee's or registrant's approved operating and emergency procedures;
2. Demonstrated understanding of the licensee's license and operating and emergency procedures by successful completion of a written or oral examination covering

1 this material;

2 3. Received training in the:

3 a. Use of the licensee's sources of radiation, the registrant's radiation machine, and
4 other radiation exposure devices;

5 b. Daily inspection of devices and associated equipment; and

6 c. Use of radiation survey instruments; and

7 4. Demonstrated an understanding of the use of radiographic exposure devices,
8 sources, survey instruments, and associated equipment described in paragraphs (a)
9 and (c) of this subsection, by successful completion of a practical examination covering
10 the material;

11 (d) Shall not permit an individual to act as a radiographer's assistant as defined in
12 902 KAR 100:010 until the individual has:

13 1. Received copies of and instructions in the following:

14 a. Provisions contained in this administrative regulation;

15 b. Requirements of 902 KAR 100:019, 100:040, 100:070, and 100:165;

16 c. Conditions of the license or registration certificate issued by the cabinet; and

17 d. The licensee's or registrant's operating and emergency procedures;

18 2. Demonstrated competence to use, under the personal supervision of the radio-
19 grapher, the sources of radiation, radiographic exposure devices, radiation machines,
20 associated equipment, and radiation survey instruments that the assistant uses; and

21 3. Demonstrated:

22 a. Understanding of the instructions provided in paragraph (a) of this subsection by
23 successfully completing a written test on the subjects covered; and

1 b. Competence in the use of hardware described in paragraph (b) of this subsection
2 by successfully completing a practical examination on the use of the hardware; and

3 (e) Shall provide annual refresher safety training for a radiographer and radiograph-
4 er's assistant at intervals not to exceed twelve (12) months.

5 (2)(a) Except in those operations in which a single individual shall serve as both radi-
6 ographer and RSO and shall perform all radiography operations, the RSO or designee
7 shall conduct an inspection program of the job performance of a radiographer and radi-
8 ographer's assistant to ensure that 902 KAR Chapter 100, license requirements, and
9 the applicant's operating and emergency procedures are followed.

10 (b) The inspection program shall include observation of the performance of the radio-
11 grapher and radiographer's assistant during an actual industrial radiographic operation,
12 at intervals not to exceed six (6) months;

13 (c) If a radiographer or a radiographer's assistant has not participated in an industrial
14 radiographic operation for more than six (6) months since the last inspection, the radio-
15 grapher shall demonstrate knowledge of the training requirements of subsection (3) of
16 this section and the radiographer's assistant shall demonstrate knowledge of the train-
17 ing requirements of subsection (1)(d)2 of this section by a practical examination before
18 either person may next participate in a radiographic operation; and

19 (d) The cabinet shall consider alternatives in those situations in which the individual
20 serves as both radiographer and RSO.

21 (3) Records of training specified in subsection (1)(c) of this section shall be main-
22 tained by a licensee or registrant for inspection by the cabinet for three (3) years after
23 the record is made.

(a) Records shall include:

1. Radiographer certification documents;

2. Verification of certification status;

3. Copies or written tests;

4. Dates of oral tests and practical examinations;

5. Names of individuals conducting and receiving the oral and practical examinations;

and

6. Documentation of annual refresher safety training and semi-annual inspections of job performance for a radiographer and a radiographer's assistant, which shall include:

a. Topics discussed during the refresher safety training;

b. Dates the annual refresher safety training was conducted; and

c. Names of the instructors and attendees.

(b) For inspections of job performance, the records shall also include a list showing the items checked and all noncompliances observed by the RSO.

(4) The licensee or registrant shall include the following subjects required in subsection (1)(b) of this section:

(a) Fundamentals of radiation safety including:

1. Characteristics of gamma radiation;

2. Units of radiation dose and quantity of radioactivity;

3. Hazards of exposure to radiation;

4. Levels of radiation from radioactive material; and

5. Methods of controlling radiation dose by time, distance, and shielding;

(b) Radiation detection instruments including:

1 1. Use, operation, calibration, and limitations of radiation survey instruments;

2 2. Survey techniques; and

3 3. Use of personnel monitoring equipment;

4 (c) Equipment to be used including:

5 1. Operation and control of radiographic exposure equipment, remote handling
6 equipment, and storage containers, including pictures or models of source assemblies
7 (pigtailed);

8 2. Storage, control, and disposal of radioactive material;

9 3. Inspection and maintenance of equipment; and

10 4. Operation and control of radiation machines;

11 (d) The requirements of 902 KAR Chapter 100, as applicable; and

12 (e) Case histories of accidents in radiography.

13 (5) A licensee or registrant shall have one (1) year from June 27, 1998 to comply with
14 the additional training requirements specified in subsections (1)(c) and (d) of this sec-
15 tion.

16 (6) Licensees and registrants shall have one (1) year from June 27, 1999, to comply
17 with the certification requirements specified in subsection (1) of this section. Records of
18 radiographer certification maintained in accordance with
19 subsection (3) of this section shall provide appropriate affirmation of certification re-
20 quirements specified in subsection (1) of this section.

21 Section 15. Operating and Emergency Procedures. (1) A licensee's or registrant's
22 operating and emergency procedures shall include instructions in at least the following:

23 (a) The handling and use of sources of radiation to be employed so an individual is

not likely to be exposed to radiation doses in excess of the limits established in 902 KAR 100:019, Section 3;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to radiographic areas;

(d) Methods and occasions for locking and securing a source of radiation, radiographic exposure device, or transport and storage container;

(e) Personnel monitoring and the use of personnel monitoring equipment, including steps that shall be taken immediately by radiography personnel if a pocket dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly;

(f) Transportation of sources of radiation to field locations, including:

1. Packing of a radiographic exposure device and storage container in a vehicle;

2. Placarding of a vehicle if needed; and

3. Control of sources of radiation during transportation;

(g) Minimizing exposure of individuals if an accident occurs;

(h) The procedure for notifying proper personnel if an accident occurs;

(i) Maintenance of records; and

(j) The inspection, maintenance, and operability checks of radiographic exposure devices, radiation machines, storage containers, survey instruments, and transport containers.

(2) The licensee or registrant shall maintain copies of current operating and emergency procedures until the cabinet terminates the license.

(3) Superseded material shall be retained for three (3) years after the change is made.

Section 16. Personnel Monitoring. (1) A licensee or registrant shall not permit an individual to act as a radiographer or radiographer's assistant unless, at all times during radiographic operations, the individual wears on the trunk of the body a direct reading pocket dosimeter, an operating alarm ratemeter, and a personal dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.

(2) The wearing of an alarm ratemeter shall not be required for permanent radiography facilities in which another appropriate alarming or warning device is in routine use or during radiographic operations using radiation machines.

