

February 26, 2008

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

Dear Mr. Crawford:

We have reviewed the proposed changes to the Kentucky regulations 902 KAR Chapter 100, received by our office on January 16, 2008. 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 Matthew McKinley on February 19, 2008.

As a result of our review, we have 17 comments that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that the Kentucky regulations meet the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final Kentucky regulations. However, we have determined that if your proposed regulations were adopted, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure [SA-200](#).

We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in FSME Procedure SA-201, "Review of State Regulatory Requirements," please highlight the final changes, and provide a copy to Division of Materials Safety and State Agreements, FSME. The SRS Data Sheet summarizes our knowledge of the status of other 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://www.hsrdrn.gov/nrc/rulemaking.htm>.

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: kxs@nrc.gov) or Monica Orendi at (301) 415-3938 (email: mlo1@nrc.gov).

Sincerely,

Robert J. Lewis, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures:
As stated

February 25, 2008

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

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Sincerely,
IRA By ADWhite For
Robert J. Lewis, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures: As stated

Distribution:

DIR RF (8-2, 8-3, 8-4)

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[KY] File

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COMPATIBILITY COMMENTS ON KENTUCKY PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	100:010 Section 1 (217)	35.2	2005-2 2006-1	B	<p>Definition Radiation Safety Officer</p> <p>Kentucky omits paragraph (2) from its definition of Radiation Safety Officer. [(2) Is identified as a Radiation Safety Officer on- (i) A specific ...]</p> <p>Kentucky needs to add paragraph to of 10 CFR 35.2 definition of Radiation Safety officer to its definition in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Radiation Safety Officer.</p>
2	100:072 Section 64	35.50	2005-2 2006-1	B	<p>Training for a Radiation Safety Officer</p> <p>Kentucky has used the words “written certification” instead of the words “written attestation”in their 100:072 Section 64 (4).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.50.</p>
3	100:072 Section 65	35.51	2005-2 2006-1	B	<p>Training for an Authorized Medical Physicist</p> <p>Kentucky has used the words “written certification” instead of the words “written attestation”in their 100:072 Section 65 (2)(b).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.51.</p>
4	100:072 Section 66	35.55	2005-2	B	<p>Training for an Authorized Nuclear Pharmacist</p> <p>Kentucky has used the words “written certification” instead of the words “written attestation”in their 100:072 Section 66 (2)(b).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.55.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
5	100:072 Section 68	35.190	2005-2 2006-1	B	<p>Training for Uptake, Dilution, and Excretion Studies</p> <p>Kentucky needs to remove 100:072 Section 68 (3)(a)(2) from its current location and leave Section 68 (3)(a)(3) where it is but recodify it to state (3)(a)(2). Also Kentucky has used the words "written certification" instead of the words "written attestation" in their 100:072 Section 68 (3)(b).</p> <p>Kentucky needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 35.190.</p>
6	100:072 Section 69	35.290	2005-2 2006-1	B	<p>Training for Imaging and Localization Studies</p> <p>Kentucky has used the words "written certification" instead of the words "written attestation" in their 100:072 Section 69 (3)(b).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.290.</p>
7	100:072 Section 70	35.390	2005-2 2006-1	B	<p>Training for the use of Unsealed Byproduct Material for Which a Written Directive is Required</p> <p>Kentucky has used the words "written certification" instead of the words "written attestation" in their 100:072 Section 70(2)(b).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.390. (Please note the word "certification" appears twice in Section 70(2)(b). Both instances need to be changed to the word "attestation")</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	100:072 Section 71	35.392	2005-2 2006-1	B	<p>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)</p> <p>Kentucky has used the words "written certification" instead of the words "written attestation" in their 100:072 Section 71(3)(c).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.392. (Please note the word "certification" appears twice in Section 71(3)(c). Both instances need to be changed to the word "attestation".)</p>
9	100:072 Section 72	35.394	2005-2 2006-1	B	<p>Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater than 1.22 Gigabecquerels (33 millicuries)</p> <p>Kentucky has used the words "written certification" instead of the words "written attestation" in their 100:072 Section 72(3)(d).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.394. (Please note the word "certification" appears twice in Section 72(3)(d). Both instances need to be changed to the word "attestation". Also it appears that there is no Section 72 (3)(c) so this section may need to be changes from (3)(d) to (3)(c).)</p>
10	100:072 Section 73	35.396	2005-2 2006-1	B	<p>Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive</p> <p>Kentucky has used the words "written certification" instead of the words "written attestation" in their 100:072 Section 73(4)(b).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.396. (Please note the word "certification" appears twice in Section 73(4)(b). Both instances need to be changed to the word "attestation".)</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
11	100.072 Section 74	35.490	2005-2 2006-1	B	<p>Training for use of Manual Brachytherapy Sources</p> <p>Kentucky has used the words “written certification” instead of the words “written attestation” in their 100:072 Section 74(2)(c).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.490.</p>
12	100:072 Section 75	35.491	2005-2 2006-1	B	<p>Training for Ophthalmic Use of Strontium-90</p> <p>Kentucky has used the words “written certification” instead of the words “written attestation” in their 100:072 Section 75(2)(c).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.491.</p>
13	100:072 Section 77	35.690	2005-2 2006-1	B	<p>Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.</p> <p>Kentucky has used the words “written certification” instead of the words “written attestation” in their 100:072 Section 77(2)(c).</p> <p>Kentucky needs to change the word certification to attestation in order to meet the Compatibility Category B designation assigned to 10 CFR 35.690.</p>
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 10 CFR 32.72 (a)(2)(iv) “Operating as a nuclear pharmacy within a Federal medical institution.” from its regulations.</p> <p>Kentucky needs to add the above to 100:058 Section 9 in order to meet the Compatibility category B designation assigned to 10 CFR 32.72.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
15	100:010 Section 1 (23)	35.2	2006-1	B	<p>Definitions: Authorized Medical Physicist</p> <p>Kentucky omits paragraphs (2)(ii) "A medical use permit issued by a Commission master material licensee" and paragraph (2)(iv) "A permit issued by a Commission master material license broad scope medical use permittee."</p> <p>Kentucky needs to add the above to 100:010 Section 1 (23) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 definition Authorized medical physicist.</p>
16	100:010 Section 1 (24)	35.2	2006-1	B	<p>Definition Authorized Nuclear Pharmacist</p> <p>Kentucky omits paragraphs (2)(ii) "A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy" and paragraph (2)(iv) "A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy."</p> <p>Kentucky needs to add the above to 100:010 Section 1 (24) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 definition Authorized nuclear pharmacist</p>
17	100:010 Section 1 (25)	35.2	2006-1	B	<p>Definition Authorized User</p> <p>Kentucky omits paragraphs (2)(ii) "A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material" and paragraph (2)(iv) "A permit issued by a Commission master material license broad scope medical use permittee that is authorized to permit the medical use of byproduct material."</p> <p>Kentucky needs to add the above to 100:010 Section 1 (25) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 definition Authorized user.</p>

STATE REGULATION STATUS

State: Kentucky

[12 Amendments reviewed identified by a ★ at the beginning of the equivalent NRC requirement.]

Tracking Ticket Number: 8-02,8-03,8-04

Date: February 25, 2008

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F	N 3/15/96	4/11/94
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required ³
Standards for Protection Against Radiation-Part 20	56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94)	1991-3	F	N 4/17/98	4/11/94
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F	N 3/15/96	4/19/95
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F	N 3/15/96	4/11/95
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2			Not required ³
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	F	N 3/15/96	4/19/95
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Not applicable SECY-95-112 ⁴
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable SECY-95-112 ⁴
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1			Not required ³
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not required ³
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F	N 4/17/98	8/20/97
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767; 59 FR 65243 60 FR 322; (1/1/98)	1995-1	F	N 4/17/98	8/20/97

