

NUCLEAR REGULATORY COMMISSION

Commonwealth of Pennsylvania: Draft NRC Staff Assessment of a Proposed Agreement
Between the Nuclear Regulatory Commission and the Commonwealth of Pennsylvania

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of a proposed Agreement with the Commonwealth of Pennsylvania.

SUMMARY: By letter dated November 9, 2006, Governor Edward G. Rendell of Pennsylvania requested that the U. S. Nuclear Regulatory Commission (NRC or Commission) enter into an Agreement with the Commonwealth as authorized by Section 274 of the Atomic Energy Act of 1954, as amended (Act).

Under the proposed Agreement, the Commission would give up, and Pennsylvania would take over, portions of the Commission's regulatory authority exercised within the Commonwealth. As required by the Act, the NRC is publishing the proposed Agreement for public comment. The NRC is also publishing the summary of an assessment by the NRC staff of the Pennsylvania regulatory program. Comments are requested on the proposed Agreement, especially its effect on public health and safety. Comments are also requested on the draft NRC staff assessment, the adequacy of the Pennsylvania program, and the Commonwealth's program staff, as discussed in this notice.

The proposed Agreement would release (exempt) persons who possess or use certain radioactive materials in Pennsylvania from portions of the Commission's regulatory authority.

The Act requires that the NRC publish those exemptions. Notice is hereby given that the pertinent exemptions have been previously published in the Federal Register and are codified in the Commission's regulations as 10 CFR Part 150.

DATES: The comment period expires (30 days after date of FIRST publication). Comments received after this date will be considered if it is practical to do so, but the Commission cannot assure consideration of comments received after the expiration date.

ADDRESSES: Written comments may be submitted to Mr. Michael T. Lesar, Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration, Washington, DC 20555-0001. Comments may be submitted electronically at nrerep@nrc.gov.

The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html>. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) reference staff at (800) 397-4209, or (301) 415-4737, or by e-mail to pdr@nrc.gov.

Copies of comments received by NRC may be examined at the NRC Public Document Room, 11555 Rockville Pike, Public File Area O-1-F21, Rockville, Maryland. Copies of the request for an Agreement by the Governor of Pennsylvania including all information and documentation submitted in support of the request, and copies of the full text of the NRC Draft

Staff Assessment are also available for public inspection in the NRC's Public Document Room--ADAMS Accession Numbers: ML070240128, ML063400549, ML070240055, ML063330295, ML070290041, ML070290046, ML070260116, ML070260179, ML070260026, ML070260119, ML070250054, ML063400559, ML070790604, ML070790609, ML070790612, ML070790616, ML070790620, and ML070890378

FOR FURTHER INFORMATION CONTACT: Mr. Andrew N. Mauer, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone (301) 415-3962 or e-mail to anm@nrc.gov.

SUPPLEMENTARY INFORMATION: Since Section 274 of the Atomic Energy Act of 1954, as amended (Act) was added in 1959, the Commission has entered into Agreements with 34 States. The Agreement States currently regulate approximately 17,600 Agreement material licenses, while the NRC regulates approximately 4,400 licenses. Under the proposed Agreement, approximately 690 NRC licenses will transfer to Pennsylvania. The NRC periodically reviews the performance of the Agreement States to assure compliance with the provisions of Section 274.

Section 274e requires that the terms of the proposed Agreement be published in the *Federal Register* for public comment once each week for four consecutive weeks. This notice is being published in fulfillment of the requirement.

I. Background

(a) Section 274b of the Act provides the mechanism for a State to assume regulatory authority, from the NRC, over certain radioactive materials¹ and activities that involve use of the materials.

In a letter dated November 9, 2006, Governor Rendell certified that the Commonwealth of Pennsylvania has a program for the control of radiation hazards that is adequate to protect public health and safety within Pennsylvania for the materials and activities specified in the proposed Agreement, and that the Commonwealth desires to assume regulatory responsibility for these materials and activities. Included with the letter was the text of the proposed Agreement, which is shown in Appendix A to this notice.

