

September 23, 2005

Robert E. Owen, Chief
Bureau of Radiation Protection
Department of Health
P.O. Box 118
Columbus, OH 43216-0118

Dear Mr. Owen:

We have reviewed the proposed changes to the Ohio regulations in Ohio Administrative Code Chapter 3701:1-50 "Packaging and Transportation of Radioactive Material," received by our office on July 20, 2005. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Part 71 and the requirements of the one amendment identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Mike Snee on August 4, 2005.

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. Under our current procedure, a finding that the Ohio 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 Ohio 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 State and Tribal Programs (STP) Procedure SA-200.

We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in STP Procedure SA-201, "Review of State Regulatory Requirements," please highlight the final changes and provide a copy to STP.

The SRS Data Sheet summarizes our knowledge of the status of other Ohio 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 STP website: <http://www.hsr.d.ornl.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 me, or Jim Lynch at (630) 829-9661 or by e-mail at jl2@nrc.gov.

Sincerely,

IRA By KNSchneider For

Dennis Rathbun, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

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IRA By KNSchneider For

Dennis Rathbun, Deputy Director
Office of State and Tribal Programs

Enclosures: As stated

Distribution:

DIR RF (5-211)

SISP Review Complete

DCD (SP07) : Publicly Available Non-Publicly Available
: Non-Sensitive Sensitive

Jlynch, RSAO Dsollenberger, ASPO BUilton Ohio File

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OFFICE	Rlll	STP	OGC	STP:DD
NAME	JLynch	WRautzen	STreby	DRathbun
DATE	09/8/05*	09/8/05*	09/21/05*	09/23/05*

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COMPATIBILITY COMMENTS ON OHIO PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	50-05(A)	71.5(a)	2004-1	B	<p>Transportation of Licensed Material</p> <p>The Ohio rule is missing the expanded reference to DOT regulations (See the <i>Federal Register</i> Final Rule Correction).</p> <p>Ohio needs to add the DOT references to 50-05(A) to meet the Compatibility Category B designation assigned to Section 10 CFR 71.5(a).</p>
2	50-05(A)	71.5(a)	2004-1	B	<p>Transportation of Licensed Material</p> <p>The Ohio rule is missing the “Security plans” reference in 71.5(a)(1)(vii) (See the <i>Federal Register</i> Final Rule Correction).</p> <p>Ohio needs to add the “Security plans” reference to 50-05(A) to meet the Compatibility Category B designation assigned to Section 10 CFR 71.5(a).</p>
3	50-05(B)	71.5(b)	2004-1	B	<p>Transportation of Licensed Material</p> <p>The Ohio rule is missing the paragraph “A request for modification, waiver, or exemption...”.</p> <p>Ohio needs to add this paragraph to 50-05(B) to meet the Compatibility Category B designation assigned to Section 10 CFR 71.5(b).</p>
4	50-26	71.13	2004-1	B	<p>Exemption of Physicians</p> <p>The Ohio rule is significantly different, and more restrictive, than 10 CFR 71.13.</p> <p>Ohio needs to adopt 10 CFR 71.13 to 50-05(B) to meet the Compatibility Category B designation assigned to Section 10 CFR 71.13.</p>
5	50-07(C)(3)	71.17(c)(3)	2004-1	B	<p>General License: NRC-Approved Package</p> <p>The Ohio rule is missing the required information to submit to the NRC before first use of a package found in 10 CFR 71.17.</p> <p>Ohio needs to add this information to 50-07(C)(3) to meet the Compatibility Category B designation assigned to Section 10 CFR 71.17(c)(3).</p>
6	50-09	71.20(e)	2004-1	B	<p>General License: DOT Specification Container</p> <p>The Ohio rule is missing the equivalent to paragraph (e) which provides an expiration date for the requirements of the section.</p> <p>Ohio needs to add this information to 50-09 to meet the Compatibility Category B designation assigned to Section 10 CFR 71.20.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
7	50-10	71.21(d)(2)	2004-1	B	<p>General License: Use of Foreign Approved Package</p> <p>Since Ohio states that this rule applies to general licensees who have “a quality assurance program approved by the United States Nuclear Regulatory Commission”, Ohio should reference Subpart H of Part 71 (or 50-24 of their own rules), and state that licensees are “exempt from design, construction, and fabrication considerations”.</p> <p>Ohio needs to add this information to 50-10 to meet the Compatibility Category B designation assigned to Section 10 CFR 71.21(d)(2).</p>
8	50-11(C)(1)	71.22(c)(1)	2004-1	B	<p>General License: Fissile Material</p> <p>Ohio’s rule reads “Contain less than a type A quantity of fissile material”. This leads to a potential problem if the quantity transported is exactly equal to a type A quantity of fissile material. Paragraph (C)(1) should be changed to read “Contain no more than a Type A quantity of radioactive material; and” (See the <i>Federal Register</i> Final Rule Correction).</p> <p>Ohio needs to add this phrase to 50-11(C)(1) to meet the Compatibility Category B designation assigned to Section 10 CFR 71.22(c)(1).</p>
9	50-12(C)(1)	71.23(c)(1)	2004-1	B	<p>General License: Plutonium-Beryllium Special Form Material</p> <p>Ohio’s rule reads “Contain less than a type A quantity of material”. This leads to a potential problem if the quantity transported is exactly equal to a type A quantity of radioactive material. Paragraph (C)(1) should read “Contain no more than a Type A quantity of radioactive material; and” (See the <i>Federal Register</i> Final Rule Correction).</p> <p>Ohio needs to add this phrase to 50-12(C)(1) to meet the Compatibility Category B designation assigned to Section 10 CFR 71.23(c)(1).</p>
10	50-18(B)	71.88(b)	2004-1	B	<p>Air Transport of Plutonium</p> <p>Paragraph (B) uses language different than that of 10 CFR 71.88. The phrase “The requirements of paragraph (A) of this rule are in addition to the requirements of 10 CFR 73.24.” should be changed to “Nothing in paragraph (a) of this section is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24 of this chapter.”</p> <p>Ohio needs to add this phrase to 50-18(B) to meet the Compatibility Category B designation assigned to Section 10 CFR 71.88(b).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
11	50-23	71.97	2004-1	B	<p>Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste</p> <p>Paragraphs (A) and (C)(1) do not reference that the advance notifications need to be made to the governor of a State, or the governor's designee.</p> <p>Ohio needs to add this information to 50-23 to meet the Compatibility Category B designation assigned to Section 10 CFR 71.97.</p>
12	50-25(A) and (D)	Part 71, Appendix A	2004-1	B	<p>Determination of A₁ and A₂</p> <p>Paragraph (A) of the Ohio rule is different than Appendix A to 10 CFR 71 (See the <i>Federal Register</i> Final Rule Correction). The revised language establishes the Terabecquerel values as the regulatory standard.</p> <p>Ohio needs to add this information to 50-25(A) and (D) to meet the Compatibility Category B designation assigned to Appendix A of 10 CFR 71.</p>
13	50-25(A) and (D)	Part 71, Appendix A	2004-1	B	<p>Determination of A₁ and A₂</p> <p>The Ohio rule is missing the equivalent of Appendix A (IV)(e) and (f) paragraphs regarding the exempt activity concentration for mixtures of radionuclides.</p> <p>Ohio needs to add this information to 50-25(A) and (D) to meet the Compatibility Category B designation assigned to Appendix A of 10 CFR 71.</p>
14	50-25, Table 25-2	Part 71, Appendix A, Table A-2	2004-1	B	<p>Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides</p> <p>The Ohio rule is missing "footnote g" which references unirradiated uranium.</p> <p>Ohio needs to add this footnote to 50-25(A) and (D) to meet the Compatibility Category B designation assigned to Table A-2 in Appendix A of 10 CFR 71.</p>

STATE REGULATION STATUS

State: OHIO

[The one amendment reviewed is identified by a i
at the beginning of the equivalent NRC regulation.]

Tracking Ticket Number:5-211

Date: September 23, 2005

NRC Chronology Identification	FR Notice (Date Due for State Implementation)	RATS ID	Proposed (P) / Final (F) ¹ Rule / ML # ⁴	NRC Review / Y, N ¹ / Date / ML # ⁴	Final State Regulation ¹ (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F ML023250117	N 1/9/03 ML030060349	10/20/02
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2	F ML023250117	N 1/9/03 ML030060349	10/20/02
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 ML040920160	N 4/14/04 ML041060011	7/22/01
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	P	Y 7/26/00	
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1-7/95)	1992-1	P ML042230062	N 10/14/2004 ML042890002	
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2	P ML042230062	N 10/14/2004 ML042890002	10/9/98 ⁶
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	P	Y 7/26/00	10/9/98 ⁵
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	F ML023250117	N 1/19/03 ML030060349	10/20/02
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			10/9/98 ⁶
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1			10/9/98 ⁶
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			10/9/98 ⁵
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	P	N 7/26/00	10/9/98 ⁵
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 ML023180373	N 1/9/03 ML030220061	10/20/02
Frequency of Medical Examinations for Use of Respiratory Protection Equipment- Part 20	60 FR 7900; (3/13/98)	1995-2	F ML041240504	N 6/14/04 ML041670402	10/9/98 ⁵
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	F ML040920160	N 4/14/04 ML041060011	7/22/01
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	P ML012500056	N 1/14/02 ML020170450	10/20/02
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F ML040920160	N 4/14/04 ML041060011	7/22/01

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Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	P	N 7/26/00	10/9/98 ⁵
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	P ML042230062	N 10/14/2004 ML042890002 L	10/9/98 ⁵
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28723 (4/1/99)	1996-1	P ML010380259 ML010870344	Y 9/25/01 ML012710319	10/9/98 ⁵
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2			10/9/98 ⁶
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	P	N 7/26/00	10/9/98 ⁵
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1	F ML041240504 F ML041900134	N 6/14/04 ML041670402 N 8/9/04 ML042220269	07/26/01
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 ML041240504	N 6/14/04 ML041670402	11/27/02
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	P ML042230062	N 10/14/2004 ML042890002	10/9/98 ⁵
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			10/9/98 ⁶
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	P ML023250117	N 1/9/03 ML030060349	10/20/02 ⁵
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39058; (8/20/00)	1997-6			10/9/98 ⁵
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7	F ML041240504	6/14/04 ML041670402	10/18/02
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	P ML010380259 ML010870344	N 12/12/01 ML013530072	10/9/98 ⁵
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			10/9/98 ⁶
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			10/9/98 ⁶
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	F ML041240504	N 6/14/04 ML041670402	10/18/02
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5			10/9/98 ⁵

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Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F ML041240504 N ML041900134	Y 6/14/04 ML041670402 N 8/9/04 ML042220269	7/26/01
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			Not required ³
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3	F ML040920160	N 4/14/04 ML041060011	7/22/01
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML012500049	N 1/9/03 ML030060349	10/20/02
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63749; (1/8/04)	2000-2	F ML023250117	N 1/9/03 ML030060349	10/20/02
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F ML041240504 F ML041900134	Y 6/14/04 ML041670402 N 8/9/04 ML042220269	10/18/02
Revision of the Skin Dose Limit-Part 20	67 FR 1629; (4/5/05)	2002-1	P ML042230062	N 10/14/2004 ML042890002	
Medical Use of Byproduct Material-Parts 20, 32, 35	67 FR 20249; (4/24/05)	2002-2	P ML042230062	N 10/14/2004 ML042890002	
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1			
i Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1	P ML052020573	Y 9/23/2005 ML052660013	
Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1			
Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; (4/29/08)	2005-2			

1. For 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. ADAMS ML Number
5. Ohio became an Agreement State effective 08/31/99. The State incorporated NRC regulations by reference 10/9/98 and therefore, these regulations were found compatible.
6. Although these items are not required for purposes of compatibility, the State incorporated NRC regulations by reference on 10/9/98 which included these items.