(3) Pocket dosimeters shall have a range from zero to at least 200 milliroentgens (two (2) millisieverts) and shall be recharged daily or at the start of a shift. Electronic personal dosimeters may be used in place of ion-chamber pocket dosimeters only.

(4) A personal dosimeter shall be assigned to, and worn by, only one (1) individual.

(5) A film badge shall be replaced each month, and other personal dosimeters processed and evaluated by an accredited NVLAP processor shall be replaced at intervals not to exceed three (3) months.

(6) After replacement, each personal dosimeter shall be processed as soon as possible.

(7) Direct reading dosimeters, such as pocket dosimeters or electronic personal dosimeters, shall be read and exposures recorded at the beginning and end of a shift.

(a) If an individual's pocket dosimeter is found to be off scale, or if the electronic personal dosimeter reads greater than 200 millirems (two (2) millisieverts), and the possibility of radiation exposure cannot be ruled out as the cause:

1 1. The individual's personal dosimeter shall be sent for processing within twenty-four
2 (24) hours;

3 2. Radiographic operations by the individual shall cease; and

4 3. The individual shall not return to work with sources of radiation until a determina-
5 tion of the radiation exposure has been made by the RSO or the RSO's designee. The
6 results shall be included in the records maintained in accordance with paragraph (b) of
7 this subsection and subsection (10)(b)~~[(9)(b)]~~ of this section.

8 (b) A licensee or registrant shall maintain the following exposure records:

9 1. Direct reading dosimeter readings and yearly operability checks for three (3) years
10 after the record is made;

11 2. Reports received from the NVLAP processor of personal dosimeter results until the
12 cabinet terminates the license; and

13 3. Records of estimates of exposures as a result of off-scale personal direct reading
14 dosimeters, or lost or damaged personal dosimeters, until the cabinet terminates the li-
15 cense.

16 (8) If a personal dosimeter is lost or damaged, the worker shall cease work imme-
17 diately until:

18 (a) A replacement personal dosimeter meeting the requirements of subsection (1) of
19 this section is provided; and

20 (b) The exposure is calculated for the time period from issuance to loss or damage of
21 the personal dosimeter. The results of the calculated exposure and the time period for
22 which the personal dosimeter was
23 lost or damaged shall be included in the records maintained in accordance with subsec-

tion (7) of this section.

(9)(a) Pocket dosimeters, or electronic personal dosimeters, shall be checked for correct response to radiation at periods not to exceed twelve (12) months.

(b) Acceptable dosimeters shall read within plus or minus twenty (20) percent of the true radiation exposure.

(10)(a) An alarm ratemeter shall:

1. Be checked to ensure that the audible alarm functions properly prior to use at the start of a shift;

2. Be set to give an alarm signal at a preset dose rate of 500 mR/hr (5mSv/hr);

3. Require special means to change the preset alarm functions;

4. Be calibrated at periods not to exceed twelve (12) months for correct response to radiation; and

5. Alarm within plus or minus twenty (20) percent of the true radiation dose rate.

(b) Records of alarm ratemeter calibrations shall be maintained for three (3) years after the record is made.

Section 17. Documents Required at Field Stations and Temporary Job Sites. A licensee or registrant shall have the following records available for inspection by the cabinet at each field station, if applicable, and at each job site:

(1) A copy of the operating and emergency procedures;

(2) A current copy of the radioactive material license or registration certificate;

(3) A copy of 902 KAR 100:019, 100:100, and 100:165;

(4) Latest survey records required by Section 22 of this administrative regulation;

(5) Records of direct reading dosimeters, such as pocket dosimeters or electronic

1 personal dosimeters readings, as required by Section 16 of this administrative regula-
2 tion;

3 (6) Evidence of The latest instrument calibration of the radiation survey instrumenta-
4 tion in use at the site, as required by Section 5 of this administrative regulation;

5 (7) Utilization records for each radiographic exposure device dispatched from that lo-
6 cation, as required by Section 8 of this administrative regulation;

7 (8) Records of equipment problems identified in daily checks of equipment required
8 by Section 9 of this administrative regulation;

9 (9) Records of alarm system and entrance control checks required by Section 10 of
10 this administrative regulation, if applicable;

11 (10) Evidence of the latest calibrations of alarm ratemeters and operability checks of
12 pocket dosimeters and electronic personal dosimeters, as required by Section 16 of this
13 administrative regulation;

14 (11) The shipping papers for the transportation of radioactive materials required by
15 902 KAR 100:070; and

16 (12) If operating in accordance with reciprocity pursuant to 902 KAR 100:065, a copy
17 of the agreement state or U.S. Nuclear Regulatory Commission license authorizing the
18 use of radioactive materials.

19 Section 18. Specific Provisions for Radiographic Personnel Performing Industrial Ra-
20 diography. (1) At a job site, the following shall be supplied by a licensee or registrant:

21 (a) At least one (1) operable, calibrated survey instrument for every exposure device
22 or radiation machine in use;

23 (b) A current whole body personnel monitor (TLD or film badge) for an individual per-

forming radiographic operations;

(c) An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for a worker performing radiographic operations;

(d) Appropriate barrier ropes and signs; and

(e) An operable, calibrated, alarming ratemeter for every person performing radiographic operations using a radiographic exposure device.

(2) A radiographer at a job site shall have on the radiographer's person a valid certificate ID card issued by a certifying entity.

(3) An industrial radiographic operation shall not be performed if the items in subsections (1) and (2) of this section are not available at the job site or they are inoperable.

(4) During an inspection by the cabinet, the cabinet shall terminate an operation if items in subsections (1) and (2) of this section are not available or not operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until required conditions are met.

Section 19. Surveillance. During a radiographic operation, a radiographer or the other individual present, as required by Section 12 of this administrative regulation, shall maintain direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, except at a permanent radiographic installation where:

(1) Entryways are locked; and

(2) The requirements of Section 10 of this administrative regulation are met.

Section 20. Posting. (1) An area in which radiography is being performed shall be conspicuously posted, as required in 902 KAR 100:019, Section 24(1) and (2).

(2) Exceptions listed in 902 KAR 100:019 do not apply to an industrial radiographic

operation.

Section 21. Special Provisions and Exemptions for Cabinet X-ray Systems. (1) The use of a certified or certifiable cabinet x-ray system shall be exempt from the requirements of this administrative regulation, except for the following:

(a) For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

1. A registrant shall not permit an individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit.

2. A test for proper operation of interlocks shall be conducted and recorded at intervals not to exceed six (6) months.

3. A registrant shall perform an evaluation of the radiation dose limits to determine compliance with 902 KAR 100:019, Section 10, and 21 C.F.R. 1020.40, Cabinet X-ray Systems, at intervals not to exceed one (1) year.

