February 10, 1997

FOR: The Commissioners

FROM: Hugh L. Thompson, Jr. /s/
Acting Executive Director for Operations

SUBJECT: AGREEMENT BETWEEN THE COMMONWEALTH OF MASSACHUSETTS AND THE COMMISSION PURSUANT TO SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

PURPOSE:

To request Commission approval of the proposed Agreement with Massachusetts.

SUMMARY:

By letter dated March 28, 1996, Governor William F. Weld of Massachusetts requested that the Commission enter into an Agreement under Section 274b of the Atomic Energy Act of 1954, as amended (Act). As required by Section 274e of the Act, the proposed Agreement was published for four consecutive weeks in the *Federal Register* (SECY-96-228). A summary of NRC staff's assessment of the proposed Massachusetts regulatory program for Agreement Materials was also published in the *Federal Register* notices. The comment period for the notices ended on January 23, 1997.

Under the terms of the Agreement, Massachusetts would assume regulatory authority over byproduct material (as defined in Section 11e.(1) only), source material, and special nuclear material in quantities not sufficient to form a critical mass. The authority assumed would include the evaluation and approval of sealed source and device designs manufactured in Massachusetts, and the regulation of the land disposal of low-level radioactive waste received from others, but would not include the regulation of Section 11e.(2) byproduct material, uranium and thorium milling activities. As discussed below, the proposed date for the Agreement to become effective, if possible, is March 21, 1997. The importance of having the Agreement in place relates, in part, to fees and licensee eligibility to receive a 50 percent refund of any NRC Part 171 fees if the Agreement is in place prior to March 31, 1997.

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BACKGROUND:

Section 274b of the Act authorizes the Commission to enter into an agreement with the Governor of a State providing for the discontinuance of the regulatory authority of the Commission with respect to certain materials. The Commission in 1981 adopted the revised policy statement entitled "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 statements published on July 16, 1981 (46 FR 36969), and on July 21, 1983 (48 FR 33376), referred to hereafter as the "policy statement." Subsequently, staff adopted an internal procedure for applying the policy statement in the processing of a new agreement. The criteria elements and approaches in these documents form the basis for the staff's evaluation of the Massachusetts request.

DISCUSSION:

In his letter, Governor Weld requested that the Commission enter into an Agreement with the Commonwealth pursuant to Section 274b of the Act. Governor Weld certified that the Commonwealth has a program for the control of radiation hazards which is adequate to protect public health and safety within the Commonwealth with respect to the materials covered by the proposed Agreement. The Governor further certified that the Commonwealth wishes to assume the regulatory responsibility for those materials.

The Governor requested five specific authorities be discontinued by the Commission. They are (1) the regulation of the acquisition, receipt, possession, use, and transfer of byproduct material as defined in Section 11e.(1) of the Act; (2) the regulation of the acquisition, receipt, possession, use, and transfer of source material; (3) the regulation of the acquisition, receipt, possession, use, and transfer of special nuclear material in quantities not sufficient to form a critical mass; (4) the regulation of the land disposal of source, special nuclear, and byproduct material as defined in Section 11e.(1) in the form of waste (as defined in 10 CFR Part 61) received from others; and (5) the evaluation of the suitability for licensing for use in interstate commerce of sealed sources and devices utilizing source, special nuclear, and byproduct material as defined in Section 11e.(1). The authority to regulate activities producing byproduct material as defined in Section 11e.(2) of the Act, i.e., uranium and thorium milling activities, was not requested.

The importance of having an effective agreement in place before the end of March relates, in part, to fees. Licensees would be eligible for a 50 percent rebate of their NRC Part 171 annual fee if the agreement is in place before March 31, 1997. After March 31, licensees would be subject to a full annual fee under Part 171 and could be subjected to "double" billing (i.e., billing by both NRC and Massachusetts), when Massachusetts issues fee bills for their fiscal year, which begins on July 1, 1997. Massachusetts' staff has requested that NRC attempt to avoid such possible double billing to the extent possible.

NRC and Massachusetts staffs have negotiated March 21, 1997, as the date for the Agreement to become effective, if possible. To help ensure that adequate time is available for an orderly transfer of license files, and assumption of authority by Massachusetts by March 21, 1997, Commission approval

of the Agreement would be necessary on or before February 21, 1997. The text of the final agreement, as amended to reflect the revised effective date, to conform the text to Commission comments on SECY-96-228, and to reflect Governor Weld's stated preference to sign the Agreement by mail rather than in ceremony, is shown in Attachment 1.

As required by Section 274e of the Act, the proposed Agreement was published in the *Federal Register* once a week for four consecutive weeks on December 26, 1996 (61 FR 68066), January 2, 1997 (62 FR 117), January 9, 1997 (62 FR 1343), and January 16, 1997 (62 FR 2395). A summary of the NRC staff assessment of the Commonwealth's proposed program for the regulation of materials and activities covered by the Agreement was included in the notice. Interested persons were invited to submit comments by January 23, 1997.

One comment was received which requested that NRC retain jurisdiction over a site listed on the Site Decommissioning Management Plan until the NRC license for the site is terminated. However, NRC staff believe that under the provisions of Section 274 of the Act, NRC cannot (absent national security considerations) retain jurisdiction over a single licensee in a category of licensees over which regulatory authority is assumed by a State. Therefore, the jurisdiction over the site must be transferred to Massachusetts unless the NRC license is terminated prior to the effective date of the Agreement. NRC staff is expediting efforts to complete the actions necessary to terminate the license. In addition, NRC staff and Massachusetts staff have been working closely to assure that the Massachusetts program is prepared to proceed with timely license termination action if transfer is necessary.

The Commission in SECY-96-228 approved the NRC staff's recommendations in regard to the definition of "pharmacist," and the plan by Massachusetts staff for the imposition of the requirements of 10 CFR Part 71, as amended effective April 1, 1996, as an order to licensees. The full text of the staff assessment, along with SECY-96-228, was made available in the Public Document Room. NRC staff has prepared a final staff assessment which is shown in Attachment 2.

The final assessment differs from the draft attached to SECY-96-228 in three places. In criterion 9(b), the third paragraph, the last sentence (which was intended to note a similar end point reached in another Agreement State) was deleted in response to NRC staff comments noting the different approach used by Massachusetts. In criterion 13, the third paragraph was added to clarify how the authority to evaluate sealed sources and devices will be transferred to Massachusetts, in response to questions raised by Commission staff during their consideration of SECY-96-228. In criterion 20, the previous estimate of the number of licenses to be transferred was refined by the staff of Region I.

Region I staff has identified 430 materials licenses in Massachusetts that will be transferred to the Commonwealth. NRC will retain 25 licenses such as those for federal facilities at Veteran Affairs medical locations. Approximately 72 other NRC licenses authorize activity both in Massachusetts and in other States over which the Commission will maintain regulatory authority after the Agreement is signed. In these cases, the licensee will decide whether to retain or not retain all or part of the NRC license. For this reason, an exact count of the final license distribution is not available and NRC resources will be adjusted accordingly based on the transfer.

NRC staff has worked with the Massachusetts radiation control program staff to assure a smooth transition. In addition to the active licenses, Massachusetts sites listed in NRC's Site Decommissioning Management Plan (SDMP) will be transferred. NRC staff has planned, as far as is practical, for regulatory activities concerning these sites to be at a convenient stage for the transfer. NRC staff has and will continue to coordinate with the Massachusetts staff on current or pending licensing, inspection, and enforcement activities involving the licensees to be transferred, to assure the smooth continuation of regulatory actions after the transfer.