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Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F	N 4/17/98	1/14/97
★Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	P ML080150503	N 2/26/08 ML080560200	
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F	N 3/15/96	4/19/95
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	N 4/17/98	9/11/00
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	P	N 6/21/00	9/11/00
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7			
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28723 (4/1/99)	1996-1	F	Y 6/21/00	
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required ³
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F	N 6/21/00	9/11/00
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1	F	N 4/17/98	11/14/97
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2	F ML010780156	N 3/30/01 ML010890409	2/2/01
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F	N 4/17/98	11/14/97
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required ³

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F)¹ Rule / License Condition (LC) ML #⁵	NRC Review / Y, N² / Date / ML #⁵	Final State Regulation¹ (Effective Date)
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28948; (6/27/00)	1997-5	F ML010780156	Y 3/30/01 ML010890409	2/2/01
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39058; (8/20/00)	1997-6	F	N 6/21/00	9/11/00
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7	F	N 4/17/98	11/14/97
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	F	N 6/21/00	10/16/00
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required ³
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	F ML010780156	N 3/30/01 ML010890409	2/2/01
★Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5	P ML080150503	N 2/26/08 ML080560200	
★Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	P ML080150503	N 2/26/08 ML080560200	
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			Not required ³
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			Not required ³
★Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3	P ML080150503	N 2/26/08 ML080560200	
★Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	P ML080150503	N 2/26/08 ML080560200	
★New Dosimetry Technology- Parts 34, 36, 39	65 FR 63749; (1/8/04)	2000-2	P ML080150503	N 2/26/08 ML080560200	

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	LC for 32.52 (a) & (b) ML040550046	Y 3/16/04 ML040770705	
★Revision of the Skin Dose Limit-Part 20	67 FR 1629; (4/5/05)	2002-1	P ML080150503	N 2/26/08 ML08	
Medical Use of Byproduct Material-Parts 20, 32, 35	67 FR 20249; (4/24/05)	2002-2	P ML042720262	Y 10/28/2004 ML043030121	
★Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1	P ML080150503	N 2/26/08 ML080560200	
★Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1	P ML080150503	N 2/26/08 ML080560200	
★Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1	P ML080150503	N 2/26/08 ML080560200	
★Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2	P ML080150503	Y 2/26/08 ML080560200	
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) ⁶	70 FR 72128; (12/1/05)	2005-3	LC ML053180137	N 11/15/2005 ML053190005	
★Minor Amendments - Parts 20, 30, 32, 35, 40, and 70	71 FR 15005 (3/27/09)	2006-1	P ML081050503	Y 2/26/08 ML080060200	
National Source Tracking System - Serialization Requirements - Part 32 with reference to Part 20 Appendix E	71 FR 65685 (2/6/07)	2006-2			N/A 03/02/07 ML070610044
National Source Tracking System - Part 20	71 FR 65865, 72 FR 59162 (01/31/09)	2006-3			
Medical Use of Byproduct Material-Minor Corrections and Clarifications-Parts 32 and 35	72 FR 45147, 54207 (10/29/10)	2007-1			

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material; Licensing and Reporting Requirements Parts-30, 31, 32, 150	72 FR 58472 (12/17/10)	2007-2			
Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150	72 FR 55864 (11/30/2010)	2007-3			
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)	2007-4			
Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20	72 FR 68043 (02/15/2011)	2008-1			

1. Or other generic Legally Binding Requirements.
2. (Y/N) Y means "Yes," there are comments in the review letter that the State needs to address. N means "No," there are no comments in the review letter.
3. Not required means these regulations are not required for purposes of compatibility.
4. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1. Time Frame for Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
5. ADAMS ML Number
6. By letter dated September 2, 2005, from Paul H. Lohaus, Director, Office of State and Tribal Programs, Agreement States were given 90 days to issue legally binding requirements satisfying the requirements of NRC Order EA-05-090.