

DEC 19 1996

MEMORANDUM TO: David L. Meyer, Chief
Rules Review and Directives Branch
Division of Freedom of Information
and Publications Services
Office of Administration

FROM: Paul H. Lohaus, Deputy Director
Office of State Programs

Original Signed By:
PAUL H. LOHAUS

SUBJECT: FEDERAL REGISTER NOTICE

Attached is the following notice for publication in the Federal Register:

Notice of proposed Agreement with the Commonwealth of Massachusetts.

We request that the notice be published as soon as possible. The Atomic Energy Act requires that the notice be published once each week for four consecutive weeks. A 30-day comment period, commencing on the date of the first publication, should be specified.

If you have any questions or if any problems develop, please contact Mr. Richard Blanton of my staff at 415-2322.

Attachment:
As stated

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

December 19, 1996

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Rules Review and Directives Branch
Division of Freedom of Information
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Office of Administration

FROM: Paul H. Lohaus, Deputy Director
Office of State Programs

SUBJECT: FEDERAL REGISTER NOTICE

A handwritten signature in dark ink, appearing to read "Paul H. Lohaus", is written over the typed name in the "FROM:" field.

Attached is the following notice for publication in the Federal Register:

Notice of proposed Agreement with the Commonwealth of Massachusetts.

We request that the notice be published as soon as possible. The Atomic Energy Act requires that the notice be published once each week for four consecutive weeks. A 30-day comment period, commencing on the date of the first publication, should be specified.

If you have any questions or if any problems develop, please contact Mr. Richard Blanton of my staff at 415-2322.

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NUCLEAR REGULATORY COMMISSION

Commonwealth of Massachusetts: Staff Assessment of Proposed Agreement Between the Nuclear Regulatory Commission and the Commonwealth of Massachusetts.

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of proposed Agreement with the Commonwealth of Massachusetts.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC) has received, from the Governor of the Commonwealth of Massachusetts, a proposal to enter into an Agreement pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act). The proposed Agreement would permit Massachusetts to assume certain portions of the Commission's regulatory authority. As required by the Act, NRC is publishing the proposed Agreement for public comment. NRC is also publishing a summary of the NRC staff assessment of the proposed Massachusetts radiation control program. Comments are requested on the proposed Agreement, especially public health and safety aspects, and the assessment.

The Agreement will effectively release (exempt) persons in Massachusetts from certain portions of the Commission's regulatory authority. The Act also requires that 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 (four weeks after first publication). Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments

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received on or before this date.

ADDRESSES: Written comments may be submitted to Mr. David L. Meyer, Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, Washington, DC 20555-0001. Copies of comments received by NRC may be examined at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Copies of the proposed Agreement, along with copies of the request by Governor Weld including referenced enclosures, applicable legislation, regulations for the control of radiation, and the full text of the NRC staff assessment are also available for public inspection in the NRC's Public Document Room.

FOR FURTHER INFORMATION CONTACT: Richard L. Blanton, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone (301) 415-2322 or e-mail RLB@NRC.GOV.

SUPPLEMENTARY INFORMATION: The Commission has received a request from Governor William Weld of Massachusetts to enter into an Agreement whereby the NRC would discontinue, and the Commonwealth would assume, certain regulatory authority as specified in the Act. Section 274 of the Act authorizes the Commission to enter into such an agreement.

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

I. Background

(a) Section 274d of the Act provides the mechanism whereby a State may assume regulatory authority, otherwise reserved to the NRC, over certain radioactive materials¹ and uses thereof. In a letter dated March 28, 1996, Governor Weld certified that the Commonwealth of Massachusetts has a program for the control of radiation hazards that is adequate to protect health and safety of the public within the Commonwealth with respect to the materials covered by the proposed Agreement, and that the Commonwealth desires to assume regulatory responsibility for these materials. Included with the letter was the text of the proposed Agreement, which is shown in Appendix A to this notice.

The specific authorities requested by the Commonwealth of Massachusetts under this proposed Agreement are (1) the regulation of byproduct materials as defined in Section 11e.(1) of the Act, (2) the regulation of source materials, (3) the regulation of special nuclear materials in quantities not sufficient to form a critical mass, (4) the evaluation of the safety of sealed sources and devices (containing materials covered by the Agreement) for distribution in interstate commerce, and (5) the land disposal of low-level radioactive waste (as defined in the Low-Level Radioactive Waste Policy Amendments Act of 1985, 42 U.S.C. 2021b) received from other persons. The Commonwealth does not wish to assume authority over the regulation of byproduct materials as defined in Section 11e.(2) of the Act, that is over tailings from the recovery of

¹The 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.(2) of the Act; (c) Source materials as defined in Section 11z. of the Act; and (d) Special nuclear materials as defined in Section 11aa. of the Act, restricted to quantities not sufficient to form a critical mass.

source materials from ore, but does reserve the right to apply at a future date for an amended agreement to assume authority in this area.

(b) The proposed agreement contains nine articles that (1) list the materials and activities to be covered by the Agreement; (2) specify the activity for which the Commission will retain regulatory authority; (3) allow for future amendment of the Agreement; (4) allow for certain regulatory changes by the Commission; (5) reference the continued authority of the Commission for purposes of safeguarding nuclear materials and restricted data; (6) commit the Commonwealth and NRC to exchange information necessary to maintain coordinated and compatible programs; (7) recognize reciprocity of licenses issued by the respective agencies; (8) identify criteria for the suspension or termination of the Agreement; and (9) specify the proposed effective date. 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 in style. Also, because of several issues posed by this request which required resolution before the Agreement could be concluded, the effective date requested by the Governor could not be realized. The final text of the Agreement, with the actual effective date, will be published after the Agreement is approved by the Commission.

(c) The Massachusetts radiation control program currently regulates users of naturally-occurring and accelerator-produced radioactive materials, and users of certain radiation-producing electronic machines. The program was enabled by Massachusetts law (Massachusetts General Law [M.G.L.] Chapter 111, § 5B) in 1958. This statute was later replaced by M.G.L. Chapter 111, Sections 5M through 5P. In 1987, M.G.L. Chapter 111H was added to provide for the regulation of low-level radioactive waste. Section 7 of the legislation

contains the authority for the Governor to enter into an Agreement with the Commission.

The Massachusetts regulations contain provisions for the orderly transfer of authority over NRC licenses to the regulatory control of the Commonwealth. After the effective date of this proposed Agreement, licenses issued by NRC will continue in effect under Massachusetts regulatory authority until these licenses expire or are replaced by Commonwealth issued licenses.

(d) The NRC staff assessment finds the proposed Massachusetts program adequate to protect public health and safety, and compatible with the NRC program for materials regulation.

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

NRC staff has examined the proposed Massachusetts radiation control program with respect to the ability of the 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" (referred to herein as the "criteria") (46 FR 7540; January 23, 1981, as amended).

(a) *Organization and Personnel*. The proposed program unit responsible for regulating agreement materials will consist of 13 technical/professional positions within the existing radiation control program of the Massachusetts Department of Public Health. The qualifications for staff members specified in the personnel position descriptions, and the qualifications of the current staff members, meet the criteria for education, training and experience. 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. Most staff members hold advanced degrees, and have had additional training and experience in radiation protection. Senior staff have more than five years experience each in radiation control programs. The program director has a master's degree in public health and 15 years experience in regulatory health physics.

(b) *Legislation and regulations.* The Massachusetts Department of Public Health is designated by statute to be the radiation control agency. The Department is provided by statute with the authority to promulgate regulations, issue licenses, issue orders, conduct inspections, and to enforce compliance with regulations, license conditions, and orders. Licensees are required by law to provide access to inspectors.

The Department has adopted regulations (Massachusetts Regulations for the Control of Radiation or MRCR) providing radiation protection standards essentially identical to the standards in 10 CFR Part 20. Technical definitions in the MRCR are also essentially identical. The MRCR require consideration of the total radiation doses to individuals from all sources of radiation (except background radiation and radiation from medical treatment or examinations, as is the case in the NRC rules), whether the sources are in the possession of the licensee or not. The MRCR also require appropriate surveys and personnel monitoring under the close supervision of technically competent people, and the use of radiation labels, signs and symbols essentially identical to those contained in 10 CFR Part 20. Posting requirements and instruction of workers requirements adopted in the MRCR are compatible with the equivalent current requirements of the NRC.

Nothing in the Massachusetts statutes or regulations seeks to regulate areas not permitted by the Atomic Energy Act. The MRCR contain a provision to avoid interference with those regulatory requirements imposed by NRC pursuant to the Act, and for which Commonwealth licensees have not been exempted under the agreement.

(c) *Storage and Disposal*. The MRCR also contain compatible requirements for the storage of radioactive material, and for the disposal of radioactive material as waste. The waste disposal requirements cover both waste disposal by material users and the land disposal of waste received from other persons. The NRC staff noted some differences in the MRCR waste regulations as compared to the NRC regulations in 10 CFR Part 61, but determined that the differences are related either to the prohibition of shallow land burial as a disposal technology or to the ownership of the disposal site by the Massachusetts Low-Level Radioactive Waste Management Board. Because of these special provisions, NRC staff determined that the differences in the regulations do not reduce the ability of the Massachusetts radiation control program to protect health and safety, nor reduce the compatibility of the program or the regulations themselves.

(d) *Transportation of Radioactive Material*. The MRCR contains rules equivalent to 10 CFR Part 71 as in effect prior to April 1, 1996. Effective on that date, the NRC amended Part 71. Under current policy, an existing Agreement State is allowed up to three years after NRC adopts a final rule to adopt a compatible rule, or to impose each regulatory provision of the rule using an alternate legally binding requirement (LBR), such as an order or license condition. A State seeking an agreement is expected to have effective rules or LBRs compatible with those of NRC in effect at the time the agreement

becomes effective. The intent of this expectation is to spare licensees in the new Agreement State from the "whipsaw" effect of being subjected first to the new NRC requirements, then the old requirements when the agreement takes effect, then again to the new requirements when later adopted by the State. Massachusetts is in the process of adopting rules compatible with the revised 10 CFR Part 71. However, these rules may not become effective before the Agreement is signed. Massachusetts intends to impose the requirements of the new Part 71 rules in the interim by issuing appropriate orders to the affected licensees.

(e) *Recordkeeping and Incident Reporting.* The MRCR incident reporting requirements are similar to the requirements in the NRC rules. The NRC staff noted that for some NRC rules that specify a records retention period of less than five years, the retention period specified in the MRCR is shorter. The NRC staff concluded, however, that the retention periods specified in the MRCR rules are adequate since the retention periods are long enough to permit examination of the records during routine inspections. The MRCR imposes retention requirements similar to the NRC rules for records which must be retained indefinitely or until the license is terminated.

(f) *Evaluation of License Applications.* The MRCR contains requirements equivalent to the current NRC regulations specifying the required content of applications for licenses, renewals, and amendments. The MRCR also provide requirements equivalent to the NRC requirements for issuing licenses and specifying the terms and conditions of licenses. The agreement materials program unit has adopted a procedure for processing applications that assures the regulatory requirements will be met, or, if appropriate, exceptions granted. The program unit has the authority by Statute to impose requirements

in addition to the requirements specified in the regulations. The program unit also retains by regulation the authority to grant specific exemptions from the requirements of the regulations. The MRCR specifies qualifications for the use of radioactive materials in or on humans that are similar to the NRC requirements in 10 CFR Part 35.

The Massachusetts licensing procedures manual, along with the accompanying regulatory guides, are adapted from similar NRC documents and contain adequate guidance for the agreement materials program unit staff to use when evaluating license applications.

(g) *Inspections and Enforcement.* The Massachusetts radiation control program has adopted a schedule providing for the inspection of licensees as frequently as, or more frequently than, the inspection schedule used by NRC. The agreement materials program unit has adopted procedures for the conduct of inspections, the reporting of inspection findings, and the report of inspection results to the licensees. The program has also adopted procedures for enforcement in the MRCR.

(h) *Regulatory Administration.* The Massachusetts Department of Public Health is bound by procedures specified in Commonwealth statute for rulemaking. The program has adopted procedures to assure fair and impartial treatment of license applicants.

(i) *Cooperation with Other Agencies.* The MRCR deems the holder of an NRC license on the effective date of the Agreement to possess a like license issued by Massachusetts. The MRCR 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 earlier. The MRCR 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. Licenses in timely renewal are not excluded from the transfer continuation provision. The MRCR provide exemptions from the Commonwealth's requirements for licensing of sources of radiation for NRC and U.S. Department of Energy contractors or subcontractors.

The Department of Public Health and the Department of Labor and Industries have entered into a Memorandum of Understanding, as authorized elsewhere in Massachusetts law, which provides for the Department of Public Health to exercise the responsibility and authority of the Department of Labor and Industries with respect to radiation and radioactive materials. The Department of Environmental Protection is designated as the agency to adopt the suitability standards for any proposed disposal site under the Massachusetts Low-Level Radioactive Waste Management Act. The Department of Public Health will license and regulate the site only after the Executive Secretary for Environmental Affairs has determined that the report on the site characterization study is in conformance with the suitability standards, and the Low-Level Radioactive Waste Management Board has selected the operator.

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 like 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

Subsection 274d of the Act provides that the Commission shall enter into an agreement under subsection 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 materials within the State covered by the proposed Agreement, and that the State desires to assume regulatory responsibility for such materials; and

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

On the basis of its assessment, the NRC staff has concluded that the Commonwealth of Massachusetts meets the requirements of Section 274 of the Act. The Commonwealth's statutes, regulations, personnel, licensing, inspection, and administrative procedures are compatible with those of the Commission and adequate to protect public health and safety with respect to the materials covered by the proposed Agreement. Since the Commonwealth is not seeking authority over byproduct material as defined in Section 11e.(2) of the Act, Subsection 274o is not applicable to the proposed Agreement. The language of the Agreement requested by Governor Weld has been revised to reflect that the effective date of the proposed Agreement and the location at which it will be signed remain to be determined. Certain conventions have been used to highlight the proposed revisions. New language is shown inside boldfaced

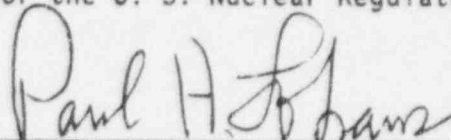
arrows, while language that would be deleted is set off with brackets.

IV. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

Dated at Rockville, Maryland, this 19th day of December, 1996.

For the U. S. Nuclear Regulatory Commission.

A handwritten signature in dark ink, appearing to read "Paul H. Lohaus", written over a horizontal line.

Paul H. Lohaus
Acting Director, Office of State Programs.

APPENDIX A
PROPOSED AGREEMENT

AGREEMENT
BETWEEN
THE UNITED STATES NUCLEAR REGULATORY COMMISSION
AND
THE COMMONWEALTH OF MASSACHUSETTS
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 (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act), to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to by-product materials as defined in Sections 11e.(1) and (2) 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 Massachusetts is authorized under Massachusetts General Laws, Chapter 111H, to enter into this Agreement with the Commission; and,

WHEREAS, The Governor of the Commonwealth of Massachusetts certified on [June 1, 1995,] >March 28, 1996,< that the Commonwealth of Massachusetts (hereinafter referred to as the Commonwealth) has a program for the control of radiation hazards adequate to protect [the] 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 [November 1, 1995,] >(date to be determined)< 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[s] 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 reciprocal recognition of licenses and exemptions from licensing of those materials subject to this Agreement; and,

WHEREAS, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

NOW, THEREFORE, It is hereby agreed between the Commission and the Governor of the Commonwealth, acting in 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:

- A. By-product materials as defined in Section 11e.(1) of the Act;
- B. Source materials;
- C. Special nuclear materials in quantities not sufficient to form a critical mass; and,
- D. Licensing of Low-Level Radioactive Waste Facilities.

ARTICLE II

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

- A. The construction and operation of any production or utilization facility;
- B. The export from or import into the United States of by-product, source,

or special nuclear material, or of any production or utilization facility;

- C. The disposal into the ocean or sea of by-product, source, or special nuclear waste materials as defined in regulations or orders of the Commission;
- D. The disposal of such other by-product, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission; and,
- E. The extraction or concentration of source material from source material ore and the management and disposal of the resulting by-product material.

ARTICLE III

This Agreement may be amended, upon application by the Commonwealth and approval by the Commission, to include the additional area(s) specified in Article II, paragraph E, whereby the Commonwealth can exert regulatory control over the materials stated therein.

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, by-product, 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 use its best efforts to 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 Commonwealth and Commission programs for protection against hazards of radiation will be coordinated and compatible. The Commonwealth will use its best efforts 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 like materials. The Commonwealth and the Commission will use their best efforts to

keep each other informed of proposed changes in their respective rules and regulations and licensing, inspection and enforcement policies and criteria, and to obtain the comments and assistance of the other party thereon.

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 State agree to use their best efforts 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 judgement 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 this Agreement and actions taken by the Commonwealth under this Agreement to ensure compliance with Section 274 of the Act.

ARTICLE IX

This Agreement shall become effective on [April 24, 1996,] >(date to be determined)< and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at [Boston, Massachusetts] >(location to be determined)<, in triplicate, this [24]th Day of [April, 1996] >(date to be determined)<.

FOR THE UNITED STATES NUCLEAR REGULATORY COMMISSION

Shirley Ann Jackson, Chairman

FOR THE COMMONWEALTH OF MASSACHUSETTS

William F. Weld, Governor