4. Records shall be maintained demonstrating compliance with subsections (1)(a)1 and 2 of this section until disposal is authorized by the cabinet.

5. Records of the evaluation required by subparagraph 3 of this paragraph shall be maintained for two (2) years after the evaluation is performed.

(b)1. Certified cabinet x-ray systems shall be maintained in compliance with 21 C.F.R. 1020.40, Cabinet X-ray Systems.

2. A modification shall not be made to the system unless prior cabinet approval has been granted.

(2) An industrial use of a hand-held light intensified imaging device shall be exempt

1 from the requirements of this administrative regulation if the dose rate eighteen (18)
2 inches from the source of radiation to any individual does not exceed two (2) millirem
3 per hour. A device exceeding this limit shall meet the applicable requirements of this
4 administrative regulation and the licensing or registration requirements of 902 KAR
5 100:040 and 100:110, as applicable.

6 Section 22. Radiation Surveys and Survey Records. (1) A radiographic operation
7 shall not be conducted unless calibrated and operable radiation survey instrumentation,
8 as described in Section 5 of this administrative regulation, is available and used at a
9 location of radiographic operations.

10 (2) A survey with a radiation survey instrument shall be made after a radiographic
11 exposure of the radiographic exposure device and the guide tube if approaching the de-
12 vice or guide tube to determine that the sealed source has been returned to its shielded
13 position before exchanging films, repositioning the exposure head, or dismantling
14 equipment.

15 (3) A survey shall be conducted of the radiographic exposure device with a calibrated
16 radiation survey instrument if the source is exchanged and if a radiographic exposure
17 device is placed in a storage area, to ensure that the source is in its shielded position.

18 (4) A physical radiation survey shall be made after a radiographic exposure using ra-
19 diographic machines to determine that the machine is "off."

20 (5) Records shall be kept of the exposure device survey conducted before the device
21 is placed in storage as specified in subsection (3) of this section if that survey is the last
22 one performed in the workday. The records shall be maintained for inspection by the
23 cabinet for three (3) years after it is made.

1 Section 23. Supervision of Radiographer's Assistant. (1) If a radiographer's assistant
2 uses radiographic exposure devices, associated equipment, sealed sources, or con-
3 ducts radiation surveys required by Section 22 of this administrative regulation to de-
4 termine that the sealed source has returned to the shielded position after an exposure
5 or the radiation machine is off, the radiographer's assistant shall be under the personal
6 supervision of a radiographer.

7 (2) The radiographer shall:

8 (a) Be physically present at the site where a source of radiation and associated
9 equipment is being used;

10 (b) Watch, by direct visual observation, the performance of the operations performed
11 by the radiographer's assistant referred to in this section; and

12 (c) Be in close proximity so that immediate assistance shall be given if required.

13 Section 24. Reporting Requirements. (1) In addition to the reporting requirements
14 specified in 902 KAR 100:040, Section 15, and in accordance with other sections of this
15 administrative regulation, a licensee or registrant shall provide a written report to the
16 Cabinet for Health and Family Services, Radiation Health Branch within thirty (30) days
17 of the occurrence of the following incidents involving radiographic equipment:

18 (a) Unintentional disconnection of the source assembly from the control cable;

19 (b) Inability to retract the source assembly to its fully shielded position and secure it in
20 this position;

21 (c) Failure of a component, critical to safe operation of the device, to properly perform
22 its intended function;

23 (d) Failure of an indicator on a radiation machine to show that radiation is being pro-

duced;

(e) Failure of an exposure switch to terminate production of radiation if turned to the off position; or

(f) Failure of a safety interlock to terminate x-ray production.

(2) The licensee or registrant shall include the following information in a report submitted in accordance with subsection (1) of this section:

(a) A description of the equipment problem;

(b) Cause of an incident, if known;

(c) Manufacturer and model number of equipment involved in the incident;

(d) Place, time, and date of the incident;

(e) Actions taken to establish normal operations;

(f) Corrective actions taken or planned to prevent recurrence; and

(g) Qualifications of personnel involved in the incident.

(3) A report of an overexposure submitted under 902 KAR 100:019, Section 40, involving failure of a safety component of radiography equipment shall include the information specified in subsection (2) of this section.

(4) A licensee shall notify the cabinet if conducting radiographic operations or storing radioactive material at a location not listed on the license for a period in excess of 180 days in a calendar year.

Section 25. Incorporation by Reference. (1) The American National Standard Institute (ANSI) N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography", published in NBS Handbook 136, issued January 1981, is incorporated by reference.

1 (2) This material may be inspected, copied, or obtained, subject to applicable copy-
2 right law, at the Department for Public Health, Office of the Commissioner, 275 East
3 Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. until 4:30 p.m.

902 KAR 100:100 Industrial radiography

REVIEWED:

Date

Steve Davis, MD
Acting Commissioner
Department for Public Health

APPROVED:

Date

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

PUBLIC HEARING AND COMMENT PERIOD

A public hearing on this administrative regulation shall, if requested, be held on September 21, 2012, at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by September 14, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business October 1, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 902 KAR 100:100

Contact Person: Matt McKinley (502) 564-3700 extension 3701

(1) Provide a brief summary of:

(a) What this administrative regulation does: It requires the personal dosimeters used by industrial radiographers and their assistants be processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. This makes radiography dosimetry requirements consistent with the general dosimetry requirements found in 902 KAR 100:019 Section 12(3). It also updates the proper names of the Branch (Radiation Health Branch) and the Cabinet (Cabinet for Health and Family Services).

(b) The necessity of this administrative regulation: The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:100 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How this administrative regulation conforms to the content of the authorizing statutes: The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: It will clarify dosimetry requirements for industrial radiographers and their assistants.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: It adds language to section 16 regarding dosimetry processing. It also updates the proper names of the Branch (Radiation Health Branch) and the Cabinet (Cabinet for Health and Family Services).

(b) The necessity of the amendment to this administrative regulation: To ensure compliance with the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste. This amendment updates the requirement for measuring radioactivity to conform to federal regulations.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will make the federal and state regulations consistent with one another thus making it easier to enforce compliance.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Approximately 11 industrial radiographers licensed by the Kentucky Radiation Health Branch who actively conduct business in Kentucky.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: No additional action by the regulated is necessary. They are all already in compliance with the requirements of 902 KAR 100:019.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No cost of compliance is involved. They are already in compliance.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The regulated entities will have increased assurance of regulatory compliance with both federal and state regulations.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional cost will be incurred as a result of amending this administrative regulation.

