

June 14, 2004

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

Dear Mr. Owen:

We have reviewed the final revisions to the Ohio regulations in Ohio Rule 3701: 1-38, "*General Radiation Protection Standards for Sources of Radiation*", Rule 3701: 1-40 "*Licensing Requirements for By-Product and Accelerator Produced Radioactive Materials*", Rule 3701: 1-46 "*General Licenses and Licenses for Manufacturing and Distribution*", and Rule 3701: 1-48, "*Radioactive Material Standards - Industrial Radiographers*", received by this office on April 30, 2004. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) regulations in 10 CFR Part 20, 30, 31, 32, 34 and 150 and the requirements of the 6 amendments identified in the enclosed States Regulation Status Data Sheet (SRS). We discussed our review of the regulations with Michael Snee on June 9, 2004.

As a result of our review, we have three comments. Under our current procedure, a finding that a State regulation meets the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final State regulation. Please provide a final, amended version of your rules showing the location of any changes made in response to our comments. If there are any comments which the State believes are in error, Ohio should identify the section of their regulations that meet the designated compatibility category. Please note, that we have limited our review to regulations required for compatibility and/or health and safety, but have determined that if these regulations are adopted, incorporating our comments and without 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](#).

The SRS Data Sheet summarizes our knowledge 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 Web Site: <http://www.hsrd.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 Patricia Eng at (301) 415-7206 or PLE@NRC.GOV.

Sincerely,

IRA By K.N. Schneider For

Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

Enclosure:
As stated

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Distribution:

DIR RF [4-105] DCD (SP07) PDR (YES✓) JLynch BUsilton
DSollenberger, ASP Ohio File **Response to Incoming Document: ML041240504**

DOCUMENT NAME: C:\NRC\Regs\4-105.wpd

***See previous concurrence.**

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|--------|-----------|--|------------|--|----------|--|------------|--|
| OFFICE | STP | | STP | | OGC | | STP:DD | |
| NAME | PLEng* | | JGZabko* | | SATreby* | | JMPiccone* | |
| DATE | 05/18/04* | | 06/01/04 * | | 06/07/04 | | 06/14/04 | |

ML041670402

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**COMMENTS ON PROPOSED OHIO REGULATIONS
AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES**

| Number | State Regulation | NRC Regulation | RATS ID | Category | Subject and Comments |
|--------|------------------|----------------|---------|----------|---|
| 1 | N/A | 20.2203 | 1997-1 | C | <p><u>REPORTS OF EXPOSURES, RADIATION LEVELS, AND CONCENTRATIONS OF RADIOACTIVE MATERIAL EXCEEDING THE CONSTRAINTS OR LIMITS</u></p> <p>The State did not include the new paragraphs (a)(2)(vi) and did not revise paragraph (b)(1)(iv).</p> <p>The State needs to include these changes in order to meet the essential objectives of the regulation.</p> |
| 2 | 3701:1-38-19H | 20.2006 | 1998-6 | B | <p><u>TRANSFER FOR DISPOSAL AND MANIFESTS</u></p> <p>State's proposed regulations do not include the phrase, "and transfer this recorded manifest information to the intended consignee in accordance with" in paragraph (b).</p> <p>The State needs to include the phrase, "and transfer this recorded manifest information to the intended consignee in accordance with"</p> |
| 3 | 3701: 1-46-31 A | 32.51a(d) | 2001-1 | B | <p><u>SAME: CONDITIONS OF LICENSES (BYPRODUCT MATERIAL CONTAINED IN DEVICES FOR USE UNDER §31.5; REQUIREMENTS FOR LICENSE TO MANUFACTURE; OR INITIALLY TRANSFER/CONDITIONS OF LICENSES)</u></p> <p>The State did not include paragraph (d) in their proposed regulations.</p> <p>The State needs to revise their regulations to include the labeling requirements for transferred devices.</p> |

STATE REGULATION STATUS

State: OHIO

[Six Amendments reviewed are identified by a ★ at the beginning of each equivalent NRC regulation.]

Tracking Ticket Number: 4-105

Date: June 14, 2004

| NRC Chronology Identification | FR Notice (Date Due for State Implementation) | RATS ID | Proposed (P) / Final (F) ¹ Rule / ML # ⁴ | NRC Review / Y, N ² / 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 ⁵ |
| 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; (1/27/95) | 1992-1 | | | |
| Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35 | 57 FR 45566; (none) | 1992-2 | | | 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 |

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|---|--|---------|--|---|--|
| 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 | P ML012340364 | Y 12/11/01 ML013510454 | 10/9/98 ⁵ |
| Frequency of Medical Examinations for Use of Respiratory Protection Equipment- Part 20 | 60 FR 7900; (3/13/98) | 1995-2 | F 4/14/04 ML041060011 | 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 ⁵ |
| Performance Requirements for Radiography Equipment-Part 34 | 60 FR 28323; (6/30/98) | 1995-4 | P ML012500056 | N 1/14/02 ML020170450 | 10/20/025 |
| 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 ⁵ |
| 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 | | | 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 | Y 6/14/04 ML041670402 | 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 | | | 10/9/98 ⁵ |
| Fissile Material Shipments and Exemptions-Part 71 | 62 FR 5907; (none) | 1997-4 | | | 10/9/98 ⁶ |

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|--|--|----------------|---|--|--|
| 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 ML023250117 | N 1/9/03 ML030060349 | 1020/02 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 | N 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 |
| ★Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20 | 63 FR 50127; (11/20/01) | 1998-6 | F ML041240504 | Y 6/14/04 ML041670402 | 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 ⁵ |
| 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 |

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|--|---|---------|--|---|--|
| ★Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32 | 65 FR 79162; (2/16/04) | 2001-1 | F ML041240504 | Y 6/14/04 ML041670402 | 10/18/02 |
| Revision of the Skin Dose Limit-Part 20 | 67 FR 1629; (4/5/05) | 2002-1 | | | |
| Medical Use of Byproduct Material-Parts 20, 32, 35 | 67 FR 20249; (4/24/05) | 2002-2 | | | |
| Financial Assurance for Materials Licensees – Parts 30, 40, 70 | 68 FR 57327 12/3/06 | 2003-1 | | | |

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. 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.