[7590-01-P]

NUCLEAR REGULATORY COMMISSION

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

AGENCY: Nuclear Regulatory Commission.

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

SUMMARY: By letter dated June 12, 2008, Governor Timothy M. Kaine of Virginia requested that the U. S. Nuclear Regulatory Commission (NRC or Commission) enter into an Agreement with the Commonwealth of Virginia (Commonwealth or Virginia) as authorized by Section 274 of the Atomic Energy Act of 1954, as amended (Act).

Under the proposed Agreement, the Commission would relinquish, and the Commonwealth would assume, 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 Commonwealth's regulatory program. Comments are requested on the proposed Agreement, especially its effect on public health and safety. Comments are also requested on the NRC staff assessment, the adequacy of the Commonwealth's 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 the Commonwealth 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 nrcrep.resource@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.resource@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 Virginia 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: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624, ML082470314, and ML083180102.

FOR FURTHER INFORMATION CONTACT: Ms. Monica L. Orendi, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone (301) 415-3938 or e-mail to monica.orendi@nrc.gov.

SUPPLEMENTARY INFORMATION: Since Section 274 of the Act was added in 1959, the Commission has entered into Agreements with 35 States. The Agreement States currently regulate approximately 18,000 Agreement material licenses, while the NRC regulates approximately 4,000 licenses. Under the proposed Agreement, approximately 400 NRC licenses will transfer to the Commonwealth. 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 materials[1] and activities that involve use of the materials.

In a letter dated June 12, 2008, Governor Kaine certified that the Commonwealth of Virginia has a program for the control of radiation hazards that is adequate to protect public health and safety within Virginia for the materials and activities specified in the proposed

[1]The 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.

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 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;

(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; and

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

The materials and activities the Commonwealth is not requesting authority over are:

1) The regulation of extraction or concentration of source material from source material ore and the management and disposal of the resulting byproduct material;

2) The regulation of land disposal of byproduct material or special nuclear material waste received from other persons; and

3) 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.

(b) The proposed Agreement contains articles that:

1) Specify the materials and activities over which authority is transferred;
2) Specify the activities over which the Commission will retain regulatory authority;
3) Continue the authority of the Commission to safeguard nuclear materials and restricted data;
4) Commit the Commonwealth and NRC to exchange information as necessary to maintain coordinated and compatible programs;
5) Provide for the reciprocal recognition of licenses;
6) Provide for the suspension or termination of the Agreement; and
7) 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 Virginia.

(c) The regulatory program is authorized by law under the Code of Virginia (32.1-227 – 32.1-238). Section 32.1-235 provides the Governor with the authority to enter into an Agreement with the Commission. Virginia 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 Commonwealth licenses until the licenses expire or are replaced by Commonwealth issued licenses. NRC licenses transferred to the Commonwealth which contain requirements for decommissioning and express intent to terminate the license when decommissioning has been completed under a Commission approved decommissioning plan will continue as Commonwealth licenses and will be terminated by the Commonwealth when the Commission approved decommissioning plan has been

completed.

The Commonwealth currently regulates the users of naturally-occurring and accelerator-produced radioactive materials. The Energy Policy Act of 2005 (EPAct) 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 EPAct requirements. Under the proposed Agreement, the Commonwealth would assume regulatory authority for these radioactive materials. Therefore, if the proposed Agreement is approved, the Commission would terminate the time-limited waiver in the Commonwealth 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's Division of Radiological Health, an organizational unit of the Virginia Department of Health (VDH), 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 Commonwealth's Program for the Control of Agreement Materials

The NRC staff has examined the Commonwealth's 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 Division of Radiological Health (DRH) of the VDH. The DRH will be responsible for all regulatory activities related to the proposed Agreement.

The educational requirements for the DRH staff members are specified in the Commonwealth’s 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. All have had additional training and work experience in radiation protection. Supervisory level staff has at least 7 years working experience in radiation protection.

The DRH performed and the NRC staff reviewed an analysis of the expected workload under the proposed Agreement. Based on the NRC staff review of the DRH’s staff analysis, the DRH has an adequate number of staff to regulate radioactive materials under the terms of the Agreement. The DRH will employ a staff with at least the equivalent of 6.0 full-time professional/technical and administrative employees for the Agreement materials program.

The Commonwealth has indicated that the DRH has an adequate number of trained and qualified staff in place. The Commonwealth 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 Virginia. DRH staff is also actively supplementing their experience through direct meetings, discussions, and facility walk-downs with NRC licensees in the Commonwealth, and through self-study, in-house training, and formal training.

Overall, the NRC staff believes that the DRH technical staff identified by the Commonwealth to participate in the Agreement materials program has sufficient knowledge and experience in radiation protection, the use of radioactive materials, the standards for the evaluation of applications for licensing, and the techniques of inspecting licensed users of agreement materials.

(b) Legislation and Regulations. In conjunction with the rulemaking authority vested in the Virginia Board of Health by Section 32.1-229 of the Code of Virginia, the DRH has the requisite authority to promulgate regulations for protection against radiation. The law provides DRH the authority to issue licenses and 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 the Commonwealth adopted the relevant NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 61, 70, 71, and 150 into Virginia Administrative Code Title 12, Section 5-481. The NRC staff also approved two license conditions to implement Increased Controls and Fingerprinting and Criminal History Records Check requirements for risk-significant radioactive materials for certain Commonwealth licensees under the proposed Agreement. These license conditions will replace the Orders that NRC issued (EA-05-090 and EA-07-305) to these licensees that will transfer to the

Commonwealth. As a result of the restructuring of Virginia Regulations, the Commonwealth deleted financial assurance requirements equivalent to 10 CFR 40.36. The Commonwealth is proceeding with the necessary revisions to their regulations to ensure compatibility, and these revisions will be effective by January 1, 2009. Therefore, on the proposed effective date of the Agreement, the Commonwealth will have adopted an adequate and compatible set of radiation protection regulations that apply to byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass. The NRC staff also verified that the Commonwealth will not attempt to enforce regulatory matters reserved to the Commission.

(c) Storage and Disposal. The Commonwealth has adopted NRC compatible requirements for the handling and storage of radioactive material. The Commonwealth will not seek authority to regulate the land disposal of radioactive material as waste. The Commonwealth waste disposal requirements cover the preparation, classification, and manifesting of radioactive waste generated by Commonwealth licensees for transfer for disposal to an authorized waste disposal site or broker.

(d) Transportation of Radioactive Material. Virginia has adopted compatible regulations to the NRC regulations in 10 CFR Part 71. 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. Virginia 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. The Commonwealth has adopted compatible regulations to 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. The Commonwealth has adopted compatible regulations to the NRC regulations that specify the requirements a person must meet to get a license to possess or use radioactive materials. The Commonwealth 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. The Commonwealth 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. The Commonwealth has also adopted procedures for the enforcement of regulatory requirements.

(h) Regulatory Administration. The Commonwealth 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. Commonwealth law prescribes standards of ethical conduct for Commonwealth employees.

(i) Cooperation with Other Agencies. Commonwealth law deems the holder of an NRC license on the effective date of the proposed Agreement to possess a like license issued by the Commonwealth. 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, the Commonwealth 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 the Commonwealth under the plan so long as the licensee conforms to the approved plan.

The Commonwealth 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 Code of Virginia 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 the Commonwealth 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 the Commonwealth’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 the Commonwealth 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 Virginia in the application for an Agreement submitted by Governor Kaine on June 12, 2008, and the supporting information provided by the staff of the DRH of the Virginia Department of Health, and concludes that the Commonwealth of Virginia 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 Commonwealth of Virginia 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.

Dated at Rockville, Maryland, this [ ] day of [month], 2008.

For the Nuclear Regulatory Commission.

Robert J. Lewis, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Appendix A

AN AGREEMENT
BETWEEN
THE UNITED STATES NUCLEAR REGULATORY COMMISSION
AND
THE COMMONWEALTH OF VIRGINIA
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 Virginia is authorized under the Code of Virginia Section 32.1-235, to enter into this Agreement with the Commission; and,

WHEREAS, The Governor of the Commonwealth of Virginia certified on June 12, 2008, that the Commonwealth of Virginia (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; and

5. Special nuclear materials in quantities not sufficient to form a critical mass.

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;

6. The regulation of byproduct material as defined in Section 11e.(2) of the Act;

7. The regulation of the land disposal of byproduct, source, or special nuclear material waste received from other persons.

ARTICLE III

With the exception of those activities identified in Article II.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 Commonwealth 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 [Richmond, Virginia] this [date] day of [month], [year].

FOR THE UNITED STATES NUCLEAR REGULATORY COMMISSION

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Dale E. Klein, Chairman

FOR THE COMMONWEALTH OF VIRGINIA

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Timothy M. Kaine, Governor