(b) On a continuing basis: No additional cost will be incurred as a result of amending this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: General funds are used to support this program. No fund increase is required by this regulation amendment.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change if it is an amendment: An increase in fees or funding will not be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This regulation establishes no fees either directly or indirectly.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 902 KAR 100:100 Contact Person: Matt McKinley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No

2. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? All parts of the state and local governments where these licenses operate are impacted.
3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by this administrative regulation.

The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:100 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts)

for the first year? This regulation will generate no revenue for the state or local government during its first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This regulation will generate no revenue in subsequent years for state or local governments.

(c) How much will it cost to administer this program for the first year?
This amendment will not increase program cost the first year.

(d) How much will it cost to administer this program for subsequent years?
This amendment will not increase program cost in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

1 **CABINET FOR HEALTH AND FAMILY SERVICES**

2 **Department of Public Health**

3 **Division of Public Health Protection and Safety**

4 **(Amendment)**

5 **902 KAR 100:142. Wire line service operations.**

6 RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. 39

7 STATUTORY AUTHORITY: KRS 194.050, 211.090, 211.844, 10 C.F.R. 39

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet
9 for Health and Family Services to provide by administrative regulation for the registra-
10 tion and licensing of the possession or use of sources of ionizing or electronic product
11 radiation and the handling and disposal of radioactive waste. This administrative regula-
12 tion provides radiation safety requirements for persons using sources of radiation for
13 wire line service operations including radioactive markers, mineral exploration, and sub-
14 surface tracer studies.

15 Section 1. Agreement with Well Owner or Operator. (1) A licensee shall not perform a
16 wire line service operation with a sealed source in a well or well-bore unless, prior to
17 commencement of the operation, the licensee has a written agreement with the well op-
18 erator or well or land owner ~~[,or drilling contractor]~~ that:

19 (a) If a sealed source is lodged downhole, a reasonable effort at recovery shall be
20 made;

21 (b) If a decision is made to abandon the sealed source downhole, the requirements

of this administrative regulation shall be met;

(c) A person shall not attempt to recover a sealed source in a manner, which, in the licensee's opinion, may result in its rupture;

(d) The radiation monitoring required in Section 24[14] of this administrative regulation shall be performed;

(e) If the environment, equipment, or personnel are contaminated with radioactive material, decontamination shall be performed prior to release from the site or for unrestricted use; and

(f) If the sealed source is classified as not retrievable after reasonable efforts at recovery have been expended, the requirements of Section 27[23] of this administrative regulation shall be met.

(2) The licensee shall retain a copy of the written agreement with the well operator or[;] well or land owner[~~,-or drilling contractor~~] for three (3) years after completion of the well logging operations.

Section 2. Limits on Levels of Radiation. Radioactive materials shall be used, stored, and transported in a manner that the requirements of 902 KAR 100:019 and 100:070 shall be met.

Section 3. Storage Precautions. (1) Sources of radiation, except accelerators, shall be provided with a lockable storage or transport container.

(2) The container shall be provided with a lock (or tamper seal for calibration sources) to prevent unauthorized removal of, or exposure to, the source of radiation.

(3) Sources of radiation shall be stored in a manner that shall minimize the danger from explosion or fire.

1 Section 4. Transport Precautions. Transport containers shall be physically secured to
2 the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

3 Section 5. Radiation Survey Instruments. (1) The licensee or registrant shall maintain
4 sufficient calibrated and operable radiation survey instruments, capable of detecting be-
5 ta and gamma radiation, at each field station and temporary jobsite to make physical
6 radiation surveys as required by this administrative regulation and by 902 KAR 100:019.

7 (2)(a) Instrumentation required by this section shall be capable of measuring one-
8 tenth (0.1) millirem (.001 mSv) per hour through at least fifty (50) millirem (0.5 mSv) per
9 hour.

10 (b) The licensee shall have available additional calibrated and operable radiation de-
11 tection instruments sensitive enough to detect the low radiation and contamination le-
12 vels that could be encountered if a sealed source ruptured. The licensee shall own the
13 instruments or have a procedure to obtain them quickly from a second party.

14 (3) The licensee shall have each[A] radiation survey instrument required by subsec-
15 tion (1) and (2) of this section[shall be] calibrated:

16 (a) At intervals not to exceed six (6) months and after each instrument servicing;

17 (b) At energies and exposure levels appropriate for use; and

18 (c) So that accuracy within plus or minus twenty (20) percent of the true radiation lev-
19 el shall be demonstrated on each scale.

20 (4) Records of calibration shall be maintained for a period of at least three (3)[two (2)]
21 years after the date of calibration for inspection by the cabinet.

22 Section 6. Leak Testing of Sealed Sources. (1) A licensee who uses a sealed source
23 of radioactive material shall have the source tested for leakage as specified in this sec-

tion. The licensee shall keep a record of leak test results in units of microcuries and retain the record for inspection by the cabinet.

(2) Method of Testing.

(a) The wipe of a sealed source shall be performed using a leak test kit or method approved by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state;

(b) The wipe sample shall be taken from the nearest accessible point to the sealed source where contamination might accumulate;

(c) The wipe sample shall be analyzed for radioactive contamination; and

(d) The analysis shall be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and shall be performed by a person approved by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state, as established in 10 C.F.R. Part 39.35.

(3) Test Frequency.

(a) Each sealed source, except an Energy Compensation Source (ECS), shall be tested at intervals not to exceed six (6) months;

(b) In the absence of a certificate from a transferor that a test has been made within the six (6) months before the transfer, the sealed source shall not be used until tested.

(4)(a) Each ECS, not exempted by subsection (7) of this section, shall be tested at intervals not to exceed three (3) years. In the absence of a certificate from a transferor that a test has been made with the three (3) years before the transfer, the ECS shall not be used until tested.

(5) Removal from service:

(a) If the test conducted under subsections (1) and (2) of this section reveals the

1 presence of 0.005 microcuries (185 Bq) or more of removable radioactive material, the
2 licensee shall remove the sealed source from service immediately and have it
3 decontaminated, repaired, or disposed by a cabinet, U.S. Nuclear Regulatory Commis-
4 sion, or agreement state licensee authorized to perform these functions;

5 (b) The licensee shall check the equipment associated with the leaking source for ra-
6 dioactive contamination and, if contaminated, have it decontaminated or disposed of by
7 a cabinet, U.S. Nuclear Regulatory Commission, or agreement state licensee that is au-
8 thorized to perform these functions.

9 (6) The licensee shall submit a report to the cabinet within five (5) days of receiving
10 the test results, and the report shall describe the equipment involved in the leak, the test
11 results, contamination that resulted from the leaking source, and the corrective actions
12 taken up to the time that report is made.

