

June 30, 2008

Robert Owen, Chief
Bureau of Radiation Protection
Ohio Department of Health
246 North High Street
Columbus, OH 43215

Dear Mr. Owen:

We have reviewed the proposed changes to the Ohio regulations, Medical Use of Radioactive Material, received by our office on May 14, 2008. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 32, and 35 and the requirements of the four amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Michael Snee on June 30, 2008.

As a result of our review, we have three 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 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 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 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 (301) 415-3938 (email: monica.orendi@nrc.gov).

Sincerely,

/ RA by ADWhite for /

James G. Luehman, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures:
As stated

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 (301) 415-3938 (email: monica.orendi@nrc.gov).

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Enclosures: As stated

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|--------|-----------|--|------------|--|-----------|--|-----------|--|-----------|--|
| OFFICE | SAISB | | SAISB | | OGC | | SAIS:BC | | MSSA:DD | |
| NAME | MOrendi | | KSchneider | | BJones | | DWhite | | JLuehman | |
| DATE | 06/13/08* | | 06/13/08* | | 06/25/08* | | 06/30/08* | | 06/30/08* | |

ML081820355

OFFICIAL RECORD COPY

PKG. ML081820386

COMPATIBILITY COMMENTS ON OHIO PROPOSED REGULATIONS

| STATE SECTION | | NRC SECTION | RATS ID | CATEGORY | SUBJECT and COMMENTS |
|---------------|--------------|-------------|------------------|----------|--|
| 1 | 3701:1-58-21 | 35.57 | 2005-2 | B | <p>Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.</p> <p>Ohio omits authorized medical physicist and authorized nuclear pharmacist from the list of individuals listed in 3701:1-58-21 (A).</p> <p>Ohio needs to add these two terms to 3701:1-58-21 (A) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.57.</p> |
| 2 | 3701:1-58-32 | 35.100 | 2005-2 2006-1 | H&S | <p>Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.</p> <p>Ohio has a wrong reference at the end of paragraph (B)(2). It should read "... and paragraph (C)(1)(b)(vii) of rule 3701:1-58-36 of the Administrative Code.</p> <p>Also Ohio omits the essential elements of paragraph to 10 CFR 35.100(b)(3). Ohio needs to adopt the essential elements of this paragraph.</p> <p>Ohio needs to make the above changes in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.100.</p> |
| 3 | 3701:1-46-43 | 32.72 | 2006-1 2007-1 | B | <p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.</p> <p>Ohio deletes 3701:1-46-43(A)(2)(d) and also deletes a reference to in 3701:1-46-43(B).</p> |

| STATE SECTION | | NRC SECTION | RATS ID | CATEGORY | SUBJECT and COMMENTS |
|---------------|--|-------------|---------|----------|---|
| | | | | | Ohio needs to keep section (A)(2)(d) and its reference in section (B) in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72. |

STATE REGULATION STATUS

State: Ohio

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

Tracking Ticket Number: 8-61

Date: June 30, 2008

| 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 ML023250117 | No Comments 01/09/2003 ML030060349 | Ohio 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 | Final ML023250117 | No Comments 01/09/2003 ML030060349 | Ohio 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 ML040920160 | No Comments 04/14/2004 ML041060011 | |
| 1991-4 | Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980; | 10/15/1994 | Proposed | Comments 07/26/2000 | |
| 1992-1 | Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2) | 01/27/1995 | Final ML061440106 | No Comments 06/08/2006 ML061590424 | Ohio has 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 | Final ML061440106 | No Comments 06/08/2006 ML061590424 | These regulation changes are not required to be adopted for purposes of Compatibility. |
| 1993-1 | Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628 | 10/25/1996 | Proposed | Comments 07/26/2000 | |
| 1993-2 | Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715 | 07/01/1996 | Final ML023250117 | No Comments 01/09/2003 ML030060349 | |
| 1993-3 | Definition of Land Disposal and Waste Site QA Program | 07/22/1996 | Final | No Comments | |