IMPLEMENTATION

Following the execution of an Agreement, NRC staff carries out a program of interaction with the new Agreement State. This program consists of the exchange of regulatory information, opportunities for training, and periodic on-site reviews of the State's program for the regulation of agreement materials. Communications are generally more frequent with a new Agreement State during the first year after the Agreement is signed. The regulatory information exchanged includes reports of incidents, accidents, and misadministrations, reports of enforcement actions, amendments to regulatory policies and regulations. The opportunities for training include a variety of courses related to licensing, inspection, and specific topical areas. It should be noted that under current policy some technical assistance and training will be provided on a cost reimbursement basis.

An orientation meeting will be conducted at three months to discuss initial program implementation. The first Massachusetts program review will be conducted about six months after the effective date of the Agreement. Periodic program reviews will usually occur at 12 to 48 month intervals under the Integrated Materials Performance Evaluation Program. As with the case of existing Agreement States, good performance will result in longer intervals between program reviews.

If approved by the Commission, Massachusetts will bring the number of Agreement States to 30.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel, which has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objection. Staff has obtained concurrence from OMB that this action does not constitute a "major rule" under the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA).

RECOMMENDATION:

That the Commission:

1. Find:

a. That the proposed Massachusetts program for the regulation of byproduct material as defined in Section 11e.(1) of the Act, source material, and special nuclear material in quantities not sufficient to form a critical mass is compatible with the Commission's program for the regulation of like material; and

b. That the proposed Massachusetts program is adequate to protect the public health and safety within the Commonwealth with respect to the materials and uses covered by the proposed Agreement.

2. Approve:

a. The proposed Agreement between the Commonwealth of Massachusetts and the Nuclear Regulatory Commission pursuant to Section 274 of the Act, as set forth in Attachment 1.

b. The proposed Agreement by February 21, 1997, if practicable, to afford adequate time for the signing of the Agreement, the orderly transfer of license files, and the assumption of regulatory authority by Massachusetts on March 21, 1997.

3. Note:

a. Governor Weld will be informed by letter after the Commission's decision (Attachment 3). The Governor desires to exchange the Agreement by mail for signature.

b. Pursuant to the AEA, SBREFA, and previous Commission guidance (SECY-96-228), the NRC Congressional Oversight Committees, the Speaker of the House of Representatives, the President of the Senate, the Massachusetts Congressional delegation, and the director of the General Accounting Office will be informed by letter of the Commission's decision (Attachment 4).

c. The Office of Public Affairs will issue a press release (Attachment 5).

d. The text of the Agreement will be published in the *Federal Register*, as required by section 274e, within 30 days after the Agreement is signed (Attachment 6).

Hugh L. Thompson, Jr.
Acting Executive Director for Operations

Attachments:
1. Proposed Agreement
2. Final NRC Staff Assessment of the Massachusetts Program
3. Draft Letter to Governor Weld
4. Draft Congressional Letters
5. Draft Press Release
6. Draft *Federal Register* Notice of Agreement Signing

cc: SECY
OGC
OCA
OPA

ATTACHMENT 1

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 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 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 February __, 1997, 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 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 March 21, 1997, and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at Rockville, Maryland, in triplicate, this ____ Day of _____, 1997 .

FOR THE UNITED STATES NUCLEAR REGULATORY COMMISSION

_____
Shirley Ann Jackson, Chairman

Done at Boston, Massachusetts, in triplicate, this ____ Day of _____, 1997 .

FOR THE COMMONWEALTH OF MASSACHUSETTS

_____
William F. Weld, Governor

ATTACHMENT 2

FINAL NRC STAFF ASSESSMENT
OF THE MASSACHUSETTS PROGRAM

ASSESSMENT
of the proposed
MASSACHUSETTS PROGRAM FOR THE REGULATION OF AGREEMENT MATERIALS
as described in the Commonwealth's
Request for an Agreement

This assessment, prepared by NRC staff, examines the proposed radiation control program of the Commonwealth of Massachusetts with respect to the ability of the program to regulate the possession, use, and disposal of radioactive materials subject to the Atomic Energy Act of 1954, as amended. The assessment was performed against the criteria set forth 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" (referred to below as the "criteria")[(1)] using an internal procedure developed by the Office of State Programs. Each criterion, and the NRC staff's assessment related thereto, is addressed separately below.

OBJECTIVES

1. Protection. **A State regulatory program shall be designed to protect the health and safety of the people against radiation hazards**.

The NRC staff determined that the proposed radiation control program will have an organizational subdivision identified as the "Low-Level Waste and Agreement State" unit (referred to below as the "agreement materials unit") that will have the responsibility for regulating radioactive materials licensees and an anticipated future low-level radioactive waste disposal facility. The unit will regulate both users of radioactive materials covered by the Atomic Energy Act (known as agreement materials), and users of naturally occurring or accelerator produced radioactive materials. Other organizational subdivisions of the program will have responsibilities for regulating machine produced radiation (x-ray), licensing medical radiography technologists, etc. NRC staff determined that this is a typical pattern for regulating radiation hazards that is used successfully in other Agreement States.

NRC staff concludes that the proposed Massachusetts radiation control program is appropriately designed to provide protection of the health and safety of the public against radiation hazards from the materials and uses over which the Commonwealth proposes to assume regulatory responsibility.

References: Program Narrative Description and Organizational Charts (Enclosure 3 and Attachment 1 to Enclosure 3 of the Request for an Agreement by Governor Weld.)

RADIATION PROTECTION STANDARDS

2. Standards. **The State regulatory program shall adopt a set of standards for protection against radiation which shall apply to byproduct, source and special nuclear materials in quantities not sufficient to form a critical mass**.

The review of the request found that the authority to promulgate regulations for the control of exposure to sources of radiation is contained in statute (Massachusetts General Law Chapter 111, Section 5N). In accordance with that authority, the Massachusetts Department of Public Health has adopted regulations [in Chapter 105 of the Code of Massachusetts Regulations, Section 120.001, et seq. (105 CMR 120.000, cited herein as the Massachusetts Regulations for the Control of Radiation or MRCR)] which are currently in effect. These regulations include radiation protection standards essentially identical(2) to those in 10 CFR Part 20 which will apply to agreement materials, and standards equivalent to those in 10 CFR Part 61 which will apply to the land disposal of agreement material received as waste from other persons.

Reference: Massachusetts General Law Chapter 111, Section 5N; Massachusetts Regulations for the Control of Radiation at 105 CMR 120.001 - 120.019, 105 CMR 120.120 - 120.197, 105 CMR 120.200 -120.271, 105 CMR 120.300 - 120.398, 105 CMR 120.500 - 120.576, 105 CMR 120.750 - 120.760, 105 CMR 120.770 - 120.795, 105 CMR 120.800 - 120.897, 105 CMR 120.900 - 120.961.

3. Uniformity in Radiation Standards. **It is important to strive for uniformity in technical definitions and terminology, particularly as related to such things as units of measurement and radiation dose. There shall be uniformity on maximum permissible doses and levels of radiation and concentrations of radioactivity, as fixed by 10 CFR Part 20 of the NRC regulations based on officially approved radiation protection guides**.