13 (7) The following sealed sources shall be exempt from the periodic leak test require-
14 ments in subsections (1) through (5) of this section:

15 (a) Hydrogen – 3 (tritium) sources;

16 (b) Sources containing radioactive material with a half-life of thirty (30) days or less;

17 (c) Sealed sources containing radioactive material in gaseous form;

18 (d) Sources of beta- or gamma-emitting radioactive material with an activity of ten
19 (10) microcuries (0.37 Bq) or less; and

20 (e) Sources of alpha- or neutron-emitting radioactive material with an activity of ten
21 (10) microcuries (0.37 Bq) or less.

22 Section 7. Quarterly Inventory. (1) A licensee or registrant shall conduct a quarterly
23 physical inventory to account for sources of radiation received or possessed by the li-

1 censee or registrant.

2 (2) Records of inventories shall be maintained for at least two (2) years from the date
3 of the inventory for inspection by the cabinet and shall include:

4 (a) The quantities and kinds of sources of radiation;

5 (b) The location where sources of radiation are assigned;

6 (c) The date of the inventory; and

7 (d) The name of the individual conducting the inventory.

8 Section 8. Utilization Records. A licensee or registrant shall maintain current records,
9 which shall be kept available for inspection by the cabinet for at least two (2) years from
10 the date of the recorded event showing the following information for each source of rad-
11 iation:

12 (1) A description (or make and model number or serial number) of each source of
13 radiation used;

14 (2) The identity of the logging supervisor responsible for the radioactive material
15 and identity of logging assistant present;

16 (3) Locations where used and dates of use; and

17 (4) In the case of tracer materials and radioactive markers, the utilization record shall
18 also indicate the radionuclide and activity used at a particular well site.

19 Section 9. Design and Performance Criteria for Sealed Sources used in Downhole
20 Operations. (1) A sealed source, except those containing radioactive material in ga-
21 seous form, used in downhole operations shall, as a minimum, meet the following crite-
22 ria:

23 (a) Be of double encapsulated construction;

(b) Contain radioactive material whose chemical and physical form shall be as insoluble and nondispersible as practicable; and

(c) Meets the requirements of paragraphs (2), (3), and (4) of this section.

(2) For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source in well logging applications if it meets the requirements of USASI N5.10-1968, Classification of Sealed Radioactive Sources, or the requirements in subsections (3) or (4) of this section.

(3) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for use in well logging applications if it meets the oil-well logging requirements of ANSI/HPS N43.6-1997, Sealed Radioactive Sources – Classification.

(4) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for use in well logging applications if the sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

(a) Temperature. The test source shall be held at minus forty (40) degrees Centigrade for twenty (20) minutes, 600 degrees Centigrade for one (1) hour, and then be subject to a thermal shock test with a temperature drop from 600 degrees Centigrade to twenty (20) degrees Centigrade within fifteen (15) seconds;

(b) Impact test. A five (5) kilogram steel hammer, two and five-tenths (2.5) centimeters in diameter, shall be dropped from a height of one (1) meter onto the test source;

(c) Vibration test. The test source shall be subject to a vibration from twenty-five (25) Hz to 500 Hz at five (5) g amplitude for thirty (30) minutes;

(d) Puncture test. A one (1) gram hammer and pin, three-tenths (0.3) centimeter in diameter, shall be dropped from a height of one (1) meter onto the test source.

1 (e) Pressure Test. The test source shall be subject to an external pressure of 1.695 x
2 10⁷ pascals (24,600 pounds per square inch absolute).

3 (5) The requirements in subsections (1) through (4) of this section shall not apply to
4 sealed sources that contain radioactive material in gaseous form.

5 (6) The requirements in subsections (1) through (4) of this section shall not apply to
6 ECS sources, which shall be registered with the cabinet, U.S. Nuclear Regulatory
7 Commission, or an agreement state.

8 (7) Certification documents shall be maintained for inspection by the cabinet for a pe-
9 riod of at least two (2) years after source disposal.

10 (8) For sources abandoned downhole, certification documents shall be maintained
11 until their disposal is authorized by the cabinet.

12 Section 10. Labeling. (1) A source, source holder, or logging tool containing radioac-
13 tive material shall bear a durable, legible, and clearly visible marking or label that has,
14 as a minimum, the standard radiation symbol without color requirement and the follow-
15 ing wording: DANGER (or CAUTION) RADIOACTIVE.

16 (2) This labeling shall be on the smallest component, for example, source, source
17 holder, or logging tool, that is transported as a separate piece of equipment.

18 (3) A transport container shall have permanently attached to it a durable legible and
19 clearly visible label that has, at a minimum, the standard radiation symbol and the fol-
20 lowing wording: DANGER (or CAUTION) RADIOACTIVE. Notify civil authorities (or
21 name of company) if found.

22 Section 11. Inspection and Maintenance. (1) A licensee or registrant shall conduct, at
23 intervals not to exceed six (6) months, a program of inspection of sealed sources and

1 inspection and maintenance of source holders, logging tools, source handling tools, sto-
2 rage containers, transport containers, uranium sinker bars, and injection tools to assure
3 proper labeling, operation, and physical condition.

4 (2) Records of inspection and maintenance shall be maintained for a period of at
5 least two (2) years for inspection by the cabinet.

6 (3) If an inspection conducted pursuant to this section reveals damage to labeling or
7 components critical to radiation safety, the device shall be removed from service until
8 repairs have been made.

9 (4) The repair, opening, or other modification of a sealed source shall be performed
10 only by persons specifically authorized to do so by the cabinet, the U. S. Nuclear Regu-
11 latory Commission, or an Agreement State.

12 (5) If a sealed source is stuck in the source holder, the licensee shall not perform any
13 operation, for example drilling, cutting, or chiseling on the source holder unless the li-
14 censee is specifically licensed by the cabinet, U.S. Nuclear Regulatory Commission, or
15 an agreement state to perform the operation.

16 Section 12. Training Requirements. (1) A licensee or registrant shall not permit an in-
17 dividual to act as a logging supervisor until the individual has:

18 (a) Completed a course recognized by the cabinet, an Agreement State, or the U. S.
19 Nuclear Regulatory Commission covering the subjects outlined in Section 28 of this
20 administrative regulation and shall have demonstrated an understanding of the subjects;

21 (b) Received copies of and demonstrated an understanding of the following:

22 1. The requirements contained in this administrative regulation;

23 2. Provisions of 902 KAR Chapter 100;

1 3. The conditions of the license or registration certificate issued by the cabinet; and

2 4. The licensee's or registrant's approved operating and emergency procedures;

3 (c) Completed on-the-job training and demonstrated competence in the use of
4 sources of radiation, related handling tools, and radiation survey instruments that shall
5 be employed in his assignment; and

6 (d) Demonstrated an understanding of the requirements in paragraphs (a) and (b) of
7 this subsection by successfully completing a written test.