The radioactive materials and activities (which together are usually referred to as the “categories of materials”) that the Commonwealth of Pennsylvania requests authority over are:

(1) The possession and use of byproduct materials as defined in Section 11e.(1) of the Act;

(2) The possession and use of byproduct materials as defined in Section 11e.(3) of the Act;

¹The radioactive materials, sometimes referred to as “Agreement materials,” are: (a) byproduct materials as defined in Section 11e.(1) of the Act; (b) byproduct materials as defined in Section 11e.(3) of the Act; (c) byproduct materials as defined in Section 11e.(4) of the Act; (d) source materials as defined in Section 11z. of the Act; and (e) special nuclear materials as defined in Section 11aa. of the Act, restricted to quantities not sufficient to form a critical mass.

(3) The possession and use of byproduct materials as defined in Section 11e.(4) of the Act;

(4) The possession and use of source materials;

(5) The possession and use of special nuclear materials in quantities not sufficient to form a critical mass; and

(6) The regulation of the land disposal of byproduct materials as defined in Section 11e.(1) of the Act, source, or special nuclear waste materials received from other persons.

(b) The proposed Agreement contains articles that:

- Specify the materials and activities over which authority is transferred;
- Specify the activities over which the Commission will retain regulatory authority;
- Continue the authority of the Commission to safeguard nuclear materials and restricted data;
- Commit the Commonwealth of Pennsylvania and NRC to exchange information as necessary to maintain coordinated and compatible programs;
- Provide for the reciprocal recognition of licenses;
- Provide for the suspension or termination of the Agreement; and
- Specify the effective date of the proposed Agreement.

The Commission reserves the option to modify the terms of the proposed Agreement in response to comments, to correct errors, and to make editorial changes. The final text of the Agreement, with the effective date, will be published after the Agreement is approved by the Commission, and signed by the NRC Chairman and the Governor of Pennsylvania.

(c) The regulatory program is authorized by law under the Radiation Protection Act (35 P.S. §§ 7110.101 - 7110.703). § Section 7110.201 provides the authority for the Governor to enter into an Agreement with the Commission. Pennsylvania law contains provisions for the orderly transfer of regulatory authority over affected licensees from the NRC to the Commonwealth. After the effective date of the Agreement, licenses issued by NRC would continue in effect as Pennsylvania licenses until the licenses expire or are replaced by State-issued licenses. NRC licenses transferred to Pennsylvania which contain requirements for decommissioning and express an intent to terminate the license when decommissioning has been completed under a Commission-approved decommissioning plan will continue as Pennsylvania licenses and will be terminated by Pennsylvania when the Commission-approved decommissioning plan has been completed.

Pennsylvania currently regulates the users of naturally-occurring and accelerator-produced radioactive materials. The Energy Policy Act of 2005 (EPAAct) expanded the Commission's regulatory authority over byproduct materials as defined in Sections 11e.(3) and 11e.(4) of the Act, to include certain naturally-occurring and accelerator-produced radioactive materials. On August 31, 2005, the Commission issued a time-limited waiver (70 FR 51581) of the EPAAct requirements. Under the proposed Agreement, Pennsylvania would assume regulatory authority for these radioactive materials. Therefore, if the proposed Agreement is approved, the Commission would terminate the time-limited waiver in Pennsylvania coincident with the effective date of the Agreement. Also, a notification of waiver termination would be provided in the *Federal Register* for the final Agreement.

(d) The NRC draft staff assessment finds that the Commonwealth of Pennsylvania Bureau of Radiation Protection of the Pennsylvania Department of Environmental Protection is

adequate to protect public health and safety, and is compatible with the NRC program for the regulation of Agreement materials.

II. Summary of the NRC Staff Assessment of the Pennsylvania Program for the Control of Agreement Materials

The NRC staff has examined the Pennsylvania request for an Agreement with respect to the ability of the radiation control program to regulate Agreement materials. The examination was based on the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement," (46 FR 7540; January 23, 1981, as amended by policy statements published at 46 FR 36969; July 16, 1981 and at 48 FR 33376; July 21, 1983), and the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700, "Processing an Agreement."

(a) Organization and Personnel. The Agreement materials program will be located within the existing Bureau of Radiation Protection (BRP) of the Pennsylvania Department of Environmental Protection (PADEP). The Bureau will be responsible for all regulatory activities related to the proposed Agreement.

The educational requirements for the BRP staff members are specified in the Commonwealth of Pennsylvania personnel position descriptions, and meet the NRC criteria with respect to formal education or combined education and experience requirements. All current staff members hold at least bachelor's degrees in physical or life sciences, or have a combination of education and experience at least equivalent to a bachelor's degree. Several staff members hold advanced degrees, and all have had additional training plus working

experience in radiation protection. Supervisory level staff each have at least seven years working experience in radiation protection.