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|---------|--|-----------------------------|-------------------------|--|--|
| | Part 61 58 FR 33886 | | | 10/09/1998 | |
| 1994-1 | Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618 | none | Final | No Comments 10/09/1998 | |
| 1994-2 | Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220 | 07/01/1997 | Final | No Comments 10/09/1998 | |
| 1994-3 | Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026 | 08/15/1997 | R ¹ | N 7/26/00 | |
| 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 ML061440106 | No Comments 06/08/2006 ML061590424 | |
| 1995-2 | Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900 | 03/13/1998 | Final ML041240504 | No Comments 06/14/2004 ML041670402 | |
| 1995-3 | Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983 | 03/01/1998 | Final ML040920160 | No Comments 04/14/2004 ML041060011 | |
| 1995-4 | Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superseded by 1997-5) | 06/30/1998 | Final ML023250117 | No Comments 01/09/2003 ML030060349 | Ohio has adopted Final Regulations equivalent to RATS ID: 1997-5. |
| 1995-5 | Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038 | 08/14/1998 | Final ML040920160 | No Comments 04/14/2004 ML041060011 | |
| 1995-6 | Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235 | 11/24/1998 | R ¹ | No Comments 07/26/2000 | |
| 1995-7 | Medical Administration of Radiation and Radioactive Materials | 10/20/1998 | Proposed ML042230062 | No Comments 10/14/2004 | Ohio has not yet adopted Final Regulations equivalent to RATS ID: |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|---|-----------------------------|----------------------|--|---|
| | Parts 20, 35 60 FR 48623 (Superseded by 2002-2 and 2005-2) | | | ML042890002 | 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 | Not Required | Not Required | Ohio has 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 | R ¹ | No Comments 07/26/2000 | |
| 1996-3 | Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61, 70 61 FR 24669 | 06/17/1999 | R ¹ | No Comments 07/26/2000 | |
| 1997-1 | Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120 | 01/9/2000 | Final ML041900134 | No Comments 08/09/2004 ML042220269 | |
| 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 ML041240504 | No Comments 06/14/2004 ML041670402 | |
| 1997-3 | Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120 | 05/29/2000 | R ¹ | No Comments 07/26/2000 | |
| 1997-4 | Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superseded by 2004-1) | 02/10/2000 | Not Required | Not Required | These regulation changes 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 ML023250117 | Comments 01/09/2003 ML030060349 | |
| 1997-6 | Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057 | 08/20/2000 | Final | No Comments 10/09/1998 | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|---|-----------------------------|--|--|--|
| 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 ML041240504 | No Comments 06/14/2004 ML041670402 | |
| 1998-1 | Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773 | 02/12/2001 | R ¹ ML010380259 ML010870344 | No Comments 12/12/01 ML013530072 | |
| 1998-2 | Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535 | 07/01/2001 | Final | No Comments 10/09/1998 | These regulation changes 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 regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074) Ohio has adopted Final Regulations equivalent to RATS ID: 2002-2. |
| 1998-4 | Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059 | 07/09/2001 | Final ML041240504 | No Comments 06/14/2004 ML041670402 | |
| 1998-5 | Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 35, 36 63 FR 39477; 63 FR 45393 | 10/26/2001 | Final | No Comments 10/09/1998 | |
| 1998-6 | Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127 | 11/20/2001 | Final ML041900134 | No Comments 08/09/2004 ML042220269 | |
| 1999-1 | Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506 | 06/11/2002 | Final ML060580024 | No Comments 04/13/2006 ML061030457 | |
| 1999-2 | Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 | 10/04/2002 | Not Required | Not Required | These regulation changes are not required to be adopted for purposes of Compatibility. |

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|---------|---|-----------------------------|-------------------------------|--|-------|
| | 64 FR 42269 | | | | |
| 1999-3 | Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524 | 02/02/2003 | Final ML040920160 | No Comments 04/14/2004 ML041060011 | |
| 2000-1 | Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337 | 05/17/2003 | Final ML023250117 | No Comments 01/09/2003 ML030060349 | |
| 2000-2 | New Dosimetry Technology Parts 34, 36, 39 65 FR 63750 | 01/08/2004 | Final ML023250117 | No Comments 01/09/2003 ML030060349 | |
| 2001-1 | Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31, 32 65 FR 79162 | 02/16/2004 | R ¹ ML070950457 | Comments 04/27/2007 ML071150004 | |
| 2002-1 | Revision of the Skin Dose Limit Part 20 67 FR 16298 | 04/05/2005 | Final ML061440106 | No Comments 06/08/2006 ML061590424 | |
| 2002-2 | Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249 | 10/24/2005 | Final ML061440106 | No Comments 06/08/2006 ML061590424 | |
| ★2003-1 | Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327 | 12/03/2006 | R ¹ ML081370130 | No Comments 06/30/2008 ML081820355 | |
| 2004-1 | Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697 | 10/01/2007 | Final ML063170453 | No Comments 12/15/2006 ML063490049 | |
| 2005-1 | Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001 | 07/11/2008 | Final ML071010099 | No Comments 04/25/2007 ML071150005 | |
| ★2005-2 | Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926 | 04/29/2008 | Proposed ML081370130 | Comments 06/30/2008 ML081820355 | |

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|---------|--|-----------------------------|----------------------------------|--|--|
| 2005-3 | Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128 | 12/01/2005 | License Condition ML053120143 | No Comments 11/10/2005 ML053180026 | |
| ★2006-1 | Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005 | 03/27/2009 | Proposed ML081370130 | Comments 06/30/2008 ML081820355 | |
| 2006-2 | National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685 | 02/06/2007 | Proposed ML070380488 | No Comments 03/06/2007 ML070650102 | Ohio responded on 02/01/07 to FSME-06-110 stating that they currently had no licensees applicable to this rule ² . ML070310347 |
| 2006-3 | National Source Tracking System Part 20 71 FR 65865, 72 FR 59162 | 01/31/2009 | Proposed ML070380488 | No Comments 03/06/2007 ML070650102 | |
| ★2007-1 | Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207 | 10/29/2010 | Proposed ML081370130 | Comments 06/30/2008 ML081820355 | |
| 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 ML080460449 | No Comments 03/12/2008 ML080720077 | |
| 2008-1 | Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043 | 02/15/2011 | | | |

¹ R stands for proposed revisions to Final Regulations

² IMPEP Team: verify that Ohio does not have any licensees subject to these regulations during each review.