8 (2) A licensee or registrant shall not permit an individual to act as a logging assistant
9 until the individual has:

10 (a) Read and received instruction in the licensee's or registrant's operating and
11 emergency procedures, the requirements contained in this administrative regulation and
12 other applicable provisions of 902 KAR Chapter 100 and shall have demonstrated un-
13 derstanding of the subjects;

14 (b) Demonstrated competence to use, under the personal
15 supervision of the logging supervisor, the sources of radiation, related handling tools,
16 and radiation survey instruments that will be employed in his assignment; and

17 (c) Demonstrated understanding of the requirements in paragraphs (a) and (b) of this
18 subsection by successfully completing a written or oral test.

19 (3) A licensee or registrant shall maintain employee training records for inspection by
20 the cabinet for at least two (2) years following termination of employment.

21 Section 13. Operating and Emergency Procedures. The licensee's or registrant's op-
22 erating and emergency procedures shall include instructions in at least the following:

23 (1) The handling and use of sources of radiation to be employed so that an individu-

al is not likely to be exposed to radiation doses in excess of the limits established in 902
KAR 100:019, Section 3;

(2) The handling and use of radioactive material including the use of sealed sources
in wells without surface casing for protecting fresh water aquifers, if appropriate;

(3) The use of remote handling tools for handling sealed source and radioactive tracer
material except low-activity calibration sources;

(4) Methods and occasions for conducting radiation surveys, including surveys for detecting
contamination;

(5) Methods and occasions for locking and securing sources of radiation;

(6) Personnel monitoring and the use of personnel monitoring equipment;

(7) Transportation to temporary job sites and field stations, including:

(a) Packaging of sources of radiation in the vehicles;

(b) Placarding of vehicles, if needed; and

(c) Physically securing sources of radiation during transportation to prevent accidental
loss, tampering, or unauthorized removal;

(8) Minimizing exposures of individuals from inhalation and ingestion of radioactive
tracer material;

(9) The procedure for notifying proper personnel in the event of an accident;

(10) Maintenance of records, including records generated by logging personnel at
temporary jobsites;

(11) The inspection of sealed sources;

(12) The inspection and maintenance of source holders, logging tools, source handling
tools, storage containers, transport containers, uranium sinker bars, and injection

1 tools;

2 (13) The procedures that shall be followed in the event a sealed source is lodged
3 downhole;

4 (14) Picking up, receiving, and opening packages containing radioactive material;

5 (15) Decontamination of the environment, equipment, and personnel if tracers are
6 used; and

7 (16) Actions to be taken if a sealed source is ruptured or a sealed source is lodged in
8 a well, including steps to:

9 (a) Prevent the spread of contamination;

10 (b) Minimize inhalation and ingestion of radioactive material; and

11 (c) Obtain suitable radiation survey instruments as required by Section 5 of this ad-
12 ministrative regulation.

13 Section 14. Personnel Monitoring. (1) A licensee or registrant shall not permit an indi-
14 vidual to act as a logging supervisor or logging assistant unless the individual wears, at
15 all times during well service operations utilizing sources of radiation, a personal dosime-
16 ter that is processed and evaluated by an accredited NVLAP processor.

17 (2) A personal dosimeter shall be assigned to and worn by only one (1) individual.

18 (3) Film badges shall be replaced monthly and other personal dosimeters replaced at
19 least quarterly.

20 (4) After replacement, a personal dosimeter shall be promptly processed.

21 (5) Personnel monitoring records shall be maintained for inspection by the cabinet
22 until it authorizes disposal.

23 Section 15. Security. During logging or tracer applications, the logging supervisor

1 or other designated employee shall maintain direct surveillance of the operation to pro-
2 tect against unauthorized or unnecessary entry into a restricted area.

3 Section 16. Handling Tools. The licensee shall provide and require the use of tools
4 that shall assure remote handling of sealed sources other than low activity calibration
5 sources.

6 Section 17. Tracer Studies. (1) Protective gloves and other appropriate protective
7 clothing shall be used by personnel handling radioactive tracer material.

8 (2) Care shall be taken to avoid ingestion or inhalation of radioactive material.

9 (3) A licensee shall not permit injection of radioactive material into potable aquifers
10 without prior written authorization from the cabinet.

11 Section 18. Uranium Sinker Bars. The licensee may use a uranium sinker bar in well
12 logging applications only if it is legibly impressed with the words "CAUTION – RA-
13 DIOACTIVE – DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COM-
14 PANY NAME) IF FOUND."

15 Section 19. Energy Compensation Source (ECS). (1) The licensee may use an ener-
16 gy compensation source which is contained within a logging tool, or other tool compo-
17 nents, only if the ECS contains quantities of radioactive material not exceeding 100 mi-
18 crocuries (3.7 MBq).

19 (2) For well logging applications with a surface casing for protecting fresh water aqui-
20 fers, use of the ECS is only subject to the requirements of Sections 6, 7, and 8.

21 (3) For well logging applications without a surface casing for protecting fresh water
22 aquifers, use of the energy compensation source is only subject to the requirements of
23 Sections 1, 6, 7, 8, 20, and 27[~~25~~].

1 Section 20. Use of a Sealed Source in a Well Without a Surface Casing. A licensee
2 may use a sealed source in a well without a surface casing for protecting fresh water
3 aquifers only if the licensee follows a procedure, approved by the Cabinet, for reducing
4 the probability of the source becoming lodged in the well.

5 Section 21. Particle Accelerators. A licensee or registrant shall not permit above
6 ground testing of particle accelerators if the testing will result in the production of radia-
7 tion except in areas or facilities controlled or shielded so that the requirements of 902
8 KAR 100:019 shall be met.

9 Section 22. Tritium Neutron Generator Target Source. (1) Use of a tritium neutron
10 generator target source, containing quantities not exceeding thirty (30) curies (1,110
11 GBq) and in a well with a surface casing to protect fresh water aquifers shall be estab-
12 lished in this administrative regulation, except Sections 1, 9, and 27.

13 (2) Use of a tritium neutron generator target source, containing quantities exceeding
14 thirty (30) curies (1,110 GBq) or in a well without a surface casing to protect fresh water
15 aquifers shall be established in this administrative regulation, except Section 9 of this
16 administrative regulation.

17 Section 23. Radiation Surveys. (1) A radiation survey shall be made and recorded for
18 each area where radioactive materials are stored and used.

19 (2) A radiation survey shall be made and recorded of the radiation levels in
20 occupied positions and on the exterior of each vehicle used to transport radioactive ma-
21 terials.

22 (3) Each survey shall include each source of radiation and combination of sources of
23 radiation transported in the vehicle.

(4) After removal of the sealed source from the logging tool and before departing the job site, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

(5) A radiation survey shall be made and recorded at the job site or well head for tracer operations, except for those using hydrogen-3, carbon-14, and sulfur-35.