The BRP performed and the NRC staff reviewed an analysis of the expected workload under the proposed Agreement. Based on the NRC staff review of the BRP's staff analysis, the BRP has an adequate number of staff to regulate radioactive materials under the terms of the Agreement. The BRP will employ a staff with at least the equivalent of 17.2 full-time professional/technical and administrative employees for the Agreement materials program.

Pennsylvania has indicated that the BRP has an adequate number of trained and qualified staff in place. Pennsylvania has developed qualification procedures for license reviewers and inspectors which are similar to the NRC's procedures. The technical staff are working with NRC license reviewers in the NRC Region I Office and accompanying NRC staff on inspections of NRC licensees in Pennsylvania. Pennsylvania is also actively further supplementing their experience through direct meetings, discussions, and facility walk-downs with NRC licensees in Pennsylvania, and through self-study, in-house training, and formal training.

In the course of the NRC staff's continued interactions with Pennsylvania, the NRC staff will confirm the assurances that Pennsylvania provided concerning having an adequate number of trained and qualified staff in place, based on Pennsylvania's staff needs analysis and qualification procedures. Specifically, the NRC staff will verify how BRP staff fit into the qualification process, which staff are qualified in certain areas, and the basis for the determinations.

(b) Legislation and Regulations. In conjunction with the rulemaking authority vested in the Environmental Quality Board by Section 302 of the Pennsylvania Radiation Protection Act 1984-147, PADEP has the requisite authority to promulgate regulations for protection against radiation. The law provides PADEP the authority to issue licenses, issue orders, conduct inspections, and to enforce compliance with regulations, license conditions, and orders. Licensees are required to provide access to inspectors.

The NRC staff verified that Pennsylvania adopted the relevant NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150 into Pennsylvania Code Title 25, Environmental Protection by reference. The NRC staff also verified that Pennsylvania adopted the relevant NRC regulations in 10 CFR Part 61 into Pennsylvania Code Title 25, Environmental Protection. The NRC staff also approved an order to implement Increased Controls requirements for risk-significant radioactive materials for certain Pennsylvania licensees under the proposed Agreement. As a result of the renumbering of 10 CFR Part 71 in 2004, Pennsylvania is proceeding with necessary revisions to their regulations to ensure compatibility, that will be effective by October 1, 2007. Therefore, on the proposed effective date of the Agreement, Pennsylvania will have adopted an adequate and compatible set of radiation protection regulations which apply to byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass. The NRC staff also verified that Pennsylvania will not attempt to enforce regulatory matters reserved to the Commission.

(c) Storage and Disposal. Pennsylvania has also adopted by reference the NRC requirements for the storage of radioactive material and for the land disposal of radioactive material as waste. The waste disposal requirements cover both the disposal of waste generated by the licensee and the disposal of waste generated by and received from other persons.

(d) Transportation of Radioactive Material. Pennsylvania has adopted the NRC regulations in 10 CFR Part 71 by reference. Part 71 contains the requirements licensees must follow when preparing packages containing radioactive material for transport. Part 71 also contains requirements related to the licensing of packaging for use in transporting radioactive materials. Pennsylvania will not attempt to enforce portions of the regulations related to activities, such as approving packaging designs, which are reserved to NRC.

(e) Recordkeeping and Incident Reporting. Pennsylvania has adopted by reference the Sections of the NRC regulations which specify requirements for licensees to keep records, and to report incidents or accidents involving materials.

(f) Evaluation of License Applications. Pennsylvania has adopted by reference the NRC regulations that specify the requirements a person must meet to get a license to possess or use radioactive materials. Pennsylvania has also developed a licensing procedures manual, along with the accompanying regulatory guides, which are adapted from similar NRC documents and contain guidance for the program staff when evaluating license applications.

(g) Inspections and Enforcement. Pennsylvania has adopted a schedule providing for the inspection of licensees as frequently as, or more frequently than, the inspection schedule used by the NRC. The program has adopted procedures for the conduct of inspections, reporting of inspection findings, and reporting inspection results to the licensees. Pennsylvania has also adopted procedures for the enforcement of regulatory requirements, and is authorized by law to enforce the State rules using a variety of sanctions, including the imposition and collection of civil penalties, and the issuance of orders to suspend, modify or revoke licenses, or to impound materials.

(h) Regulatory Administration. Pennsylvania is bound by requirements specified in Commonwealth law for rulemaking, issuing licenses, and taking enforcement actions. The program has also adopted administrative procedures to assure fair and impartial treatment of license applicants. Pennsylvania law prescribes standards of ethical conduct for Commonwealth employees.

(l) Cooperation with Other Agencies. Pennsylvania law deems the holder of an NRC license on the effective date of the proposed Agreement to possess a like license issued by Pennsylvania. The law provides that these former NRC licenses will expire either 90 days after receipt from the radiation control program of a notice of expiration of such license or on the date of expiration specified in the NRC license, whichever is later. In the case of NRC licenses that are terminated under restricted conditions required by 10 CFR 20.1403 prior to the effective date of the proposed Agreement, Pennsylvania deems the termination to be final despite any other provisions of Commonwealth law or rule. For NRC licenses that, on the effective date of the proposed Agreement, contain a license condition indicating intent to terminate the license upon completion of a Commission approved decommissioning plan, the transferred license will be terminated by Pennsylvania under the plan so long as the licensee conforms to the approved plan.

Pennsylvania also provides for “timely renewal.” This provision affords the continuance of licenses for which an application for renewal has been filed more than 30 days prior to the date of expiration of the license. NRC licenses transferred while in timely renewal are included under the continuation provision. The Pennsylvania Code provides exemptions from the Commonwealth's requirements for licensing of sources of radiation for NRC and U.S. Department of Energy contractors or subcontractors. The proposed Agreement commits Pennsylvania to use its best efforts to cooperate with the NRC and the other Agreement States

in the formulation of standards and regulatory programs for the protection against hazards of radiation, and to assure that Pennsylvania's program will continue to be compatible with the Commission's program for the regulation of Agreement materials. The proposed Agreement stipulates the desirability of reciprocal recognition of licenses, and commits the Commission and Pennsylvania to use their best efforts to accord such reciprocity.

III. Staff Conclusion

Section 274d of the Act provides that the Commission shall enter into an agreement under Section 274b with any State if:

(a) The Governor of the State certifies that the State has a program for the control of radiation hazards adequate to protect public health and safety with respect to the agreement materials within the State, and that the State desires to assume regulatory responsibility for the agreement materials; and

(b) The Commission finds that the State program is in accordance with the requirements of Section 274o, and in all other respects compatible with the Commission's program for the regulation of materials, and that the State program is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

The NRC staff has reviewed the proposed Agreement, the certification by the Commonwealth of Pennsylvania in the application for an Agreement submitted by Governor Rendell on November 9, 2006, and the supporting information provided by the staff of the Bureau of Radiation Protection of the Pennsylvania Department of Environmental Protection, and concludes that, except as discussed above in Section II. "Summary of the NRC Staff Assessment of the Pennsylvania Program for the Control of Agreement Materials," (a)

“Organization and Personnel,” of this document, the Commonwealth of Pennsylvania satisfies the criteria in the Commission’s policy statement “Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement,” and therefore, meets the requirements of Section 274 of the Act. The proposed Pennsylvania program to regulate Agreement materials, as comprised of statutes, regulations, and procedures, is compatible with the program of the Commission and is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

With respect to discussion above in Section II. “Summary of the NRC Staff Assessment of the Pennsylvania Program for the Control of Agreement Materials,” (a) “Organization and Personnel,” once the NRC staff confirms the assurances provided by Pennsylvania concerning staff training and qualifications, the staff will be able to conclude that area is satisfied.

Dated at Rockville, Maryland, this [] day of [month], 2007.

For the Nuclear Regulatory Commission.

Janet R. Schlueter, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

AN AGREEMENT
BETWEEN
THE UNITED STATES NUCLEAR REGULATORY COMMISSION
AND
THE COMMONWEALTH OF PENNSYLVANIA
FOR THE
DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY
AND
RESPONSIBILITY WITHIN THE COMMONWEALTH PURSUANT TO
Section 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

WHEREAS, The United States Nuclear Regulatory Commission (the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. § 2011 *et seq.* (the Act), to enter into agreements with the Governor of any State/Commonwealth providing for discontinuance of the regulatory authority of the Commission within the Commonwealth under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e.(1), (3), and (4) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

WHEREAS, The Governor of the Commonwealth of Pennsylvania is authorized under the Pennsylvania Radiation Protection Act, Act of July 10, 1984, P.L. 688, No. 147, *as amended*, 35 P.S. § 7110.101 *et seq.*, to enter into this Agreement with the Commission; and,

WHEREAS, The Governor of the Commonwealth of Pennsylvania certified on November 8, 2006, that the Commonwealth of Pennsylvania (the Commonwealth) has a program for the control of radiation hazards adequate to protect public health and safety with respect to the materials within the Commonwealth covered by this Agreement, and that the Commonwealth desires to assume regulatory responsibility for such materials; and,

WHEREAS, The Commission found on [date] that the program of the Commonwealth for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety; and,

WHEREAS, The Commonwealth and the Commission recognize the desirability and importance of cooperation between the Commission and the Commonwealth in the formulation of standards for protection against hazards of radiation and in assuring that Commonwealth and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

WHEREAS, The Commission and the Commonwealth recognize the desirability of the reciprocal recognition of licenses, and of the granting of limited exemptions from licensing of those materials subject to this Agreement; and,

WHEREAS, This Agreement is entered into pursuant to the provisions of the Act ;

NOW, THEREFORE, It is hereby agreed between the Commission and the Governor of the Commonwealth acting on behalf of the Commonwealth as follows:

ARTICLE I

Subject to the exceptions provided in Articles II, IV, and V, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the Commonwealth under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

1. Byproduct materials as defined in Section 11e.(1) of the Act;
2. Byproduct materials as defined in Section 11e.(3) of the Act;
3. Byproduct materials as defined in Section 11e.(4) of the Act;
4. Source materials;
5. Special nuclear materials in quantities not sufficient to form a critical mass.
6. The regulation of the land disposal of all waste byproduct, source, and special nuclear materials covered by this Agreement;

ARTICLE II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to:

1. The regulation of the construction and operation of any production or utilization facility or any uranium enrichment facility;
2. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;
3. The regulation of the disposal into the ocean or sea of byproduct, source, or special nuclear materials waste as defined in the regulations or orders of the Commission;
4. The regulation of the disposal of such other byproduct, source, or special nuclear materials waste as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be disposed without a license from the Commission;
5. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission.

ARTICLE III

With the exception of those activities identified in Article II.A.1 through 4, this Agreement may be amended, upon application by the Commonwealth and approval by the Commission, to include one or more of the additional activities specified in Article II, whereby the Commonwealth may then exert regulatory authority and responsibility with respect to those activities.

ARTICLE IV

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

ARTICLE V

This Agreement shall not affect the authority of the Commission under SubSection 161b or 161i of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data, or to guard against the loss or diversion of special nuclear material.

ARTICLE VI

The Commission will cooperate with the Commonwealth and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that Commission and Commonwealth programs for protection against hazards of radiation will be coordinated and compatible. The Commonwealth agrees to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the Commonwealth and the Commission for protection against hazards of radiation and to assure that the Commonwealth's program will continue to be compatible with the program of the Commission for the regulation of materials covered by this Agreement.

The Commonwealth and the Commission agree to keep each other informed of proposed changes in their respective rules and regulations, and to provide each other the opportunity for early and substantive contribution to the proposed changes.

The Commonwealth and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implication or otherwise be of regulatory interest.

ARTICLE VII

The Commission and the Commonwealth agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any other Agreement State. Accordingly, the Commission and the Commonwealth agree to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

ARTICLE VIII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the Commonwealth, or upon request of the Governor of the Commonwealth, may terminate or suspend all or part of this agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect public health and safety, or (2) the Commonwealth has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to Section 274j of the Act, temporarily suspend all or part of this agreement if, in the judgment of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the Commonwealth has failed to take necessary steps. The Commission shall periodically review actions taken by the Commonwealth under this Agreement to ensure compliance with Section 274 of the Act which requires a Commonwealth program to be adequate to protect public health and safety with respect to the materials covered by this Agreement and to be compatible with the Commission's program.

ARTICLE IX

This Agreement shall become effective on [date], and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at [City, State] this [date] day of [month], [year].

FOR THE UNITED STATES NUCLEAR
REGULATORY COMMISSION

Dale E. Klein, Chairman

FOR THE COMMONWEALTH OF
PENNSYLVANIA

Edward G. Rendell, Governor