The NRC staff found that the technical definitions and terminology adopted in the MRCR are essentially identical to the equivalent terms in the NRC regulations. Those terms that are related to units of measurement and radiation doses are essentially identical to the terms contained in 10 CFR Part 20. The MRCR contain all of the provisions on maximum permissible doses, levels of radiation, and concentrations of radioactivity that NRC staff believes necessary in order to be compatible with the regulations of the NRC on the effective date of the Agreement between the Commonwealth and the Commission.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.005, 105 CMR 120.203, 105 CMR 120.302, 105 CMR 120.502, 105 CMR 120.772, 105 CMR 120.803, 105 CMR 120.902.

4. Total Occupational Radiation Exposure. **The regulatory authority shall consider the total occupational radiation exposure of individuals, including that from sources which are not regulated by it**.

The review determined that under the MRCR, as adopted, licensees are required to evaluate the radiation dose received by those individuals who are occupationally exposed to radiation in activities under the licensee's control. In conducting the evaluation, the licensees are required to consider the total radiation doses to the 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 definitions related to occupational exposure are essentially identical to those of the NRC.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.211 - 218, 105 CMR 120.221.

5. Surveys, Monitoring. **Appropriate surveys and personnel monitoring under the close supervision of technically competent people are essential in achieving radiological protection and shall be made in determining compliance with safety regulations**.

The review demonstrated that the MRCR impose requirements on the licensees to conduct surveys to evaluate potential exposures from sources of radiation. Likewise, the MRCR contain requirements for personnel monitoring. All of these requirements are based on, and consistent with, the equivalent requirements contained in NRC regulations.

The MRCR further specify requirements similar to those in NRC regulations for the training and experience of workers. The NRC staff believes that the

MRCR requirements are adequate to assure the technical competency of workers conducting surveys and monitoring.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.225.

6. Labels, Signs, Symbols. **It is desirable to achieve uniformity in labels, signs, and symbols, and the posting thereof. However, it is essential that there be uniformity in labels, signs, and symbols affixed to radioactive products which are transferred from person to person**.

The review disclosed that the radiation labels, signs and symbols, and posting requirements adopted in the MRCR are essentially identical to those contained in 10 CFR Part 20. The Massachusetts requirements for labeling radioactive products and the equivalent NRC requirements also exhibit the required degree of uniformity.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.122G, 105 CMR 120.122I, 105 CMR 120.241 - 120.245.

7. Instruction. **Persons working in or frequenting restricted areas shall be instructed with respect to the health risks associated with exposure to radioactive materials and in precautions to minimize exposure. Workers shall have the right to request regulatory authority inspections as per 10 CFR 19, Section 19.16 and to be represented during inspections as specified in Section 19.14 of 10 CFR 19.**

The NRC staff found that the MRCR contain all of the requirements for instructions, notices to workers, notifications to and reports to individuals, that are required in order for the rules to be consistent with those in 10 CFR Part 19. The MRCR specifically provide workers with the same rights as the NRC rules to request inspections and to be represented during inspections.

It is noted that the NRC regulations and definitions in 10 CFR Parts 19 and 20 have been amended since the Commission adopted the criteria. In reviewing the Massachusetts request, NRC staff has evaluated the MRCR in comparison to the current NRC rules. In particular, 10 CFR 19.12 was amended effective August 14, 1995 (60 FR 36038; July 13, 1995). Criterion number seven reflects, in part, the pre-amendment rule. In performing the review, NRC staff has considered the amended statement of the rule, which requires instruction to be provided to all individuals who, in the course of their employment, are likely to receive an occupational dose in excess of 100 millirem in one year, whether the dose is received in a restricted area or not. The equivalent MRCR rule is found to be compatible with the current NRC rule.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.750 - 120.760.

8. Storage. **Licensed radioactive material in storage shall be secured against unauthorized removal**.

The NRC staff determined that the section in the MRCR imposing the requirements for the security of stored radioactive material is compatible with the equivalent section of the NRC regulations.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.235.

9. Radioactive Waste Disposal. **(a) Waste disposal by material users. The standards for the disposal of radioactive materials into the air, water and sewer, and burial in the soil shall be in accordance with 10 CFR Part 20. Holders of radioactive material desiring to release or dispose of quantities or concentrations of radioactive materials in excess of prescribed limits shall be required to obtain special permission from the appropriate regulatory authority**.

Requirements for transfer of waste for the purpose of ultimate disposal at a land disposal facility (waste transfer and manifest system) shall be in accordance with 10 CFR 20. The waste disposal standards shall include a waste classification scheme and provisions for waste form, applicable to waste generators, that is equivalent to that contained in 10 CFR Part 61.

The review confirmed that the MRCR contain provisions relating to the disposal of radioactive materials into the air, water and sewer, and by burial in soil which are at least as protective as the equivalent rules in 10 CFR Part 20. The MRCR require licensees to apply for and obtain a specific license condition to dispose of radioactive waste using methods other than as provided in the rules.

Waste transfer and manifest system requirements applicable to transfers of waste intended for ultimate disposal at a land disposal facility were also identified in the review and found to be as protective as the NRC rules. The Massachusetts waste disposal requirements include a waste classification scheme and requirements for waste form that were found to be equivalent to the requirements in 10 CFR Part 61.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.251 - 120.257.

(b) Land Disposal of waste received from other persons. The State shall promulgate regulations containing licensing requirements for land disposal of radioactive waste received from other persons which are compatible with the applicable technical definitions, performance objectives, technical requirements and applicable supporting sections set forth in 10 CFR Part 61. Adequate financial arrangements (under terms established by regulation) shall be required of each waste disposal site licensee to ensure sufficient funds for decontamination, closure and stabilization of a disposal site. In addition, Agreement State financial arrangements for long-term monitoring and maintenance of a specific site must be reviewed and approved by the Commission prior to relieving the site operator of licensed responsibility (Section 151(a)(2), Pub. L. 97-425).

Massachusetts has requested the authority to regulate the disposal of low-level radioactive waste received from other persons at a land disposal site. In support of this requested authority, Massachusetts has promulgated regulations that are equivalent to those in 10 CFR Part 61. The NRC staff review of

these regulations determined that they contain all of the specified requirements of compatibility with two caveats.

First, it is noted that Massachusetts prohibits, by statute, shallow land burial as a disposal method. Secondly, an agency of the Commonwealth, the Low-Level Radioactive Waste Management Board (Board), is designated by statute to be the owner of the site. The Board will select an operator for the site who will be the site licensee during operations. At the end of the site operation, the operator will transfer the license to the Board to start the institutional control period. Thus the Board will act as the custodial agency as defined in 10 CFR Part 61. The Board will, by statute, remain the site owner and licensee indefinitely.

Several definitions and rules related to waste disposal in the MRCR are different from the equivalent NRC definitions and rules in reflection of the statutory requirements noted above. For example, there is no provision for termination of the waste site license once issued.