(6) Each survey shall include radiation levels prior to and after the operation.

(7) Records required pursuant to this section shall include:

(a) The dates;

(b) The identification of the individual making the survey;

(c) Identification of survey instrument used; and

(d) An exact description of the location of the survey.

(8) Each survey record shall be maintained for inspection by the cabinet for at least two (2) years after completion of the survey.

Section 24. Radioactive Contamination Control. (1) If the licensee has reason to believe that, as a result of an operation involving a sealed source, the encapsulation of the sealed source may be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.

(2) If the licensee detects evidence that a sealed source has ruptured or radioactive materials have caused contamination, the licensee shall initiate immediately the emergency procedures required by Section 13 of this administrative regulation.

(3) If contamination results from the use of radioactive material in well logging, the licensee shall decontaminate work areas, equipment, and unrestricted areas.

(4) During efforts to recover a sealed source lodged in the well, the licensee shall

continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if present, to check for contamination resulting from damage to the sealed source.

Section 25. Records Required at Field Stations. A licensee or registrant maintaining field stations from which well service operations are conducted shall have copies of the following records available at each station for inspection by the cabinet:

- (1) Appropriate license or certificate of registration;
- (2) Operating and emergency procedures;
- (3) A copy of 902 KAR 100:019, 100:142, and 100:165;
- (4) Survey records required pursuant to Section 23 of this administrative regulation;
- (5) Quarterly inventories required pursuant to Section 7 of this administrative regulation;
- (6) Utilization records required pursuant to Section 8 of this administrative regulation;
- (7) Records of inspection and maintenance required pursuant to Section 11 of this administrative regulation;
- (8) Records of the latest survey instrument calibration pursuant to Section 5 of this administrative regulation;
- (9) Records of the latest leak test results pursuant to Section 6 of this administrative regulation; and
- (10) Training records required by Section 12 of this administrative regulation.

Section 26. Records Required at Temporary Job Sites. (1) A licensee or registrant conducting a well service operation at a temporary job site shall have the following records available at that site for inspection by the cabinet:

1 (a) Operating and emergency procedures;

2 (b) Survey records required pursuant to Section 23 of this administrative regulation
3 for the period of operation at the site;

4 (c) Evidence of current calibration for the radiation survey instruments in use at the
5 site; and

6 (d) The shipping papers for the transportation of radioactive materials.

7 (2) In addition to the record requirements of this section, at each temporary job site
8 where a well service operation is conducted under cabinet authorization granted pur-
9 suant to 902 KAR 100:065, a licensee or registrant shall have the following records
10 available for inspection by the cabinet:

11 (a) Current leak test records for the sealed sources in use at the site;

12 (b) The appropriate license and certification of registration or equivalent document;
13 and

14 (c) Shipping papers for the transport of radioactive material.

15 Section 27. Notification of Incidents and Lost Sources. (1) If the licensee knows or
16 has reason to believe that a sealed source has been ruptured, the licensee shall:

17 (a) Immediately notify by telephone the Cabinet for Health and Family Services, Rad-
18 iation Health Branch at (502) 564-3700 from 8 a.m.-4:30 p.m. Monday through Friday or
19 at (800) 255-2587 at other hours; and

20 (b) Within thirty (30) days, notify by confirmatory letter to the Manager, Radiation
21 Health Branch, 275 East Main Street, Frankfort, Kentucky 40621.

22 The letter shall:

23 1. Designate the well or other location;

1 2. Describe the magnitude and extent of the escape of radioactive materials;

2 3. Assess the consequences of the rupture; and

3 4. Explain efforts planned or being taken to mitigate these consequences.

4 (2) The licensee shall notify the Cabinet for Health and Family Services, Radiation
5 Health Branch of the theft or loss of radioactive materials, radiation overexposures, ex-
6 cessive levels and concentrations of radiation, and certain other accidents as required
7 by 902 KAR 100:019, Sections 38, 39, and 40 and 100:040, Section 15.

8 (3) If a sealed source or device containing radioactive material is lodged in a well and
9 it becomes apparent that efforts to recover the sealed source will not be successful, the
10 licensee shall:

11 (a) Notify the Cabinet for Health and Family Services, Radiation Health Branch, im-
12 mediately by telephone at (502) 564-3700 from 8 a.m. - 4:30 p.m., Monday through Fri-
13 day or at (800) 255-2587 at other hours of the circumstances that resulted in the inabili-
14 ty to retrieve the source and obtain cabinet approval to implement abandonment proce-
15 dures; or

16 (b) That the licensee implemented abandonment before receiving cabinet approval
17 because the licensee believed there was an immediate threat to public health and safe-
18 ty.

19 (4) If it becomes apparent that efforts to recover the radioactive source shall not be
20 successful, the licensee shall:

21 (a) Advise the well owner or well-operator of the requirements of this administrative
22 regulation regarding abandonment and an appropriate method of abandonment, which
23 shall include:

1 1. The immobilization and sealing in place of the radioactive source with a cement
2 plug;

3 2. A means to prevent inadvertent intrusion on the source, unless the source is not
4 accessible to any subsequent drilling operations; and

5 3. The mounting of a permanent identification plaque, containing information required
6 by this section, at the surface of the well, unless the mounting of the plaque is not prac-
7 tical;

8 (b) Either ensure that abandonment procedures are implemented within thirty (30)
9 days after the sealed source has been classified as irretrievable or request an extension
10 of time if unable to complete the abandonment procedures; and

11 (c) File a written report on the abandonment with the Manager, Radiation Health
12 Branch, 275 East Main Street, Frankfort, Kentucky 40621 within thirty (30) days after a
13 sealed source has been classified as irretrievable. The report shall be sent to each ap-
14 propriate state or federal agency that issued permits or approved of the drilling opera-
15 tion and shall include the following information:

16 1. Date of occurrence and a brief description of attempts to recover the source;

17 2. Description of the radioactive source involved, including radionuclide, quantity, and
18 chemical and physical form;

19 3. Surface location and identification of well;

20 4. Results of efforts to immobilize and seal the source in place;

21 5. A brief description of the attempted recovery effort;

22 6. Depth of the radioactive source;

23 7. Depth of the top of the cement plug;

1 8. Depth of the well;

2 9. The immediate threat to public health and safety justification for implementing ab-
3 andonment if prior cabinet approval was not obtained in accordance with subsection (6)
4 of this section;

5 10. Information such as a warning statement, contained on the permanent identifica-
6 tion plaque; and

7 11. State and federal agencies receiving a copy of this report.

