

December 11, 2001

Mr. Roger L. Suppes, Chief
Bureau of Radiation Protection
Ohio Department of Health
P. O. Box 118
Columbus, OH 43266-0118

Dear Mr. Suppes:

As requested, we have reviewed the proposed regulations in Ohio Rule 3701: 1-46, "General Licenses and Licenses for Manufacturing and Distribution" dated August 9, 2001. The proposed regulations will replace the referenced NRC regulations currently in place. The proposed regulations also are in response to the amendment identified in the enclosed State Regulation Status (SRS) Data Sheet. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 31 and 32. We discussed our review of the regulations with Marcia Howard and Mike Snee on October 3, 2001.

As a result of our review, we have 28 comments and four editorial changes that have been identified in the enclosures. 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 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. However, we have determined that if your proposed regulations were adopted incorporating the comments and without other significant change, they would meet the compatibility and health and safety categories established in 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 Regulations* (November 10, 1998), please highlight any changes and send one hard copy to STP.

The SRS Data Sheet summarizes our knowledge of the status of other Ohio regulations. 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.hsrn.ornl.gov/nrc/rulemaking.htm>

If you have any questions regarding the comments, the compatibility and health categories, or any of the NRC regulations used in the review, please contact me or James Lynch at (630) 829-9661 or JLL2@NRC.GOV.

Sincerely,

/RA/

Frederick C. Combs, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

Distribution:

DIR RF (1-170)

DCD (SP07) PDR (YES_✓)

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STP-AG-31

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

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
1-46-13 Title and (A)	32.11	1995-1	C	<p>Exempt Concentrations in Products</p> <p>The regulation title is missing the word “byproduct.” “...and transfer of ownership or possession of <u>byproduct</u>, accelerator produced material or...” Sub item (A) is also missing the word “byproduct” in a similar place.</p> <p>This appears to be an error in the draft rule.</p>
1-46-13(B) and (C)	32.11	1995-1	B	<p>Exempt Concentrations in Products</p> <p>Paragraph C is added. Paragraph C refers to exempt licensing which is reserved to the NRC.</p> <p>Paragraph C should be removed to meet the Compatibility Category.</p> <p>Compatibility Category B requires adoption of program elements essentially identical to those of NRC.</p>
1-46-14 Title	32.12	1995-1	C	<p>Same: Records and Material Transfer Reports</p> <p>The regulation title is missing the word “byproduct.” “...and transfer of ownership or possession of <u>byproduct</u>, accelerator produced material or...”</p> <p>This appears to be an error in the draft rule.</p>
1-46-15 Title	32.13	1995-1	C	<p>Same: Prohibition of Introduction</p> <p>The regulation title is missing the word “byproduct.” “...and transfer of ownership or possession of <u>byproduct</u>, accelerator produced material or...”</p> <p>This appears to be an error in the draft rule.</p>

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
1-46-16	32.14	1995-1	NRC	<p>Certain Items; Requirements for License</p> <p>The Statement of Consideration in 31 FR 5314, dated April 2, 1966–The Commission determined that these items are intended for use by the general public. Accordingly, pursuant to Section 150.15(a)(6) of 10 CFR 150, Exemptions and Continued Regulatory Authority in Agreement States under Section 274, the transfer of their possession or control by the manufacturer, processor, or producer is subject to the Commission’s licensing and regulatory requirements even if the product is manufactured pursuant to an Agreement State license.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-17	32.15	1995-1	NRC	<p>Same: QA, Prohibition of Transfer and Labeling</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-18	32.16	1995-1	NRC	<p>Same: Records and Reports of Transfer</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-19	32.17	1995-1	B	<p>Resins containing scandium-46</p> <p>The State regulation states a limit of “one thousand four hundred microcurie/milliter.” The correct limit is “fourteen one-thousandths microcurie/milliter” (.0014).</p> <p>This limit needs to be corrected to meet compatibility.</p>
1-46-20	32.18	1995-1	NRC	<p>Exempt Quantities</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
1-46-21	32.19	1995-1	NRC	<p>Same: Conditions of Licenses</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-22	32.20	1995-1	NRC	<p>Same: Records and Material Transfer Reports</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-23	32.21	1995-1	NRC	<p>Radioactive Drugs</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-24	32.21a	1995-1	NRC	<p>Same: Conditions of License</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-25	32.22	1995-1	NRC	<p>Self Luminous Products</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-26	32.23	1995-1	NRC	<p>Same: Safety Criteria</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-27	32.26	1995-1	NRC	<p>Gas and Aerosol Detectors</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
1-46-28	32.27	1995-1	NRC	<p>Same: Safety Criteria</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-28 Appendix A	32.28	1995-1	NRC	<p>Same: Table of Organ Doses</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-29	32.40	1995-1	NRC	<p>Automobile Lock Illuminators</p> <p>See above.</p> <p>This regulation should be deleted to meet the NRC Compatibility Category.</p>
1-46-31(A)(4) and (B)(3)	32.51a	1995-1	B	<p>Generally Licensed Devices; Conditions of Licenses</p> <p>The qualifier “at the time of the purchase” was added to the disposal information required to be provided to general licensees. This term should be deleted.</p> <p>Compatibility Category B requires adoption of program elements essentially identical to those of NRC.</p>
1-46-31(A)	32.51a	1995-1	B	<p>Generally Licensed Devices; Conditions of Licenses</p> <p>Subitem (a)(5) is missing. “An indication that NRC’s policy is to issue high civil penalties for improper disposal.” This sentence provides a deterrent to general licensees. A similar statement should be added to the rule to meet the Compatibility Category.</p> <p>Compatibility Category B requires adoption of program elements essentially identical to those of NRC.</p>

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
1-46-32(A)(7)	32.52	1995-1	B	<p>Same: Material Transfer Reports and Records</p> <p>The words “or from” are missing from this subitem. “If no transfers have been made to <u>or from</u> persons generally licensed...” These words should be added to meet the Compatibility Category.</p> <p>Compatibility Category B requires adoption of program elements essentially identical to those of NRC.</p>
1-46-32(C)	32.52	1995-1	B	<p>Same: Material Transfer Reports and Records</p> <p>The first sentence of Subitem C is substantially different than 32.52(c). This subitem should be modified to meet the Compatibility Category.</p> <p>Compatibility Category B requires adoption of program elements essentially identical to those of NRC.</p>
1-46-35(B)(3)	32.55	1995-1	B	<p>Aircraft Luminous Safety Devices; Prohibition of Transfer</p> <p>The term “IRAD” is used instead of “millirad.”</p> <p>This appears to be an error in the draft rule.</p>
1-46-35(C)(1)	32.55	1995-1	B	<p>Aircraft Luminous Safety Devices; Prohibition of Transfer</p> <p>The first sentence of this subitem should read “...a leakage rate exceeding <u>0.1</u> percent...”</p> <p>This appears to be an error in the draft rule.</p>
1-46-44(A)(3)	32.74	1995-1	B	<p>Medical Use Sources and Devices</p> <p>This subitem is missing the word “or” as follows: “...material identified in 10 CFR 35.57, 10 CFR 35.400, <u>or</u> 10 CFR 35.500...”</p> <p>This appears to be an error in the draft rule.</p>

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
1-46-45(A) Table 1	32.101	1995-1	B	<p>Prototype Tests for Aircraft Luminous Safety Devices</p> <p>In Step 1 and Step 4, the word “minus” is missing from the Fahrenheit temperatures.</p> <p>This appears to be an error in the draft rule.</p>
1-46-48(B)(1)	32.110	1995-1	B	<p>Acceptance Sampling Procedures</p> <p>In the “Lot Tolerance Percent Defective 0.5 Percent” table, the sample sizes for two lot sizes are incorrect:</p> <p>The 401-500 sample size should be 300.</p> <p>The 501-600 sample size should be 320.</p> <p>This appears to be an error in the draft rule.</p>

Editorial Changes

1. The table in Section 1-46-46 uses references to paragraph B and D. The paragraph doesn't contain lettered paragraphs.
2. Section 1-46-14(B)(4) should read "The initial concentrations of the radionuclide in the product material." The text appears to be transposed incorrectly.
3. Section 1-46-34(A). The paragraph at the end of the labeling requirements, explaining alternative labeling, should be moved so it does not appear to be a part of the labeling requirements.
4. Section 1-46-43(B)(5). The partial phrase "The Ohio" appears in the paragraph. It does not seem to follow the topic of the paragraph.

STATE REGULATION STATUS

State: Ohio

One proposed amendment (8/09/01) reviewed is identified by a ★ at the beginning of each equivalent NRC regulation.

Tracking Ticket Number: 1-170

Date: December 11, 2001

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			
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			10/9/98 ⁶
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	P ML003772297 ML010330197	Y 5/14/01 ML011360572	10/9/98 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
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			10/9/98 ⁶
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	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	P ML003772297 ML010330197	N 5/14/01 ML011360572	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	P ML003772297 ML010330197	Y 5/14/01 ML011360572	10/9/98 ⁵

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Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4			10/9/98 ⁵
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	P ML003772297 ML010330197	Y 5/14/01 ML011360572	10/9/98 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	P ML003772297 ML010330197	N 5/14/01 ML011360572	10/9/98 ⁵
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	P	N 7/26/00	10/9/98 ⁵
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
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	N 7/26/00	10/9/98 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	P	N 7/26/00	10/9/98 ⁵
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	P	Y 7/26/00	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

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)
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4			10/9/98 ⁵
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	P ML003772297 ML010330197	N 5/14/01 ML011360572	
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 55525 (2/2/03)	1999-3	P ML003772297 ML010330197	Y 5/14/01 ML011360572	
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1			
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63749; (1/8/04)	2000-2			

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.