NRC staff also considered two other issues concerning the handling and disposal of radioactive materials received as waste from other persons. As provided in 105 CMR 120.801(B), Massachusetts will apply the radiation protection standard in 105 CMR 120.811 (the equivalent to 10 CFR 61.41) to waste storage facilities and waste processing facilities that receive radioactive materials as waste from other persons. Under NRC regulations, such facilities would not be subject to 10 CFR 61.41, rather only to the radiation protection standard in 10 CFR 20.1301 (Massachusetts has an equivalent standard in 105 CMR 120.221). NRC staff requested an interpretation of the provisions by Massachusetts legal staff, which was provided by the Deputy General Counsel for the Massachusetts Department of Public Health. Under the interpretation, the requirements of 105 CMR 120.811 will be enforced as a radiation protection standard for waste disposal facilities, and as a performance objective for waste treatment and waste storage facilities.

The other issue considered by NRC staff is the Massachusetts requirement in statute (Massachusetts General Law Chapter 111H, Section 38(b)), and in regulation (105 CMR 120.801(G)) which effectively prohibits a radioactive waste disposal site in Massachusetts from accepting waste from "an electric-power-generating facility" if the waste requires "more stringent management" than waste received from other licensees. It was of concern that this provision could cause a gap in the regulation of radioactive waste by creating an "orphan" waste stream, since waste management under NRC rules is related only to the classification of the waste pursuant to 10 CFR 61.55, regardless of the source of the waste. NRC staff requested an interpretation of the Massachusetts provisions by Massachusetts legal staff, which was provided by the General Counsel for the Massachusetts Low-Level Radioactive Waste Management Board. Under the interpretation, waste from any source will be accepted provided it is properly classified according to the specifications of 105 CMR 120.299(A) (equivalent to 10 CFR 61.55), is properly packaged and labeled, and arrives undamaged and not leaking with a properly executed shipping manifest.

NRC staff believes that on whole the provisions of Massachusetts law and regulations related to the management of low-level radioactive waste provide at least the same protection as is provided by the NRC requirements, and that the Massachusetts program for the management of low-level radioactive waste is compatible with the program of the Commission.

References: Massachusetts General Law Chapter 111H, Section 38(b); Massachusetts Regulations for the Control of Radiation at 105 CMR 120.800 - 120.897; Letter with attachments from Massachusetts Department of Public Health Commissioner Mulligan dated August 14, 1996.

10. Regulations Governing Shipment of Radioactive Materials. **The State shall, to the extent of its jurisdiction, promulgate regulations applicable to the shipment of radioactive materials, such regulations to be compatible with those established by the U.S. Department of Transportation and other agencies of the United States whose jurisdiction over interstate shipment of such materials necessarily continues. State regulations regarding transportation of radioactive materials must be compatible with 10 CFR Part 71.**

The NRC staff's review of the MRCR determined that the sections applicable to the preparation of radioactive materials for shipment are similar to the NRC regulations in 10 CFR Part 71 that were effective prior to April 1, 1996. On that date, amended regulations in Part 71 became effective. Since negotiations pursuant to Section 274b of the Act were already in progress, Massachusetts chose to continue with the request for an Agreement while developing amended State regulations in parallel. NRC staff does not expect the amended Massachusetts rules to become effective before the Agreement is signed.

The Massachusetts radiation control program has committed to enforcing the provisions of the amended Part 71 rules by issuing appropriate regulatory orders to the affected licensees, and to continue the process of adopting amendments to the Massachusetts rules. The orders are intended to spare NRC licensees transferred to Massachusetts from the "whipsaw" effect of being regulated first under the amended NRC regulations, then the old regulations when the Agreement takes effect, then again under the amended regulations when later adopted by Massachusetts. Previously, NRC has required a State proposing to enter into an agreement to have regulations equivalent to current NRC regulations in effect at the time the agreement is signed. However, the Commission's legal counsel has indicated that Agreement States have the flexibility to use alternate legally binding methods of imposing NRC regulatory requirements on their licensees. On this basis, NRC staff find that the Massachusetts plan is acceptable.

Since the amended NRC regulations are coordinated with the regulations of the U. S. Department of Transportation (DOT), the amended Massachusetts regulations will also be compatible with the DOT regulations. The NRC staff concludes, therefore, that the Massachusetts radiation control program will satisfy the elements of this criterion.

References: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.770 - 120.795; Letter with attachments from Massachusetts Department of Public Health Commissioner Mulligan dated August 14, 1996

11. Records and Reports. **The State regulatory program shall require that holders and users of radioactive materials (a) maintain records covering personnel radiation exposures, radiation surveys, and disposals of materials; (b) keep records of the receipt and transfer of the materials; (c) report significant incidents involving the materials, as prescribed by the regulatory authority; (d) make available upon request of a former employee a report of the employee's exposure to radiation; (e) at request of an employee advise the employee of his**

or her annual radiation exposure; and (f) inform each employee in writing when the employee has received radiation exposure in excess of the prescribed limits.

The review confirmed that the MRCR require licensees to maintain the specified records and to make reports similar to those specified in NRC regulations. The requirements are generally consistent with the equivalent NRC requirements. 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.

The MRCR contains sections similar to the rules in 10 CFR Part 19 that include the reporting requirements of Part 19, as reflected in criterion 11.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.261 - 120.284.

12. Additional Requirements and Exemptions. **Consistent with the overall criteria here enumerated and to accommodate special cases and circumstances, the State regulatory authority shall be authorized in individual cases to impose additional requirements to protect health and safety, or to grant necessary exemptions which will not jeopardize health and safety**.

The NRC staff determined that the Massachusetts radiation control program has the authority by Statute to impose additional requirements to the effective requirements specified in the regulations. The MRCR rule implementing the statute is similar in its provisions and conditions to the equivalent NRC rule.

The radiation control program also retains by regulation the authority to grant specific exemptions from the requirements of the regulations; this provision is essentially identical to the equivalent NRC rule.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.130, 105 CMR 120.005.

PRIOR EVALUATION OF USES OF RADIOACTIVE MATERIALS

13. Prior Evaluation of Hazards and Uses, Exceptions. **In the present state of knowledge, it is necessary in regulating the possession and use of byproduct, source and special nuclear materials that the State regulatory authority require the submission of information on, and evaluation of, the potential hazards, and the capability of the user or possessor prior to his receipt of the materials. This criterion is subject to certain exceptions and to continuing reappraisal as knowledge and experience in the atomic energy field increase. Frequently there are, and increasingly in the future there may be, categories of materials and uses as to which there is sufficient knowledge to permit possession and use without prior evaluation of the hazards and the capability of the possessor and user. These categories fall into two groups -- those materials and uses which may be completely exempt from regulatory controls, and those materials and uses in which sanctions for misuse are maintained without pre-evaluation of the individual possession or use. In authorizing research and development or other activities involving multiple uses of radioactive materials, where an institution has people with extensive training and experience, the State regulatory authority may wish to provide a means for authorizing broad use of materials without evaluating each specific use**.

The review concluded that the MRCR contain regulations similar to the current NRC regulations specifying the required content of applications for licenses, renewals, and amendments. The MRCR also contain requirements similar to the NRC requirements for issuing licenses and specifying the terms and conditions of licenses. In some cases, the Massachusetts requirements may be more stringent than the equivalent NRC requirements to reflect concerns unique to the Commonwealth. The agreement materials unit has adopted procedures for processing applications that assure the regulatory requirements will be met or exceptions granted as provided for by regulation.

The MRCR also provide for general licenses compatible with those provided by the NRC regulations. The MRCR allow the possession and use of agreement materials exempt from license under the same conditions as allowed by NRC. The MRCR note that a license authorizing the distribution of agreement materials that will subsequently be exempt from regulatory control may be issued only by the NRC. The agreement materials unit will regulate several licensees to whom NRC has issued licenses of broad scope. Staff has determined that the MRCR contains provisions equivalent to the rules in 10 CFR Part 33 for the regulation of broad scope licenses.

Since criterion nine was adopted, the Commission in SECY-95-136 determined that the regulatory authority to conduct safety evaluations of sealed sources and devices should be retained by the NRC, unless the State requests assumption of the authority and the State has in place an adequate and compatible program to implement the authority. Massachusetts has requested the authority to conduct safety evaluations of sealed sources and devices. NRC staff have evaluated the regulations and procedures related to that program element, and determined that they are adequate and compatible. In the proposed Agreement, the authority to conduct safety evaluations of sealed sources and devices is transferred as part of the overall authority to issue licenses.

The NRC staff finds that the Massachusetts regulations and procedures for licensing are adequate, and compatible with those of the NRC.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.133 - 120.135.

14. Evaluation Criteria. **In evaluating a proposal to use radioactive materials, the regulatory authority shall determine the adequacy of the applicant's facilities and safety equipment, his training and experience in the use of the materials for the purpose requested, and his proposed administrative controls. States should develop guidance documents for use by license applicants. This guidance should be**

consistent with NRC licensing and regulatory guides for various categories of licensed activities.

The NRC staff found that the Massachusetts agreement materials unit licensing procedures manual contains instructions to the unit staff addressing the specific elements listed in the criterion. The licensing procedures manual and the accompanying Massachusetts regulatory guides are similar to NRC licensing procedures and regulatory guides.

References: Massachusetts Radioactive Materials Licensing Procedures Manual, Attachment 6 to Enclosure 3 of the Request for an Agreement by Governor Weld; Letter with attachments from Massachusetts Department of Public Health Commissioner Mulligan dated August 14, 1996.

15. Human Use. **The use of radioactive materials and radiation on or in humans shall not be permitted except by properly qualified persons (normally licensed physicians) possessing prescribed minimum experience in the use of radioisotopes or radiation**.

The staff determined that Massachusetts has adopted regulations similar to those found in 10 CFR Part 35. The training and experience requirements for persons to be licensed for the use of agreement materials on or in humans is specified in these regulations.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.566 - 120.572.

INSPECTION

16. Purpose, Frequency. **The possession and use of radioactive materials shall be subject to inspection by the regulatory authority and shall be subject to the performance of tests, as required by the regulatory authority. Inspection and testing is conducted to determine and to assist in obtaining compliance with regulatory requirements. Frequency of inspection shall be related directly to the amount and kind of material and type of operation licensed, and it shall be adequate to insure compliance**.

The review found that the Massachusetts radiation control program has the necessary statutory authority to conduct inspections of licensees. The MRCR contain provisions relating to inspections and tests that are equivalent to the NRC requirements found in 10 CFR Part 30. The program has also adopted a policy providing for the inspection of licensees at least as frequently as the schedule used by NRC.

References: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.007 - 120.008; and Radioactive Materials Inspections Procedures Manual, Attachment 7 to Enclosure 3 of the Request for an Agreement by Governor Weld.

17. Inspections Compulsory. **Licensees shall be under obligation by law to provide access to inspectors**.

The review confirmed that authority for Massachusetts radiation control program inspectors to enter public or private property at all reasonable times exists in the Massachusetts statute.

Reference: Massachusetts General Law Chapter 111, Section 5N.

18. Notification of Results of Inspection. **Licensees are entitled to be advised of the results of inspections and to notice as to whether or not they are in compliance**.

The review found that Massachusetts has adopted policies, procedures, and form letters to convey the results of inspections to the licensees, both when violations are found, and when no violations are found.

Reference: Radioactive Materials Inspection Manual, Attachment 7 to Enclosure 3 of the Request for an Agreement by Governor Weld.

ENFORCEMENT

19. Enforcement. **Possession and use of radioactive materials should be amenable to enforcement through legal sanctions, and the regulatory authority shall be equipped or assisted by law with the necessary powers for prompt enforcement. This may include, as appropriate, administrative remedies looking toward issuance of orders requiring affirmative action or suspension or revocation of the right to possess and use materials, and the impounding of materials; the obtaining of injunctive relief; and the imposing of civil or criminal penalties**.

The review found that the radiation control program is authorized by statute to enforce the regulations using a variety of sanctions, including the imposition of civil penalties and the issuing of orders to suspend, modify or revoke licenses. Although the impounding of materials is not directly provided, Massachusetts General Law Chapter 111, Section 5O allows the program to seek restraining orders, which may bar the use of materials or the access to premises. The program has adopted procedures to implement this authority.

References: Massachusetts General Law Chapter 111, Section 5O; Massachusetts Regulations for the Control of Radiation at 105 CMR 120.016 - 120.019.

PERSONNEL

20. Qualifications of Regulatory and Inspection Personnel. **The regulatory agency shall be staffed with sufficient trained personnel. Prior evaluation of applications for licenses or authorizations and inspection of licensees must be conducted by persons possessing the training and experience relevant to the type and level of radioactivity in the proposed use to be evaluated and inspected. This requires competency to evaluate various potential radiological hazards associated with the many uses of radioactive material and includes concentrations of radioactive materials in air and water, conditions of shielding, the making of radiation measurements, knowledge of**

radiation instruments--their selection, use and calibration--laboratory design, contamination control, other general principles and practices of radiation protection, and use of management controls in assuring adherence to safety procedures. In order to evaluate some complex cases, the State regulatory staff may need to be supplemented by consultants or other State agencies with expertise in geology, hydrology, water quality, radiobiology and engineering disciplines.

To perform the functions involved in evaluation and inspection, it is desirable that there be personnel educated and trained in the physical and/or life sciences, including biology, chemistry, physics and engineering, and that the personnel have had training and experience in radiation protection. For example, the person who will be responsible for the actual performance of evaluation and inspection of all of the various uses of byproduct, source and special nuclear material which might come to the regulatory body should have substantial training and extensive experience in the field of radiation protection. It is desirable that such a person have a bachelor's degree or equivalent in the physical or life sciences, and specific training - radiation protection.

It is recognized that there will also be persons in the program performing a more limited function in evaluation and inspection. These persons will perform the day-to-day work of the regulatory program and deal with both routine situations as well as some which will be out of the ordinary. These people should have a bachelor's degree or equivalent in the physical or life sciences, training in health physics, and approximately two years of actual work experience in the field of radiation protection.

The foregoing are considered desirable qualifications for the staff who will be responsible for the actual performance of evaluation and inspection. In addition, there will probably be trainees associated with the regulatory program who will have an academic background in the physical or life sciences as well as varying amounts of specific training in radiation protection but little or no actual work experience in this field. The background and specific training of these persons will indicate to some extent their potential role in the regulatory program. These trainees, of course, could be used initially to evaluate and inspect those applications of radioactive materials which are considered routine or more standardized from the radiation safety standpoint, for example, inspection of industrial gauges, small research programs, and diagnostic medical programs. As they gain experience and competence in the field, the trainees could be used progressively to deal with the more complex or difficult types of radioactive material applications. It is desirable that such trainees have a bachelor's degree or equivalent in the physical or life sciences and specific training in radiation protection. In determining the requirement for academic training of individuals in all of the foregoing categories, proper consideration should be given to equivalent competency which has been gained by appropriate technical and radiation protection experience.

It is recognized that radioactive materials and their uses are so varied that the evaluation and inspection functions will require skills and experience in the different disciplines which will not always reside in one person. The regulatory authority should have the composite of such skills either in its employ or at its command, not only for routine functions, but also for emergency cases.

The NRC staff reviewed the organizational charts and position descriptions for the Massachusetts program staff, and the curricula vitae for the current program staff members.

1. Assessment of the Agreement Materials Unit Staffing

There are approximately 460 NRC licenses in Massachusetts, of which about 430 would be transferred to the program under the proposed Agreement. These would be added to the approximately 180 NARM licenses that the program currently regulates, for a total of approximately 600 licenses. Based on the experience of other States, NRC staff expects many of the NARM licensees to also hold NRC licenses, and that over a period of time facilities holding both NARM and agreement materials licenses will seek to combine them. This experience suggests a final number of 450 to 500 licenses.

The organizational chart shows 31 professional staff positions, of which 13 would be assigned to the agreement materials program unit. Currently, there are 7 individuals assigned to the unit full-time, and 5 assigned part time, with 1 vacancy. One of the part-time staff members is the program director, who will also act as the unit manager. The combined effort of the 5 part-time individuals sums to 2 full-time-equivalents (FTE). The NRC staff sums the total technical/professional effort of the 12 individuals to equal 9 FTEs.

Although there is no current quantitative guideline in this area, NRC has, in the past, used a guideline indicator of 1.0 to 1.5 FTE per 100 licenses in reviewing existing Agreement State programs. Using the estimates of 9 technical/professional FTEs in the agreement materials unit, and 600 licenses initially, there would be approximately 1.5 technical/professional FTE per 100 licenses. While this number is at the high end of the range, NRC staff notes that the Commonwealth will assume regulatory responsibility for several licensees with unusually complex operations, including large medical, university, and industrial manufacturing programs. NRC staff believes, therefore, that an initial staffing level at or above the high end of the range is appropriate.

NRC staff further notes that several of the agreement materials unit positions will, in the future, be dedicated to the licensing and regulation of an anticipated low-level radioactive waste disposal site. The program does not, however, expect to receive an application for a waste disposal site in the near future. The anticipated combination of NARM and agreement materials licenses by facilities that currently hold both types will reduce the total number of licenses as described above and increase the staff-to-materials-license ratio. This will have the effect of allowing staff members to be reassigned to waste site issues. Further, when an application is received, the program plans to supplement staff with contractors. For current activities related to waste management, the Massachusetts program director has stated that less than one professional FTE is required.

Based on the above, the NRC staff concludes that the Massachusetts program staffing plan provides an adequate number of personnel to meet the anticipated program needs.

2. Assessment of Staff Education, Training and Experience

The 12 individual members of the agreement materials unit's professional/technical staff are trained in physics or health physics (5), life sciences including radiologic technology, biophysics, and public health (6), and physical sciences (geophysics - 1).

Of the seven full-time agreement materials unit staff members, one has 15 years experience in the Massachusetts program. The other six full-time staff members have 4 years or less experience in the Massachusetts program, although one individual has 3 years experience working in another radiation control program. Each of the six, however, has 5 years or more working experience in the fields of health physics, reactor health physics, or medical physics. The duties of these positions typically included the application of radiation protection principles and the occasional development of license amendments or renewals.

All of the agreement materials unit part-time staff members have more than 5 years experience in the Massachusetts radiation control program.

The review also disclosed that all 12 full- or part-time agreement materials unit staff members hold bachelor's degrees or have the equivalent in training and experience. One individual holds an Associate degree in Science and has more than 5 years experience in radiation protection. All others hold bachelor (1), master (9), or doctorate (1) degrees.

Agreement materials unit staff members have also completed specialty training courses, provided by NRC, for NRC and Agreement State regulatory personnel. Various unit staff members have completed training courses related to materials facilities licensing procedures, materials facilities inspection procedures, safety requirements for industrial radiography, safety requirements for medical uses of radioactive materials, sealed source and device safety evaluation, safety requirements for transportation of radioactive material, safety requirements for well-logging, and safety requirements for medical teletherapy. The NRC staff concludes that the unit staff, as a whole, has completed adequate speciality training to meet the program needs.

The unit has adopted a written program for the training and qualification of staff members, which covers both new staff members and the continuing qualification of existing staff. Criterion 20 contains no specific elements to address such programs. However, NRC staff notes that the Massachusetts radiation control program will be evaluated under the Commission's Integrated Materials Performance Evaluation Program (IMPEP). One IMPEP criterion addresses staff training and qualifications, and an element of the IMPEP criterion addresses training and qualification plans. NRC staff believes that the Massachusetts training and qualification plan meets the IMPEP criteria.

Based on the above, the NRC staff review concluded that the Massachusetts staff has substantial training and experience in radiation protection, that the staff training and experience is adequate, and that the unit has an adequate program for staff training and qualification.

References: Organization Charts, (Attachment 1 to Enclosure 3), and Resumes/Lists of Nuclear Regulatory Training Courses Attended, (Attachment 2 to Enclosure 3), Attachments to the Program Description Statement (Enclosure 3 to the Request for an Agreement by Governor Weld).

21. Conditions Applicable to Special Nuclear Material, Source Material and Tritium. **Nothing in the State's regulatory program shall interfere with the duties imposed on the holder of the materials by the NRC, for example, the duty to report to the NRC, on NRC prescribed forms (1) transfers of special nuclear material, source material and tritium and (2) periodic inventory data**.

The review found that the Massachusetts regulations do contain a provision to avoid interference with the duties imposed on State licensees by the NRC.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.002.

22. Special Nuclear Material Defined. **Special nuclear material, in quantities not sufficient to form a critical mass, for present purposes means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination should not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:**

175 (grams contained U-235)/350 + 50 (grams U-233)/200 + 50 (grams Pu)/200 = 1
(This definition is subject to change by future Commission rule or regulation.)

The review of Massachusetts regulations equivalent to 10 CFR Part 150 revealed that the definition of the term "special nuclear material in quantities not sufficient to form a critical mass" therein is essentially identical to the above definition.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.005, Definition of Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

ADMINISTRATION

23. Fair and Impartial Administration. **State practices for assuring the fair and impartial administration of regulatory law, including provision for public participation where appropriate, should be incorporated in procedures for:**

- **a. Formulation of rules of general applicability;**
- **b. Approving or denying applications for licenses or authorization to possess and use radioactive materials, and**
- **c. Taking disciplinary actions against licensees**.

The Massachusetts radiation control program is bound by statutory provisions with respect to providing the opportunity for public participation in rulemaking, licensing actions, and disciplinary actions. The program has adopted regulations to implement the enforcement authority granted by law. The legislation also provides for the administrative and judicial review of actions taken by the program.

NRC staff has reviewed the pertinent statutes and regulations and determined that the criterion is met.

Reference: Massachusetts General Law Chapter 111, Section 5O.

24. State Agency Designation. **The State should indicate which agency or agencies will have authority for carrying on the program and should provide the NRC with a summary of that legal authority. There should be assurances against duplicate regulation and licensing by State and local authorities, and it may be desirable that there be a single or central regulatory authority**.

The Massachusetts Department of Public Health is designated to be the State's radiation control agency in the Massachusetts Low-Level Radioactive Waste Management Act. The law also provides that the regulations adopted by the Department shall apply exclusively throughout the Commonwealth.

The Massachusetts Department of Labor and Industries has, by statute, the general responsibility and authority to inspect workplace safety, and to adopt regulations to prevent workplace accidents and industrial or occupational diseases. 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 this responsibility and authority with respect to radiation and radioactive materials.

The Department of Environmental Protection is designated under the Low-Level Radioactive Waste Management Act as the agency to adopt regulatory standards for the suitability of any proposed disposal site. The Department of Public Health will license and regulate the site only after the Executive Secretary for Environmental Affairs has determined that a site characterization study shows the site to be suitable and the Low-Level Radioactive Waste Management Board has selected the operator.

References: Massachusetts General Law Chapter 111, Section 5N, and Chapter 111H, Sections 2, and 14 through 31.

25. Existing NRC Licenses and Pending Applications. **In effecting the discontinuance of jurisdiction, appropriate arrangements will be made by NRC and the State to ensure that there will be no interference with or interruption of licensed activities or the processing of license applications by reason of the transfer. For example, one approach might be that the State, in assuming jurisdiction, could recognize and continue in effect, for an appropriate period of time under State law, existing NRC licenses, including licenses for which timely applications for renewal have been filed, except where good cause warrants the earlier reexamination or termination of the license.**

The review of the Massachusetts regulations verified that a provision has been included which deems the holder of an NRC license on the date of transfer to possess a like license issued under the Massachusetts regulations and law. The regulations further provide that these licenses will expire either 90 days after receipt from the Massachusetts 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 Massachusetts regulations also provide for "timely renewal," 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.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 120.133, 120.136.

26. Relations With Federal Government and Other States. **There should be an interchange of Federal and State information and assistance in connection with the issuance of regulations and licenses or authorizations, inspection of licensees, reporting of incidents and violations, and training and education problems**.

The NRC staff found that 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.

Reference: Proposed Agreement between the Commonwealth of Massachusetts and the Nuclear Regulatory Commission, Article VI.

27. Coverage, Amendments, Reciprocity. **An Agreement providing for discontinuance of NRC regulatory authority and the assumption of regulatory authority by the State may relate to any one or more of the following categories of materials within the State, as contemplated by Public Law 86-373 and Public Law 95-604:**

- **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,**
- **d. Special nuclear materials in quantities not sufficient to form a critical mass,**
- **e. Low-level wastes in permanent disposal facilities, as defined by statute or Commission rules or regulations containing one or more of the materials stated in a, c, and d above but not including byproduct material as defined in Section 11e(2) of the Act; but must relate to the whole of such category or categories and not to a part of any category. If less than the five categories are included in any discontinuance of jurisdiction, discontinuance of NRC regulatory authority**

and the assumption of regulatory authority by the State of the others may be accomplished subsequently by an amendment or by a later agreement.

Arrangements should be made for the reciprocal recognition of State licenses and NRC licenses in connection with out-of-jurisdiction operations by a State or NRC licensee.

The review of the proposed Agreement disclosed that it provides for the Commission to discontinue, and the Commonwealth to assume, regulatory authority for categories a, c, d, and e. The proposed Agreement does not provide for the discontinuance of Commission regulatory authority for category b, however, it does contain a provision allowing the Agreement to be amended to include this category.

The NRC staff notes that since the criterion was adopted, the Commission has determined in the Staff Requirements Memorandum SECY-95-136, dated June 30, 1995, that Agreement States may assume the authority to evaluate the safety of sealed sources and devices as a separate portion of the Agreement, or allow NRC to retain that authority. Massachusetts has chosen to assume this authority.

Reference: Proposed Agreement between the Commonwealth of Massachusetts and the Nuclear Regulatory Commission, Articles I, II, and III.

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.

Reference: Proposed Agreement between the Commonwealth of Massachusetts and the Nuclear Regulatory Commission, Article VII.

28. NRC and Department of Energy Contractors. **The State should provide exemptions for NRC and DOE contractors which are substantially equivalent to the following exemptions:**

a. Prime contractors performing work for the DOE at U.S. Government-owned or controlled sites;

b. Prime contractors performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

c. Prime contractors using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and

d. Any other prime contractor or subcontractor of DOE or NRC when the State and the NRC jointly determine (i) that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and (ii) that the exemption of such contractor or subcontractor is authorized by law.

The NRC staff review of the Massachusetts regulations determined that the regulations do provide exemptions from the State's requirements for licensing of sources of radiation for NRC and DOE contractors or subcontractors in accordance with this criterion.

Reference: Massachusetts Regulations for the Control of Radiation at 105 CMR 1006(B).

STAFF CONCLUSION

Section 274d of the Atomic Energy Act of 1954, as amended, states: "The Commission shall enter into an agreement under subsection b of this section with any State if:

(1) The Governor of that State certifies that the State has a program for the control of radiation hazards adequate to protect the 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

(2) The Commission finds that the State program is in accordance with the requirements of subsection o. 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 the public health and safety with respect to the materials covered by the proposed amendment."

The staff has concluded that the Commonwealth of Massachusetts meets the requirements of Section 274 of the Act. The statutes, regulations, personnel, licensing, inspection and administrative procedures are compatible with those of the Commission and adequate to protect the public health and safety with respect to the materials covered by the proposed Agreement. Since the Commonwealth of Massachusetts is not seeking authority over uranium milling activities, subsection o. is not applicable to the proposed Massachusetts agreement.

ATTACHMENT 3

DRAFT LETTER TO GOVERNOR WELD

The Honorable William F. Weld
Governor of Massachusetts
Boston, Massachusetts 02133
Dear Governor Weld:

I am pleased to inform you that the U. S. Nuclear Regulatory Commission has approved your proposed Agreement under which the NRC will discontinue and the Commonwealth of Massachusetts will assume regulatory authority over the acquisition, possession, use, transfer, and disposal of by-product material as define in section 11e.(1) of the Atomic Energy Act of 1954, as amended, source material, special nuclear material in quantities not sufficient to form a critical mass, and licensing of low-level radioactive waste facilities.

I am pleased to enclose three (3) copies of the Agreement for your signature. Following your execution of the Agreement, please return two copies to NRC. The third copy is for retention by the Commonwealth.

We are pleased with your continued interest in participating in the Agreement State Program and look forward to the continued excellent relationship we have enjoyed in the past.

Sincerely,

Shirley Ann Jackson

Enclosures: As stated

ATTACHMENT 4

DRAFT LETTERS TO CONGRESSIONAL ENTITIES

{Similar letters to: Senate and House subcommittee chairmen and ranking minority members, and each member of the Massachusetts delegation}
The Honorable _*_
Subcommittee on *
Committee on *
United States Senate
Washington, D. C. 20510

Dear Mr. Chairman:

We are pleased to inform the Subcommittee that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on _____ approved an Agreement with the Commonwealth of Massachusetts under which the Commonwealth will assume certain regulatory authority over byproduct materials as defined in Section 11e.(1) of the Act, source materials and special nuclear materials in quantities not sufficient to form a critical mass. The Commonwealth will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials by persons other than the licensees which generated the waste. The Commonwealth will not assume regulatory authority over byproduct materials as defined by Section 11e.(2) of the Act, for uranium and thorium milling activities.

In his March 28, 1996 proposal requesting that the Commission enter into an Agreement, Governor William F. Weld certified that the Commonwealth has a program for the control of the radiation hazards associated with the materials covered by the proposed Agreement which is adequate to protect public health and safety. Governor Weld further certified that the Commonwealth desires to assume the regulatory responsibility for such materials.

The proposed Agreement, along with a summary of the NRC staff assessment of the proposed Massachusetts program was published in the *Federal Register* for public comment as required by Section 274e of the Act. Copies of the proposal and supporting documentation were made available for inspection at the Commission's Public Document Room.

The Commission has determined that the proposed Massachusetts program is compatible with the Commission's program for the regulation of like materials and adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

Sincerely,
Dennis K. Rathbun, Director
Congressional Affairs
Office of Governmental and Public Affairs

Enclosure: As stated

ATTACHMENT 5

DRAFT PRESS RELEASE

[PRESS RELEASE LOGO]

No. 96-
Tel. 301/415-

FOR IMMEDIATE RELEASE
(Monday, February 24, 1994)

NRC APPROVES MASSACHUSETTS AGREEMENT TO REGULATE
USE OF CERTAIN RADIOACTIVE MATERIALS

The Nuclear Regulatory Commission has approved an Agreement with the Commonwealth of Massachusetts under which that State will assume part of the NRC's regulatory authority over the use of certain radioactive materials. The Agreement will become effective on March 21.

Under the Agreement, the responsibility for licensing, rulemaking, inspection and enforcement concerning the acquisition, possession, use, transfer, and disposal of by-product material as defined in section 11e.(1) of the Atomic Energy Act of 1954, as amended, source material, special nuclear material in quantities not sufficient to form a critical mass, and licensing of low-level radioactive waste facilities will be transferred to Massachusetts. There are approximately 430 NRC licenses currently in effect in Massachusetts that will be transferred to the State. The Agreement, however, does not provide for State authority over uranium or thorium milling activities.

The Massachusetts Department of Public Health will be the State agency responsible for administering the regulatory program.

The Commission has found that the radiation control program proposed by Massachusetts is compatible with the NRC program and is adequate to protect public health and safety. The text of the Agreement, as approved by the Commission, will be published in the *Federal Register*.

Massachusetts becomes the 30th State to sign such an Agreement with the NRC. Other States which have already assumed this authority from the NRC are Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maryland, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Maine, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah and Washington.

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ATTACHMENT 6

DRAFT FEDERAL REGISTER NOTICE

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

Commonwealth of Massachusetts: Discontinuance of certain Commission regulatory authority within the Commonwealth.

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Agreement with the Commonwealth of Massachusetts.

SUMMARY: Notice is hereby given that Shirley Ann Jackson, Chairman of the U. S. Nuclear Regulatory Commission (NRC) and William F. Weld, Governor of the Commonwealth of Massachusetts, have signed the Agreement set forth below for the discontinuance by the Commission and assumption by the Commonwealth of certain Commission regulatory authority. The Agreement is published pursuant to Section 274 of the Atomic Energy Act of 1954, as amended. Under the Agreement, certain persons would be exempted from certain of the regulatory requirements of the Commission. The pertinent exemptions have been previously published in the *Federal Register* and are codified in the Commission's regulations as 10 CFR Part 150.

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.

The draft of the Agreement was published in the *Federal Register* for comment on four separate dates (see, e.g. 61 FR 68066, December 26, 1996). One comment was received which requested that NRC retain jurisdiction over a site listed on the Site Decommissioning Management Plan until the NRC license for the site is terminated. However, NRC staff believe that under the provisions of Section 274 of the Act, NRC cannot (absent national security considerations) retain jurisdiction over a single licensee in a category of licensees over which regulatory authority is assumed by a State. Therefore, the jurisdiction over the site must be transferred to Massachusetts unless the NRC license is terminated prior to the effective date of the Agreement. NRC staff is expediting efforts to complete the actions necessary to terminate the license. In addition, NRC staff and Massachusetts staff have been working closely to assure that the Massachusetts program is prepared to proceed with timely license termination action if transfer is necessary.

(The text of the Agreement is contained in Attachment 1. It will be added here when the notice is submitted to the *Federal Register*.)

Dated at Rockville, Maryland, this ____ day of March, 1997.

For the U. S. Nuclear Regulatory Commission.

_____

John C. Hoyle

Secretary of the Commission

Mr. Robert P. Murphy
General Counsel
General Accounting Office
441 G Street, NW, Room 7175
Washington, DC 20548
Dear Mr. Murphy:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1966, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting the enclosed Agreement with the Commonwealth of Massachusetts.

Under Section 274 of the Atomic Energy Act of 1954, as amended, the NRC is authorized to enter into agreements with the Governor of any State, whereby the State is authorized, as an Agreement State, to regulate the use of reactor-produced isotopes (byproduct materials), source materials, special nuclear materials in quantities not sufficient to form a critical mass, uranium mill tailings, and the disposal of low-level radioactive waste. The NRC periodically reviews each Agreement State program and actions taken by the State under its Agreement to ensure compliance with Section 274 of the Act. On March 28, 1996, Governor William F. Weld requested that the Commission enter into such an Agreement with the Commonwealth of Massachusetts. Under the Agreement, the Commonwealth of Massachusetts will assume regulatory authority over the activities listed above, except for the regulation of mill tailings.

We have determined that this Agreement is not a "major rule," as defined in 5 U.S.C. 804(2). We have confirmed this determination with the Office of Management and Budget.

The enclosed Agreement will be effective March 21, 1997, and will be published in the *Federal Register* within 30 days after this Agreement is signed by NRC Chairman Jackson and Governor Weld.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: As stated

The Honorable Al Gore
President of the United States Senate
Washington, DC 20510
Dear Mr. President:

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Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: As stated

The Honorable Newt Gingrich
Speaker of the United States
House of Representatives
Washington, DC 20515
Dear Mr. Speaker:

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General Counsel
General Accounting Office
441 G Street, NW, Room 7175
Washington, DC 20548
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Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: As stated

***Identical letter sent to: The Honorable Al Gore and The Honorable Newt Gingrich**

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1. NRC Statement of Policy published in the *Federal Register* January 23, 1981 (46 FR 7540-7546), a correction was published July 16, 1981 (46 FR

36969) and a revision of Criterion 9 published in the *Federal Register* July 21, 1983 (48 FR 33376).

2. Agreement State and NRC regulations are considered "essentially identical" if they are word for word the same, except for certain specific differences, such as:

- Rule numbers may be changed to conform to the State numbering system.
- The provisions of a regulation may be re-sequenced.
- Terms may be substituted for "commission," "agency," "this part," "this chapter" or "these regulations."
- The word "rule" may be interchanged with the word "regulation," and the word "shall" may be interchanged with the word "must."
- Other non-substantive wording changes similar in nature to the above may be made to conform the regulation to the State editorial style.
- The State regulation may be expanded to incorporate sources of radiation other than source, byproduct and special nuclear materials, provided the additional sources are subject to the same requirements.
- The State regulation may specify the use of SI units for recordkeeping and reporting.
- Any portion of the text of an NRC regulation which provides supplemental information, an example, or a reference (for convenience) to another regulation may be omitted.