8 (5) If a sealed source containing radioactive material is abandoned downhole, the li-
9 censee shall provide a permanent plaque mounted at the surface of the well. This pla-
10 que shall:

11 (a) Be constructed of long-lasting material, such as stainless steel, brass, bronze, or
12 Monel. The size of the plaque shall be at least seven (7) inch, seventeen (17) cm
13 square and one-eighth (1/8) inch (3mm) thick. Letter size of the word "Caution" shall be
14 approximately twice the letter size of the rest of the information, for example, one-half
15 (1/2) inch and one-fourth (1/4) inch letter size, respectively; and

16 (b) Contain the following engraved information on its face:

17 1. The word "Caution;"

18 2. The radiation symbol (color not required);

19 3. The date of abandonment;

20 4. The name of the well operator or well owner;

21 5. The well name and well identification number or other designation;

22 6. The sealed source by radionuclide and quantity of activity;

23 7. The source depth and the depth to the top of the plug;

1 8. An appropriate warning, depending on the specific circumstances of an abandon-
2 ment, for example, "Do not drill below plug depth;" or "Do not enlarge casing;" and

3 9. The words "Do not reenter hole before contacting Radiation Health Branch, Ken-
4 tucky Cabinet for Health and Family Services."

5 (6) If the licensee knows or has reason to believe that radioactive material has been
6 lost in or to an underground potable water source, the licensee shall:

7 (a) Immediately notify the Cabinet for Health and Family Services, Radiation Health
8 Branch by telephone at (502) 564-3700 from 8 a.m. - 4:30 p.m. Monday through Friday
9 or at (800) 255-2587 at other hours; and

10 (b) Confirm by letter, within thirty (30) days, to the Manager, Radiation Health Branch,
11 275 East Main Street, Frankfort, Kentucky 40621.

12 (7) The notice shall designate the well location and shall describe the magnitude and
13 extent of loss of radioactive material, assess the consequences of the loss, and explain
14 efforts planned or being taken to mitigate consequences.

15 Section 28. Minimum Training Requirements for Logging Supervisors. Logging su-
16 pervisors shall receive minimum training in the following areas:

17 (1) Fundamentals of radiation safety:

18 (a) Characteristics of gamma, neutron, and x-radiation;

19 (b) Units of radiation dose (mrem);

20 (c) Quantity of radioactivity (curie);

21 (d) Significance of radiation dose:

22 1. Radiation protection standards; and

23 2. Biological effects of radiation dose;

1 (e) Levels of radiation from sources of radiation;

2 (f) Methods of controlling radiation dose:

3 1. Working time;

4 2. Working distance; and

5 3. Shielding; and

6 (g) Radiation safety practices including prevention of contamination and methods of
7 decontamination;

8 (2) Radiation detection instrumentation to be used:

9 (a) Use of radiation survey instruments:

10 1. Operation;

11 2. Calibration; and

12 3. Limitations;

13 (b) Survey techniques; and

14 (c) Use of personnel monitoring equipment;

15 (3) Equipment to be used:

16 (a) Remote handling equipment;

17 (b) Sources of radiation;

18 (c) Storage and transport containers; and

19 (d) Operation and control of equipment;

20 (4) The requirements of 10 C.F.R. Part 39 and 902 KAR Chapter 100;

21 (5) The licensee's or registrant's written operating and emergency procedures;

22 (6) The licensee's or registrant's recordkeeping procedures; and

23 (7) Case histories of well logging accidents.

Section 29. Material Incorporated by Reference. (1) The following material is incorporated by reference:

(a) "USASI N5.10-1968, Classification of Sealed Radioactive Sources", edition 1968; and

(b) "ANSI/HPS N43.6-1997, "Sealed Radioactive Sources – Classification", edition 1997.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of the Commissioner of Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8:00 a.m. to 4:30 p.m.

902 KAR 100:142 Wire line service operations

REVIEWED:

Date

Steve Davis, MD
Acting Commissioner
Department for Public Health

APPROVED:

Date

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

A public hearing on this administrative regulation shall, if requested, be held on September 21, 2012, at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by September 14, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business October 1, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 902 KAR 100:142

Contact Person: Matt McKinley (502) 564-3700 extension 3701

(1) Provide a brief summary of:

(a) What this administrative regulation does: This regulation establishes guidelines for wire line service operations.

(b) The necessity of this administrative regulation: The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:142 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How this administrative regulation conforms to the content of the authorizing statutes: The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: By updating the Kentucky Administrative Regulations to be consistent with the Code of Federal Regulations, it will ensure that Kentucky licensees are bound by the same requirements as their counterparts across the country.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: It updates 902 KAR 100:142 to add specific leak testing requirements for wire line operations, adds a specific requirement for making of uranium sinker bars and energy compensation sources, defines the use of tritium neutron generator target sources and, updates existing abandonment procedures

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to ensure compliance with the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste. This amendment puts the radiation program in compliance with federal regulations.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will make the federal and state regulations the same thus making enforcement easier.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will assist the 9 wire line service licensees in making Kentucky Administrative Regulations consistent with the Code of Federal Regulations.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The regulated entities will not be directly impacted by this amendment as they are already following federal standards.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to the regulated entity to comply with this regulation because they are currently in compliance.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The regulated entities will be in conformance with both state and federal regulations as the regulations will be consistent.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional cost will be incurred as a result of amending this administrative regulation.

(b) On a continuing basis: No additional cost will be incurred as a result of amending this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: General funds are used to operate this program but no additional funds are required to implement this amendment.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change if it is an amendment: An increase in fees or funding will not be necessary to implement this amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: The amendment does not establish directly or indirectly any fees.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 902 KAR 100:142 Contact Person: Matt McKinley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No

2. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? All parts of state and local government are impacted if there are radioactive materials in their area.

3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by this administrative regulation.

The U.S. Nuclear Regulatory Commission has amended its regulations. Therefore, Kentucky, as an agreement state, must amend 902 KAR 100:142 to meet the U.S. Nuclear Regulatory Commission's requirements of Agreement State Compatibility as mandated by Section 274 of the Atomic Energy Act, as amended.

The statutory authority for the promulgation of an administrative regulation relating to disposal of radioactive material is KRS 194A.030, 194A.050, 211.842 to 211.852. KRS 211.842(2) states the Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. KRS 211.842(3) states the Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. KRS 211.844 states the Cabinet for Health and Family Services shall provide administrative regulations for the registration and licensing of the possession and use of any source of ionizing radiation or electronic product radiation and the handling and disposal of radioactive waste.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not generate revenues of state or local governments in the first year

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not generate revenues of state or local governments in subsequent years.

(c) How much will it cost to administer this program for the first year?

This amendment will not cause the program to incur any additional cost in the first year.

(d) How much will it cost to administer this program for subsequent years?

This amendment will not cause the program to incur any additional cost in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: