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P.O. Box 8469
Harrisburg, PA 17105-8469

[date become agreement state]

Bureau of Radiation Protection

717-787-4937

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION

CERTIFIED MAIL

In the Matter of	:	
	:	
Licenses Authorized to	:	Order Modifying Licenses
Possess Radioactive Material	:	to Impose Increased Controls
Quantities of Concern	:	

ORDER

The Commonwealth of Pennsylvania, Department of Environmental Protection (Department), has found and determined as follows:

I

1. The Licensees identified in Attachment A to this Order previously held licenses issued in accordance with the Atomic Energy Act of 1954, 42 U.S.C. § 2011 *et seq.* (AEA), by the U.S. Nuclear Regulatory Commission (NRC) authorizing them to possess certain quantities of radioactive material of concern.

2. The Licensees were previously subject, *inter alia*, to NRC regulations set forth in 10 CFR Pt. 20. NRC regulations at 10 CFR § 20.1801 require Licensees to secure, from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas. NRC regulations at 10 CFR § 20.1802 require Licensees to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

3. On November 14, 2005, NRC issued an Order Imposing Increased Controls to the Licensees identified in Attachment A to this Order (the NRC Order). The NRC Order took effect immediately and was published in the Federal Register on December 1, 2005. *See* 70 FR 72128 (Dec. 1, 2005). As a result of an NRC staff confirmatory review of licensees potentially subject to the NRC Order, the NRC staff issued the NRC Order to an additional 635 NRC licensees that met the criteria for receiving the NRC Order but were not included in the November 14, 2005 mailing.

4. The NRC explained its action in the NRC Order, in part, as follows:

Prior to the terrorist attacks of September 11, 2001 (9/11), several national and international efforts were underway to address the potentially significant health and safety hazards posed by uncontrolled sources. These efforts recognized the need for increased control of high-risk radioactive materials to prevent inadvertent and intentional unauthorized access, primarily due to the potential health and safety hazards posed by the uncontrolled material. Following 9/11, it was recognized that these efforts should also include a heightened awareness and focus on the need to prevent intentional unauthorized access due to potential malicious acts. These efforts . . . seek to increase the control over sources to prevent unintended radiation exposure and to prevent malicious acts.

A licensee's loss of control of high-risk radioactive sources, whether it be inadvertent or through a deliberate act, has a potential to result in significant adverse health impacts and could reasonably constitute a threat to the public health and safety. In this regard, the Commission has determined that certain additional controls are required to be implemented by Licensees to supplement existing regulatory requirements in 10 CFR § 20.1801 and 10 CFR § 20.1802, in order to ensure adequate protection of, and minimize danger to, the public health and safety. Therefore, the Commission is imposing the requirements set forth in Attachment B on radioactive materials licensees who possess, or have near term plans to possess, radionuclides of concern at or above threshold limits, identified in Table 1. These requirements . . . will provide the Commission with reasonable assurance that the public health and safety continues to be adequately protected.

70 FR 72128-29.

5. The NRC recognized that Licensees may already have initiated many controls set forth in Attachment B to the NRC Order in response to previously issued advisories or on their own. It was also recognized that some controls may not be possible or necessary at some sites, or may need to be tailored to accommodate the Licensees' specific circumstances to achieve the intended objectives and avoid any unforeseen adverse effect on the safe use and storage of the sealed sources. The NRC stated further that although the additional controls implemented by the Licensees in response to Safeguards and Threat Advisories have been adequate to provide reasonable assurance of adequate protection of public health and safety, the NRC concluded that additional controls must be imposed by an Order, consistent with the established regulatory framework. 70 FR at 72129.

6. Accordingly, to provide assurance that the Licensees are implementing prudent measures to achieve a consistent level of control, the NRC ordered that all Licensees who hold licenses issued by the NRC authorizing possession of radioactive material quantities of concern as listed in Attachment B, Table 1 must implement the requirements identified in Attachment B to the NRC Order. Compliance with these requirements was required by May 13, 2006 for those licensees who received the November 14, 2005 mailing of the NRC Order, by June 2, 2006 for those licensee who received the December 22, 2005 mailing of the NRC Order, or by the first day that radionuclides of concern are possessed at or above threshold limits. Because of the

potentially significant adverse health impacts associated with failure to control high risk radioactive sources, the NRC found that the public health, safety, and interest required that the NRC Order be effective immediately, and that the requirements imposed by the NRC remain in effect until the NRC modifies its regulations to reflect increased controls. 70 FR at 72129.

