

May 15, 2003

David J. Allard, CHP, Director
Bureau of Radiation Protection
Department of Environmental Protection
Rachel Carson State Office Building
P.O.Box 8469
Harrisburg, PA. 17105-8469

Dear Mr. Allard:

As requested, we have reviewed the final Pennsylvania regulations, 25 PA. Code Chapters 215, 217, 219, 220, 224 - 226, 230 and 232, enclosed in your April 19, 2002 letter and which was received by this office on May 2, 2002. These regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 61, 70, 71, 150 and the requirements of the 35 amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. In addition, we reviewed our January 5, 2001, letter to you that addressed the proposed regulations and your response to our comments. We discussed our review of the regulations with you on May 5, 2003.

As a result of our review, we have identified 11 comments, as enclosed. We did not review your incorporation of 10 CFR 35 because your incorporation references, documented in 25 PA. Code Chapter 215, were for the old Part 35 medical rules. If the State would like to incorporate this section by reference, it is requested that you change your incorporation references and submit this section again. Please note, that we have limited our review to regulations required for compatibility and/or health and safety.

Please provide an amended final version of your rules showing the location of any changes made by the State in response to our comments. If there are any comments which the State believes are in error, the State should identify the section of their regulations that meet the designated compatibility category and submit these sections to the NRC for review.

The SRS Data Sheet summarizes our knowledge of the Pennsylvania 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.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 John Zabko of my staff at (301) 415-2308 or JGZ@NRC.GOV.

Sincerely,

/RA by Scott Flanders for/

Josephine Piccone, Deputy Director
Office of State and Tribal Programs

Enclosure(s):
As stated

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As a result of our review, we have identified 11 comments, as enclosed. We did not review your incorporation of 10 CFR 35 because your incorporation references, documented in 25 PA. Code Chapter 215, were for the old Part 35 medical rules. If the State would like to incorporate this section by reference it is requested that you change your incorporation references and submit this section again. Please note that we have limited our review to regulations required for compatibility and/or health and safety.

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Sincerely,

/By Scott Flanders for/

Josephine Piccone, Deputy Director
Office of State and Tribal Programs

Distribution:

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Response to Incoming Document:: **ML021270241 & ML031110208**

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OFFICE	STP		STP	OGC	STP: DD
NAME	LRakovan		JZabko	STreby	JPiccone (SFlanders for)**
DATE	4/ 11 /03*		4/24/03*	5/14/03*	5/15/03**

ML031360008

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**COMMENTS ON FINAL PENNSYLVANIA REGULATIONS
AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES**

State Regulation		NRC Regulation	RATS ID	Category	Subject and Comments
1	215.1	31.3	None	B	<p>Certain Devices and Equipment</p> <p>This section was excluded from the incorporation by reference.</p> <p>This section needs to be included to meet compatibility.</p>
2	230.4	71.10 (b)&(c)	None	NRC	<p>Exemptions for low level material</p> <p>This section was not excluded from the adoption by reference, but should have been. The State may not include sections reserved for the NRC in its regulations.</p> <p>The State needs to remove this section from its regulations.</p>
3	215.1	71.47	None	B	<p>External Radiation Standards For All Packages</p> <p>This section was excluded from the incorporation by reference.</p> <p>This section needs to be included to meet compatibility.</p>
4	230.3	71.83	None	B	<p>Assumptions as to Unknown Properties</p> <p>This section was excluded from the incorporation by reference.</p> <p>This section needs to be included to meet compatibility.</p>
5	230.3	71.22	None	NRC	<p>General license: Fissile material, limited quantity, Controlled Shipment</p> <p>This section was not excluded from the adoption by reference, but should have been. The State may not include sections reserved for the NRC in its regulations.</p> <p>The State needs to remove this section from its regulations.</p>

