December 13, 2005

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 June 27, 2005 letter in response to the 11 comments from our May 15, 2003 regulation review letter. Comments 2, 3, 4, 5, and 7 address 10 CFR 71 that has been subsequently revised and re-codified since our 2003 review. It is our understanding that Pennsylvania will pursue rulemaking to reflect the significant revisions and recodification in the latest revision to Part 71 and address our comments. Comments 1, 6, 8, 9, 10, and 11 were addressed adequately and we have no further comments. Comments 8-11 were discussed with Mr. Janati of your staff on October 4, 2005

In addition to the Part 71 rule revision, we have identified six additional rule amendments and an order, for a total of eight items that have become due and will need to be adopted since the 2003 review. Pennsylvania will need to adopt and submit these regulations or alternate generic legally binding requirements to the NRC for a compatibility review, prior to becoming an Agreement State. On October 5, 2005, we discussed with Mr. Urciolo and Mr. Seiber of your staff the requirement to have the regulations adopted and found compatible by NRC prior to the agreement being signed. The seven amendments and order are listed below.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material-Parts 30, 31, 32" (65 FR 79162; RATS ID 2001-1)
- "Revision of the Skin Dose Limit-Part 20" (67 FR 1629; RATS ID 2002-1)
- "Medical Use of Byproduct Material-Parts 20, 32, and 35" (67 FR 20249; RATS ID 2002-2)
- "Financial Assurance for Materials Licensees Parts 30, 40, 70" (68 FR 57327; RATS ID 2003-1)
- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments - Part 71" (69 FR 3697; RATS ID 2004-1)
- Security Requirements for Portable Gauges Containing Byproduct Material Part 30" (70 FR 2001; RATS ID 2005-1)
- "Medical Use of Byproduct Material Recognition of Specialty Boards Part 35"(70 FR 16336; RATS ID 2005-2)
- Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090)

The State Regulation Data Sheet (SRS) 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.hsrd.ornl.gov/nrc/rulemaking.htm#PA.

If you have any questions regarding the review results, the regulatory review process, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, or Dr. Terry Brock at 301-415-2323 or by e-mail at tab2@nrc.gov.

Sincerely,

\RA By KNSchneider For\

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

Enclosure: As stated The State Regulation Data Sheet (SRS) 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.hsrd.ornl.gov/nrc/rulemaking.htm#PA.

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Sincerely,

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

Enclosure: As stated

Distribution:

DIR RF 5-357 <u>SISP Review Complete</u>

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STATE REGULATION STATUS

State: Pennsylvania
[Two Amendments reviewed identified by a ★
at the beginning of each equivalent NRC Regulation] Tracking Ticket Number: 5-357 Date: December 14, 2005

at the beginning or each equiv	Date: December 14, 2005				
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

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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 12/14/05 ML053470511	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

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★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
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	ML051890349		
Revision of the Skin Dose Limit- Part 20	67 FR 16298; (4/5/05)	2002-1	ML051890349		
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (4/24/05)	2002-2	ML051890349		
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1	ML051890349		
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1	ML051890349		

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Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1	ML051890349		
Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; (4/29/08)	2005-2	ML051890349		
Increased Controls for Risk- Significant Radioactive Sources (NRC Order EA-05-090) ⁷	TBD FR TBD ; (12/2/05)	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.