7. The NRC Order stated that, to effect nationwide implementation, the measures imposed by the NRC Order have been determined by the NRC to be an immediate mandatory Category “B” matter of compatibility for Agreement States. See 62 FR 46517 (Sept. 3, 1997) (Statement of Principles and Policy for the Agreement State Program; Policy Statement on Adequacy and Compatibility of Agreement State Programs). Accordingly, the NRC Order provided that, in parallel with the NRC’s issuance of the NRC Order, each Agreement State is required to issue legally binding requirements to put essentially identical measures in place for licensees under their regulatory jurisdiction. 70 FR at 72129.

II

8. On [date] the Commonwealth of Pennsylvania and the NRC entered into an agreement, pursuant to section 274 of the AEA, 42 U.S.C. § 2021, and section 201 of the Pennsylvania Radiation Protection Act (RPA), Act of July 10, 1984, P.L. 688, No. 147, 35 P.S. § 7110.201 (the Agreement).

9. The Agreement provides for discontinuance of the regulatory authority of the NRC within the Commonwealth under Chapters 6, 7, and 8, and Section 161 of the AEA with respect to byproduct materials as defined in Sections 11e.(1), (3) and (4) of the AEA, source materials, and special nuclear materials in quantities not sufficient to form a critical mass, as well as with respect to the regulation of the land disposal of all waste byproduct, source and special nuclear materials covered by the Agreement. Pennsylvania thereby became an Agreement State upon publication of notice of the Agreement in the Federal Register on [date], and the Commonwealth assumed regulatory authority as prescribed by the Agreement.

10. Upon Pennsylvania becoming an Agreement State, the Licensees identified in Attachment A to this Order—which licensees possess a specific license issued by the NRC for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass—are deemed to possess a like license issued under the RPA and 25 Pa. Code Chapter 217. See 25 Pa. Code § 217.133. Accordingly, the Licensees identified in Attachment A to this Order now hold licenses issued in accordance with the RPA and its implementing regulations.

11. As an Agreement State, in order to comply with the NRC Order Pennsylvania must issue legally binding requirements to put essentially identical measures in place for licensees under its regulatory jurisdiction as those which are set forth in the NRC Order. Consequently, the Department is issuing this Order, which will put essentially identical measures in place for licensees now under its jurisdiction as an Agreement State. The requirements set forth in Attachment B to this Order are essentially identical to those set forth in Attachment B to the NRC Order; in addition, Attachment B, Table 1 is essentially identical in both Orders.

12. The Department is the agency with the duty and authority to administer and

enforce the RPA, section 1917-A of the Administrative Code of 1929, act of April 9, 1929, P. L. 177, No. 175, 71 P.S. § 510-17, and the rules and regulations promulgated thereunder.

13. Pennsylvania regulations incorporate 10 CFR §§ 20.1801 and 1802 by reference, see 25 Pa. Code §§ 215.1 and 219.5. In addition, 25 Pa. Code § 219.131 requires Licensees to secure from unauthorized removal or access radiation sources that are in storage, and § 219.132 requires Licensees to maintain control of radiation producing machines that are not in storage.

III

Accordingly, pursuant to Sections 301(c)(4), 301(c)(15), 303(d) and 304 of the Radiation Protection Act, 35 P.S. §§ 7110.301(c)(4), 7110.301(c)(15), 7110.303(d) and 7110.304, and the Department's regulations in 25 Pa. Code Chapters 217 and 219, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT THE LICENSES OF ALL THE LICENSEES IDENTIFIED IN ATTACHMENT A TO THIS ORDER ARE HEREBY MODIFIED ACCORDING TO THE TERMS OF THIS ORDER AND THAT ALL LICENSEES IDENTIFIED IN ATTACHMENT A TO THIS ORDER SHALL COMPLY WITH THE REQUIREMENTS OF THIS ORDER AS FOLLOWS:

A. The Licensee must comply with the requirements in Attachment B to this Order. Unless properly granted an extension of time to comply or other relief by the NRC, the Licensee shall have completed implementation by no later than June 2, 2006 or the first day that radionuclides of concern at or above threshold limits, as identified in Table 1, were possessed.