State Regulation		NRC Regulation	RATS ID	Category	Subject and Comments
6	215.1	40.33	None	NRC	<p>Issuance of a Licence for a Uranium Enrichment Facility</p> <p>This section was not excluded from the adoption by reference, but should have been. The State may not include sections reserved for the NRC in its regulations.</p> <p>The State needs to remove this section from its regulations.</p>
7	215.1	71.61	None	NRC	<p>Special Requirements for Irradiated Nuclear Fuel Shipments</p> <p>This section was not excluded from the adoption by reference, but should have been. The State may not include sections reserved for the NRC in its regulations.</p> <p>The State needs to remove this section from its regulations.</p>
8	236	61.2	None	B	<p>Definitions: Waste</p> <p>The State definition is incomplete.</p> <p>The State needs to match the Part 61 definition to meet compatibility.</p>
9	236	61.9	None	C	<p>Deliberate misconduct</p> <p>The State is missing this section and did not incorporate this by reference.</p> <p>The State needs to add this section to achieve compatibility.</p>
10	236	61.30	None	H&S	<p>Transfer of license</p> <p>The State is missing this section.</p> <p>The State needs to adopt these requirements to achieve compatibility.</p>
11	236	61.59	None	H&S	<p>Institutional requirements</p> <p>The State is missing the requirements of 61.59(b).</p> <p>The State needs to include these requirements to achieve compatibility.</p>

STATE REGULATION STATUS

State: Pennsylvania

Tracking Ticket Number: 3-62, 3-63, 3-64

[All amendments reviewed except for 2002-2]

Date: May 15, 2003

NRC Chronology Identification	FR Notice (Date Due For State Implementation)	RATS ID	Proposed (P) / Final (F) ¹ Rule / ML # ⁵	NRC Review Y, N ² / Date /ML # ⁵	Final State Regulation ¹ (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F ML021270241	N 05/15/03 ML031360008	9/15/01
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required 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; (1/1/94)	1991-3	F ML021270241	N 05/15/03 ML031360008	09/15/01
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F ML021270241	N 05/15/03 ML031360008	09/15/01
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F ML021270241	N 05/15/03 ML031360008	09/15/01
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions- Parts 30,35	57 FR 45566; (none)	1992-2			Not required ³
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	F ML021270241	N 05/15/03 ML031360008	09/15/01
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Not applicable SECY-95- 112 ⁴
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3	F ML031110208	N 05/15/03 ML031360008	09/15/01
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1			Not required ³
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not required ⁶
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F ML021270241	N 05/15/03 ML031360008	09/15/01
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 ML021270241	N 05/15/03 ML031360008	09/15/01
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F ML021270241	N 05/15/03 ML031360008	09/15/01

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Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	F ML021270241	N 05/15/03 ML031360008	09/15/01
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F ML021270241	N 05/15/03 ML031360008	09/15/01
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F ML021270241	N 05/15/03 ML031360008	09/15/01
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F ML021270241	N 05/15/03 ML031360008	09/15/01
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F ML021270241	N 05/15/03 ML031360008	09/15/01
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724 (4/1/99)	1996-1	F ML021270241	N 05/15/03 ML031360008	09/15/01
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses- Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required ³
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F ML021270241	N 05/15/03 ML031360008	09/15/01
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act- Part 20	61 FR 65120; (1/9/00)	1997-1	F ML021270241	N 05/15/03 ML031360008	09/15/01
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 ML021270241	N 05/15/03 ML031360008	09/15/01
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F ML021270241	N 05/15/03 ML031360008	09/15/01
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5	F ML021270241	N 05/15/03 ML031360008	09/15/01
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F ML021270241	N 05/15/03 ML031360008	09/15/01
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea- Part 30	62 FR 63634; (1/02/01)	1997-7	F ML021270241	N 05/15/03 ML031360008	09/15/01
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	F ML021270241	N 05/15/03 ML031360008	09/15/01

NRC Chronology Identification	FR Notice (Date Due For State Implementation)	RATS ID	Proposed (P) / Final (F)¹ Rule / ML #⁵	NRC Review Y, N² / Date /ML #⁵	Final State Regulation¹ (Effective Date)
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees-Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required ³
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	F ML021270241	N 05/15/03 ML031360008	09/15/01
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5	F ML021270241	N 05/15/03 ML031360008	09/15/01
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F ML021270241	N 05/15/03 ML031360008	09/15/01
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			Not required ⁶
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 ML021270241	N 05/15/03 ML031360008	09/15/01
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML021270241	N 05/15/03 ML031360008	09/15/01
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML021270241	N 05/15/03 ML031360008	09/15/01
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249 (10/24/05)	2002-2			

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. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1. Time Frame for Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
5. ADAMS ML Number
6. These regulations are not required since authority over 11.e(2) material will not be transferred in the Agreement.