

July 11, 2006

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

Dear Mr. Allard:

We have reviewed your May 5, 2006 e-mail in response to our December 13, 2005 regulation review letter which identified necessary revisions and recodification due to the Part 71 rule revision and six rule amendments that have become due and will need to be adopted since the 2003 review. We have reviewed the final Pennsylvania regulations, 25 PA. Code Chapter 215 which address the six additional rule amendments and the proposed rule recodification due to the Part 71 rule revision. These regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 20, 30, 31, 32, 35, 40, 70, and 71 and the requirements of the 7 amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Mr. Louis Ray Urciuolo on July 10, 2006.

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. We have determined that if these regulations are revised, incorporating our comments and without other 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](#).

We request that when you revise your regulations to address our comments, a copy of the "as published" regulations be provided to us for review. As requested in STP Procedure [SA-201](#), "Review of State Regulatory Requirements," please highlight the location of any changes made by Pennsylvania, in response to our comments and provide a copy to STP.

Additionally, we understand that Pennsylvania plans to address the requirements of NRC Order EA-05-090 (Increased Controls for Risk-Significant Radioactive Sources) through Order until such time as NRC adopts regulations to address these requirements. Pennsylvania will need to adopt and submit these legally binding requirements to the NRC for a compatibility review prior to becoming an Agreement State.

The SRS Data Sheet summarizes our knowledge of the status of other Pennsylvania 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 website: <http://www.hsr.doe.gov/nrc/rulemaking.htm>.

If you have any questions regarding the review results, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, or Kevin Hsueh at 301-415-2598 or by e-mail at kph@nrc.gov.

Sincerely,

IRA By K.Schneider For

Dennis K. Rathbun, Deputy Director
Office of State and Tribal Programs

Enclosure:
As stated

If you have any questions regarding the review results, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, or Kevin Hsueh at 301-415-2598 or by e-mail at kph@nrc.gov.

Sincerely,

RA By K.Schneider For

Dennis K. Rathbun, Deputy Director
Office of State and Tribal Programs

Enclosure:
As stated

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COMPATIBILITY COMMENTS ON PENNSYLVANIA PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	215.1(e)(13)	71.14(b) 71.19	2004-1	NRC	<p>Adoption by Reference for IAEA Transportation Amendments</p> <p>Pennsylvania's regulations include incorporation by reference for 71.14(b) and 71.19 that are reserved to NRC jurisdiction.</p> <p>Pennsylvania needs to add 71.14(b) and 71.19 to the list of items not incorporated by reference in 215.1(e)(13). These requirements are reserved to the NRC under 10 CFR 71 and should not be adopted by reference.</p>
2	215.1(e)(13)	71.13(c)&(d)	2004-1	B	<p>Adoption by Reference for IAEA Transportation Amendments</p> <p>Pennsylvania's regulations include 71.13(c)&(d) as not incorporated by reference.</p> <p>Pennsylvania needs to delete 71.13(c)&(d) reference from 215.1(e)(13) to meet the compatibility category B designation assigned to 10 CFR 71.13(c)&(d).</p>

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
3	215.1(e)(13)	71.101(c)(2), (d)&(e) 71.107 71.109 71.111 71.113 71.115 71.117 71.119 71.121 71.123 71.125	2004-1	<p data-bbox="812 262 1510 325">Adoption by Reference for IAEA Transportation Amendments</p> <p data-bbox="812 367 1510 1060">Section 71.101(b) (Establishment of a quality assurance program for packaging), which is designated as compatibility category C, states that “Each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of §§ 71.101 through 71.137....” However, sections 71.101(c)(2), (d) & (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125 have been designated as compatibility category NRC. Thus, for a state to adopt the essential objectives of 71.101(b), as would be required under compatibility category C, it would be inadvertently required to adopt requirements contained in provisions reserved to the NRC.</p> <p data-bbox="812 1102 1510 1354">Recognizing this discrepancy, staff members are re-reviewing the compatibility designation of the referenced sections. No changes to the Pennsylvania regulations are required until the NRC completes its review of part 71 and reports its results to the state.</p>

STATE REGULATION STATUS

State: Pennsylvania

[7 Amendments reviewed identified by a ★
at the beginning of each equivalent NRC Regulation]

Tracking Ticket Number:6-144

Date: July 11, 2006

NRC Chronology Identification	FR Notice (Date Due For State Implementation)	RATS ID	Proposed (P) / Final (F) ¹ Rule / License Conditions (LC) 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

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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
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 ML051890349	Y 05/15/03 ML031360008 N 12/14/05 ML053470511	09/15/01

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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 ML051890349	N 05/15/03 ML031360008 N 12/14/05 ML053470511	09/15/01
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

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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
★ Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material-Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F 5/5/06 ML051890349	N 07/11/06 ML061920410	9/15/01
★ Revision of the Skin Dose Limit-Part 20	67 FR 16298; (4/5/05)	2002-1	F 5/5/06 ML051890349	N 07/11/06 ML061920410	9/15/01
★ Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (4/24/05)	2002-2	F 5/5/06 ML051890349	N 07/11/06 ML061920410	9/15/01
★ Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1	F 5/5/06 ML051890349	N 07/11/06 ML061920410	9/15/01
★ Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1	P 5/5/06 ML051890349	Y 07/11/06 ML061920410	9/15/01
★ Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1	F 5/5/06 ML051890349	N 07/11/06 ML061920410	9/15/01

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★ Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2	F 5/5/06 ML051890349	N 07/11/06 ML061920410	9/15/01
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) ⁶	70 FR 72128; (12/1/05)	2005-3			

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.
7. The order will need to be incorporated as a generally binding license condition and will be reviewed by NRC for compatibility once PA submits their Agreement State application package.