

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).

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

Distribution:
 DIR RF (8-61)
 DCD (SP07)
 JLynch, RSAO
 MOrendi

SUNSI Review Complete

- Publicly Available Non-Publicly Available
 - Non-Sensitive Sensitive
- [OH] File

DOCUMENT NAME: G:\DMSSA\SAISB\REGULATION TOOLBOX\STATES\OHIO\8-61\8-61.DOC

ML of Incoming Document: ML081370130

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure
 "N" = No copy

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>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
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> <p>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.</p>

STATE REGULATION STATUS

State: Ohio

Tracking Ticket Number: 8-61

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

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 (Superseded 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 (Superseded 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 (Superseded 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	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Final	No Comments 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	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 (Superceded 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	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 (Superceded by 2002-2 and 2005-2)	10/20/1998	Proposed ML042230062	No Comments 10/14/2004 ML042890002	Ohio has not yet adopted Final Regulations equivalent to RATS ID: 2005-2.
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 (Superceded 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 (Superceded 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	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final	No Comments 10/09/1998	
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,	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 (Superceded 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	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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 regulation changes 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 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	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	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
★2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35	04/29/2008	Proposed ML081370130	Comments 06/30/2008 ML081820355	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC	12/01/2005	License Condition ML053120143	No Comments 11/10/2005 ML053180026	
★2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70	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	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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.