B. 1. The Licensee shall in writing, within fifteen (15) days of the date of this Order, notify the Department: (1) that the Licensee is currently in compliance with the requirements described in Attachment B or that the Licensee has been granted an extension of time for compliance by the NRC; (2) that the Licensee recognizes that it is now subject to Pennsylvania jurisdiction with respect to the materials covered by the Agreement; (3) if compliance with any of the requirements is unnecessary in its specific circumstances; or, (4) if implementation of any of the requirements would cause the Licensee to be in violation of the provisions of any Department regulation or its license. The notification shall provide the Licensee's justification for seeking relief from or variation of any specific requirement.

B. 2. If the Licensee considers that implementation of any of the requirements described in Attachment B to this Order would adversely impact safe operation of the facility, the Licensee must notify the Department, in writing, within fifteen (15) days of this Order, of the adverse safety impact, the basis for its determination that the requirement has an adverse safety impact, and either a proposal for achieving the same objectives specified in the Attachment B requirement in question, or a schedule for modifying the facility to address the adverse safety condition. If neither approach is appropriate, the Licensee must supplement its response to Condition B.1 of this Order to identify the condition as a requirement with which it cannot comply, with attendant justifications as required in Condition B.1.

C. 1. The Licensee's notification submitted pursuant to Condition B.1(1) shall include a certification that the Licensee completed each requirement in Attachment B in response to the

NRC Order and currently remains in compliance with the requirements in Attachment B to this Order, or, a schedule for completion of each requirement described in Attachment B.

C. 2. For those Licensees granted an extension of time to comply with the requirements in Attachment B, the Licensee shall report to the Department when they have achieved full compliance with the requirements in Attachment B.

D. Notwithstanding any provisions of the Department regulations to the contrary, all measures implemented or actions taken in response to this Order shall be maintained until the Department modifies its regulations to reflect increased controls.

Licensee responses to Conditions B.1, B.2, C.1, and C.2 above shall be submitted to the Director, Bureau of Radiation Protection, Pennsylvania Department of Environmental Protection, Rachel Carson State Office Building, P.O. Box 8469, Harrisburg, PA 17105-8469. Licensee's responses shall be marked as "Confidential."

The Director of the Bureau of Radiation Protection may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

IV

Any person aggrieved by this action may appeal, pursuant to Section 4 of the Environmental Hearing Board Act, 35 P.S. Section 7514, and the Administrative Agency Law, 2 Pa.C.S. Chapter 5A, to the Environmental Hearing Board, Second Floor, Rachel Carson State Office Building, 400 Market Street, P.O. Box 8457, Harrisburg, PA 17105-8457, 717-787-3483. TDD users may contact the Board through the Pennsylvania Relay Service, 800-654-5984. Appeals must be filed with the Environmental Hearing Board within 30 days of receipt of written notice of this action unless the appropriate statute provides a different time period. Copies of the appeal form and the Board's rules of practice and procedure may be obtained from the Board. The appeal form and the Board's rules of practice and procedure are also available in braille or on audiotape from the Board Secretary at 717-787-3483. This paragraph does not, in and of itself, create any right of appeal beyond that permitted by applicable statutes and decisional law.

If you want to challenge this action, your appeal must reach the Board within 30 days. You do not need a lawyer to file an appeal with the Board. Important legal rights are at stake, however, so you should show this document to a lawyer at once. If you cannot afford a lawyer, you may qualify for free pro bono representation. Call the Board Secretary (717-787-3483) for more information.

FOR THE DEPARTMENT

David Allard, Director
Bureau of Radiation Protection

Dated: