

POLICY ISSUE NOTATION VOTE

June 6, 2003

SECY-03-0096

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: SECTION 274b AGREEMENT WITH THE STATE OF WISCONSIN

PURPOSE:

To request Commission approval of the proposed Agreement with Wisconsin.

SUMMARY:

The Governor of Wisconsin has requested that the Commission enter into an Agreement under Section 274b of the Atomic Energy Act of 1954, as amended (Act). The Commission, through SECY-03-0030, agreed to publish a notice of the proposed Agreement in the Federal Register (FR). The notice was published as required by the Act and comments were requested. The comment period ended on May 8, 2003.

Based on staff's review of the proposed Wisconsin program and analysis of the comments, staff recommends that the Commission approve the Agreement (Attachment 1).

BACKGROUND:

In SECY-03-0030, staff presented a draft of its assessment of the Wisconsin Agreement and discussed the statutory and policy background of the Agreement State program. As required by Section 274e of the Act, the proposed Agreement was published in the FR on April 8, 2003 (68 FR 17090), April 15, 2003 (68 FR 18297), April 22, 2003 (68 FR 19860), and April 29, 2003 (68 FR 22759). The full text of the staff assessment was made available in the Public Document Room, and on the NRC website.

The Agreement will allow Wisconsin to assume regulatory authority over 11e.(1) byproduct material, source material, and special nuclear material (SNM) in quantities not sufficient to form a critical mass. Wisconsin is not seeking authority: (a) to conduct safety evaluations of sealed

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sources and devices manufactured in Wisconsin and distributed in interstate commerce; (b) to regulate the disposal of low-level radioactive waste at a land disposal site as described in 10 CFR Part 61; or (c) to regulate 11e.(2) byproduct material resulting from the extraction or concentration of source material from ore processed primarily for its source material content, and its management and disposal.

DISCUSSION:

(1) Public Comments

NRC staff received two comment letters in response to the Federal Register notice published on April 8, April 15, April 22, and April 29, 2003. Comments were requested in two categories: (a) the proposed Agreement; and (b) the NRC staff's assessment of the Wisconsin radiation control program.

A letter received from the Executive Director of the Conference of Radiation Control Program Directors, Inc., (CRCPD) strongly supported the proposed Agreement between the Nuclear Regulatory Commission and the State of Wisconsin. The letter stated that the CRCPD members and staff worked with the State of Wisconsin for several years while they prepared to become an Agreement State. The comment encouraged approval of the Agreement.

A second letter was received from the Principal Radiophysicist in the Radiological Health Unit of the New York State Department of Labor providing two comments on the proposed Agreement. Although this letter was issued and received after the comment period expired, the NRC staff has addressed both comments in Attachment 3. The commenter objected to the commitment by the State of Wisconsin to use its best efforts to cooperate with the NRC and other Agreement States in the formulation of standards and regulations and to assure that Wisconsin's program will continue to be compatible. Questions regarding cooperation and compatibility were considered by the combined NRC/Agreement State Compatibility Working Group and were published for public review and comment. The NRC published the Final Policy on Adequacy and Compatibility for Agreement State Programs on September 3, 1997. This policy provides guidance to the staff on applying the Commission's compatibility policy to Agreement State regulations and other program activities. The commenter also expressed a strong difference of opinion on whether the Atomic Energy Act reserves Sealed Source and Device Evaluation authority to the Commission as a separate activity. The Commission approved this policy by issuing Staff Requirements Memorandum SECY-95-136 - Options To Improve And Standardize The Evaluation And Approval Of Sealed Sources And Devices Manufactured in Agreement States, on June 30, 1995.

Both comments appear to challenge Commission authority on established policy issues which were developed cooperatively with the States and carefully considered over a period of several years. The ultimate interpretation of these policies rests with the Commission and the comments have no direct bearing on the Agreement negotiations between the State of Wisconsin and the NRC nor do they affect the NRC staff's assessment which finds that the Wisconsin Agreement materials program is adequate to protect public health and safety and compatible with the NRC's program and thus Wisconsin meets NRC's criteria for an Agreement. An analysis of public comments is contained in Attachment 3.

(2) SECY-03-0030

In the March 27, 2003, Staff Requirements Memorandum, the Commission directed the staff to address a number of changes to the Draft FR notice. These changes were addressed and are reflected in the as published version of the Final FR notice of the proposed Agreement.

(3) Transfer of Licenses

Currently, there are approximately 267 NRC licensees in Wisconsin. Staff has identified 263 licenses that will be transferred to the State in whole or in part. NRC will retain 3 licenses, which regulate Federal agencies and one license which authorizes possession of greater than critical mass quantities of SNM.

Staff is working with the Wisconsin Radiation Protection Section (RPS) staff to effect a smooth transition. The staff has coordinated with the RPS staff on current or pending licensing, inspection, and enforcement activities involving the licenses to be transferred, to assure the smooth continuation of regulatory actions after the transfer.

(4) Actions Pending Against Licensees to be transferred

The Office of Investigations has one pending investigation which may result in an escalated enforcement action against a Wisconsin licensee. The Region III office anticipates that this case will be referred to the Office of Enforcement (OE) for final action before the Agreement becomes effective, however final resolution of this case may occur after the Agreement becomes effective. The OE has no other current or pending enforcement actions or confirmatory action letters against licensees.

(5) Effective Date of the Agreement

The NRC and RPS staffs have targeted August 22, 2003, as the effective date for the Agreement. To meet this date and provide adequate time for an orderly transfer of files, and assumption of authority by Wisconsin on the effective date of the Agreement, the Commission should approve the Agreement by June 27, 2003.

(6) Procedure for Reviewing Proposed Agreements

Staff processed the Wisconsin Agreement request under the streamlined procedure for proposed Agreements that was designed to improve the efficiency and effectiveness of the reviews. The procedure directed the staff to use a self-directed team approach and to perform one comprehensive review of the application. The single comprehensive review was preceded by a team review of the draft application for completeness to ensure that the State had assembled the information required for the comprehensive review. The team members were represented by the Offices of State and Tribal Programs, Nuclear Material Safety and Safeguards, General Counsel, Region III, and Nuclear Security and Incident Response. The procedure used for this review was Office of State and Tribal Programs Internal Procedure SA-700, dated April 2, 2001.

Implementation

Following the execution of the Agreement, staff will continue a program of active interaction with the new Agreement State. The program consists of the exchange of regulatory information, notices of NRC training courses, and periodic on-site reviews of the State's program for regulation of Agreement materials. Communications are generally more frequent with a new Agreement State during the first years after the Agreement is signed. The regulatory information exchange includes reports of incidents, significant enforcement actions, and amendments to policies, regulations, or guidance.

An orientation meeting of NRC and RPS staff will be planned to occur about nine months after the Agreement becomes effective to discuss the initial program implementation. The first Integrated Materials Performance Evaluation Program (IMPEP) review of the Wisconsin program is planned for about 18 months after the effective date of the Agreement. Subsequent routine Agreement State program IMPEP reviews usually occur at 12 - 48 month intervals, with good performance resulting in the longer intervals between reviews.

If approved by the Commission, Wisconsin will bring the number of Agreement States to 33.

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 objections. Staff has obtained concurrence from the Office of Management and Budget (OMB) that this action does not constitute a "major rule" under the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA).

RECOMMENDATIONS:

That the Commission:

1. Find:
 - a. That the proposed Wisconsin program for the regulation of byproduct material, source material, and SNM 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 Wisconsin program is adequate to protect public health and safety within the State with respect to the materials and uses covered by the proposed Agreement.

2. Approve:
 - a. The proposed Agreement between the State of Wisconsin and the Nuclear Regulatory Commission pursuant to Section 274 of the Act, as set forth in Attachment 1.

- b. The proposed Agreement by June 27, 2003, 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 Wisconsin on August 22, 2003.

3. Note:

- a. The Governor of Wisconsin does not desire to sign the Agreement in a formal ceremony. Three formal copies of the Agreement will be provided, upon approval by the Commission, for signature by the Chairman and the Governor of Wisconsin.
- b. Pursuant to the Act, SBREFA, and Commission guidance, the Speaker of the House of Representatives, the President of the Senate, the Wisconsin Congressional delegation, and the director of the General Accounting Office will be informed of the Commission's decision.
- c. The Office of Public Affairs will issue a press release.
- d. The text of the Agreement will be published in the FR as required by Section 274e, within 30 days after the Agreement is signed.

/RA by William F. Kane Acting For/

William D. Travers
Executive Director
for Operations

Attachments:

1. Proposed Agreement
2. NRC Staff Assessment of the Wisconsin Program
3. Staff Analysis of Public Comments
4. Draft Letter to Wisconsin Governor Doyle
5. Draft Federal Register Notice of Agreement Signing

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- 6.

Distribution:

DIR RF (SP02) PDR (YES)
EDO RF (200100090) *See previous concurrences

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ATTACHMENT 1

PROPOSED AGREEMENT BETWEEN NRC AND THE STATE OF WISCONSIN

**Agreement
Between
The United States Nuclear Regulatory Commission
and
The State of Wisconsin
for
Discontinuance of Certain Commission Regulatory Authority
and
Responsibility Within the State 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 byproduct 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 State of Wisconsin is authorized under s. 254.335 (1), Wisconsin Statutes, to enter into this Agreement with the Commission; and,

WHEREAS, The Governor of the State of Wisconsin certified on August 21, 2002, that the State of Wisconsin (hereinafter referred to as 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 this Agreement, and that the State desires to assume regulatory authority for such materials; and,

WHEREAS, The Commission found on [date] that the program of the State 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 State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

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

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

NOW, THEREFORE, It is hereby agreed between the Commission and the Governor of the State, acting on behalf of the State, 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 State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

- A. Byproduct 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.

ARTICLE II

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

- A. The regulation of the construction and operation of any production or utilization facility or any uranium enrichment facility;
- B. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;
- C. The regulation of the disposal into the ocean or sea of byproduct, source, or special nuclear material wastes as defined in the regulations or orders of the Commission;
- D. The regulation of the disposal of such other byproduct, 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 without a license from the Commission;

- E. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission;
- F. The regulation of the land disposal of byproduct, source, or special nuclear material waste received from other persons;
- G. The extraction or concentration of source material from source material ore and the management and disposal of the resulting byproduct material.

ARTICLE III

With the exception of those activities identified in Article II, paragraphs A through D, this Agreement may be amended, upon application by the State and approval by the Commission, to include the additional areas specified in Article II, paragraphs E, F and G, whereby the State can exert regulatory authority and responsibility with respect to those activities and materials.

ARTICLE IV

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

ARTICLE V

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

ARTICLE VI

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

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

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

ARTICLE VII

The Commission and the State 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 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 State, or upon request of the Governor of the State, 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 State 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 State has failed to take necessary steps. The Commission shall periodically review this Agreement and actions taken by the State under this Agreement to ensure compliance with Section 274 of the Act which requires a State program to be adequate to protect public health and safety with respect to the materials covered by the Agreement and to be compatible with the Commission's program.

ARTICLE IX

This Agreement shall become effective on **August ??, 2003**, and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Dated at Rockville, Maryland, in triplicate, this **??** day of **June, 2003**.

FOR THE UNITED STATES NUCLEAR
REGULATORY COMMISSION

Nils J. Diaz, Chairman

Dated at Madison, Wisconsin, in triplicate, this **??** day of **July, 2003**.

FOR THE STATE OF WISCONSIN

Jim Doyle, Governor

ATTACHMENT 2

NRC STAFF ASSESSMENT OF THE WISCONSIN PROGRAM

ASSESSMENT

of the proposed

WISCONSIN PROGRAM FOR THE REGULATION OF AGREEMENT MATERIALS¹

as described in the

Request for an Agreement

This assessment, prepared by the NRC staff, examines the proposed radiation control program of the State of Wisconsin 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 (Act), as amended. The assessment was performed using the criteria in the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (referred to below as the "criteria")² using an internal procedure developed by the Office of State and Tribal Programs. Each criterion, and the NRC staff's draft 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 proposed Wisconsin program for regulating Agreement materials would be located within the existing Radiation Protection Section (RPS) of the Bureau of Environmental Health in the Division of Public Health, an organizational unit of the Wisconsin Department of Health and Family Services (DHFS). The Department's Radioactive Materials Program (RMP) currently has responsibility for registering and inspecting and fee collection for radioactive materials that occur naturally or are produced by particle accelerators. Under the proposed Agreement, the RMP would assume responsibility for licensing and inspecting byproduct, source, and small quantities of special nuclear material. The RPS also has responsibility for the regulation of electronic product radiation and non-ionizing radiation at academic, medical, and industrial facilities.

¹Agreement materials are those radioactive materials covered by the Act over which regulatory authority may be transferred to a State under the provisions of Section 274.

²NRC 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).

Support to the RMP would be provided by another RPS program responsible for laboratory analysis of radioactive material samples.

The authority to issue, suspend, or revoke licenses, and to issue orders or assess administrative fines is vested by Statute in the Director of the DHFS.

The NRC staff review verified that the Wisconsin program design for distributing regulatory responsibilities to the program staff is similar to designs used successfully in other Agreement States, and that all necessary program elements have been addressed. The staff concludes that the design of the proposed Wisconsin program for Agreement materials satisfies the criterion.

References: Program Narrative Description, and Organizational Charts of the Department of Health and Family Services, in the Request for an Agreement from Governor McCallum.

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 authority to promulgate rules for the control of exposure to sources of radiation rests with the DHFS in accordance with Wisconsin Statutes ss. 254.31 - 254.45, Revision 2001. The law requires DHFS to adopt rules and specifies activities over which the Commission will retain regulatory authority. Ancillary Statutes which also generally apply to state agency activities are s. 19.35 (1), Wisconsin Statute on open records, s. 153.50, Wisconsin Statute on the protection of patient confidentiality and Ch. 227, Wisconsin Statute on administrative procedure and review (right to hearing). The NRC staff verified that the Department adopted the relevant NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and 150 into Chapter HFS 157 - the Wisconsin Radiation Protection Code, effective August 1, 2002. Wisconsin rules have the same applicability as the NRC regulations as to materials covered by the Agreement, except that the Wisconsin rules also apply in addition to naturally occurring and accelerator-produced radioactive materials (NARM).

Wisconsin has adopted s. 254.34(1)(a) that reserves jurisdiction of certain portions of these rules to NRC. The NRC staff concludes that Wisconsin will not attempt to enforce regulatory matters reserved to the Commission.

The NRC staff reviewed the Wisconsin Radiation Protection Code (Rules) HFS-157 which became effective on August 1, 2002. As a result of this review, a number of comments were developed which were forwarded to the State to address. Wisconsin regulations are different from NRC regulations with respect to the termination of licenses. Current NRC regulations permit a license to be terminated when the facility has been decommissioned, i.e., cleaned of radioactive contamination, such that the residual radiation will not cause a total effective dose equivalent greater than 25 millirem per year to an average member of the group of individuals reasonably expected to

receive the greatest exposure. Normally, the NRC regulations require that the 25 millirem dose constraint be met without imposing any restrictions regarding the future use of the land or buildings of the facility ("unrestricted release"). Under certain circumstances, NRC regulations in 10 CFR Part 20, Subpart E, allow a license to be terminated if the 25 millirem dose constraint is met with restrictions on future site use ("restricted release"). Wisconsin law does not allow a license to be terminated under restricted release conditions. Wisconsin will instead issue a special "decommissioning-possession only" license as an alternative to license termination under restricted release.

The Wisconsin approach is not fully addressed in its regulations. Wisconsin has agreed to use license conditions to supplement its regulations pending completion of rulemaking to implement its approach. Wisconsin's current regulations together with the license conditions will meet the need to have legally binding requirements.

From a compatibility perspective, the provisions in the license termination rule, 10 CFR 20.1402 for unrestricted release, 10 CFR 20.1403 for restricted release, and 10 CFR 20.1404 for release under alternative criteria are each considered to be Compatibility Category C requirements. Under Compatibility Category C, the state must adopt the essential objectives of these requirements. The State need not address the essential objectives in the same manner as the NRC. As stated in the Statement of Considerations for the license termination rule, the States would be required to adopt the regulation but would have significant flexibility in language, and would be allowed to adopt more stringent requirements. 62 FR 39058, 39079 (June 21, 1997).

The NRC staff notes that the State of Ohio adopted a license termination regulation/decommissioning policy that provides for termination of licenses only under an unrestricted release approach similar to 10 CFR 20.1402. As to 10 CFR 20.1403 and 20.1404, Ohio adopted the essential objectives of these regulations by establishing a "decommissioning-possession only license" which is used to substitute for the NRC institutional control requirements in 10 CFR 20.1403 and 20.1404. Ohio requires the other provisions in 10 CFR 20.1403 and 20.1404 to be met before a "decommissioning-possession only license" can be issued. The Ohio approach, including use of the "possession only license," and its potential effect on compatibility regarding the impending Agreement, was considered by the Commission in SECY-98-209. The Commission approved this approach in a Staff Requirements Memorandum dated November 20, 1998. Wisconsin's approach is similar to Ohio's approach. Consequently, the staff found Wisconsin's approach to be acceptable.

The NRC staff has reviewed and considered the State's response to the comment letter on their final regulations. The NRC staff review verified that, with the comments noted above, the Wisconsin rules and legally binding requirements contain all of the provisions that are necessary in order to be compatible with the regulations of the NRC on the effective date of the Agreement between the State and the Commission.

The NRC staff concludes that the adoption of Wisconsin regulations satisfies this criterion.

References: Wisconsin Statutes ss. 254.31 - 254.45, Revision 2001, Chapter HFS 157 - the Wisconsin Radiation Protection Code, s. 19.35 (1), s. 153.50, and Ch. 227, WI stats.

3. **Uniformity of 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.**

Wisconsin, by statute, must promulgate and enforce rules for the regulation of byproduct, source and special nuclear material that are in accordance with Section 274 of the Atomic Energy Act, as amended. The State has adopted a rule compatible with 10 CFR Part 20. Other Wisconsin rules are also compatible with the equivalent NRC regulations.

The NRC staff review verified that the Wisconsin rules' technical definitions and terminology; units of measurement and dose; and permissible doses, levels of radiation and concentrations of radioactivity are consistent with those in NRC regulations.

The NRC staff concludes that the criterion is satisfied.

References: Chapter HFS 157 - the Wisconsin Radiation Protection Code.

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 NRC staff review verified that Wisconsin has adopted rules equivalent to the NRC regulations in 10 CFR Part 20, including Subpart C, the occupational dose limits and Subpart D, the dose limits to individual members of the public. Wisconsin licensees are required to consider the radiation doses to individuals from all sources of radiation, except background radiation and radiation from medical procedures. Like NRC licensees, Wisconsin licensees are required to consider the radiation dose whether the sources are in the possession of a licensee or not.

The NRC staff concludes that the criterion is satisfied.

References: Chapter HFS ss. 157.22 & .23 - Wisconsin Radiation Protection Code.

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.**

NRC requires surveys and monitoring pursuant to Subpart F of 10 CFR Part 20. The NRC staff review verified that Wisconsin has adopted a rule compatible with Subpart F.

Therefore, Wisconsin licensees are required to conduct surveys and personnel monitoring to the same standards required of NRC licensees.

The NRC staff concludes that the criterion is satisfied.

References: Chapter HFS s. 157.25 - Wisconsin Radiation Protection Code.

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 NRC staff review verified that Wisconsin has adopted regulations compatible with NRC regulations in Subpart J of 10 CFR Part 20. Therefore, the radiation labels, signs and symbols, and the posting and labeling requirements in the Wisconsin rules are identical to those contained in the NRC regulations.

The NRC staff concludes that the criterion is satisfied.

References: Chapter HFS s. 157.29 - Wisconsin Radiation Protection Code.

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 review verified that Wisconsin has adopted regulations compatible with 10 CFR Part 19. The NRC staff concludes that the criterion is satisfied.

References: Chapter HFS ss. 157.06(2), .88 & .89 - Wisconsin Radiation Protection Code.

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

The NRC staff review verified that Wisconsin has adopted a rule compatible with Subpart I of 10 CFR Part 20. The NRC staff concludes that the criterion is satisfied.

References: Chapter HFS s. 157.28 - Wisconsin Radiation Protection Code.

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 NRC staff review confirmed that Wisconsin has adopted rules that are compatible with Subpart K of 10 CFR Part 20 - Waste Disposal. This regulation deals with general requirements for waste disposal including waste classification, transfer and waste manifests and are applicable to all licensees. NRC staff concludes that criterion 9(a) is satisfied.

References: Chapter HFS s. 157.30 - Wisconsin Radiation Protection Code.

(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).

The NRC staff review confirmed that Wisconsin is not seeking authority to regulate the land disposal of low-level radioactive waste. Therefore, criterion 9(b) does not apply to Wisconsin.

References: Letter dated August 21, 2002, from Governor McCallum to Chairman Meserve, request for Agreement.

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 review verified that Wisconsin has adopted regulations compatible with 10 CFR Part 71 - Transportation. As discussed in criterion 2, Wisconsin would not attempt to enforce portions of the regulations related to activities, such as approving package designs, which are reserved to the NRC. Therefore, the NRC staff concludes that criterion 10 is satisfied.

References: Chapter HFS ss. 157.01, .02, .03, .04, .05, .06, .90, .91, .92, .93, .94, .96 - Wisconsin Radiation Protection Code.

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 NRC staff review verified that Wisconsin has adopted rules compatible with 10 CFR Part 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150. The records and reports referenced in criterion 11 are regulatory requirements in these parts. Wisconsin has adopted the record and reporting requirements and therefore the NRC staff concludes that the Wisconsin program satisfies criterion 11.

References: Chapter HFS 157 - Wisconsin Radiation Protection Code.

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 review confirmed that Wisconsin State law provides the radiation control agency authority to impose, by order or license condition, additional health and safety requirements beyond the requirements specified in law and the rules. The agency also has the legal authority to grant reasonable and necessary exceptions to the regulatory requirements, either by order or license condition. Wisconsin has adopted a rule which is compatible with 10 CFR 30.34, *Terms and conditions of licenses*.

NRC staff concludes that the criterion is satisfied.

Referenced: Chapter HFS ss. 157.34, .37, .38, and .365 - Wisconsin Radiation Protection Code. Wisconsin Statutes s. 254.13(9)(b) and (10), Revision 2001.

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 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 processor 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 specific use.

Wisconsin has adopted regulations containing regulatory requirements for applying for and issuing licenses, which are compatible with NRC's regulations.

The NRC staff review confirmed that the Wisconsin rules provide that a license authorizing the distribution of Agreement materials that will subsequently be exempt from regulatory control may only be issued by the NRC.

Since criterion 9 was adopted, the Commission has determined that the regulatory authority to conduct safety evaluations of sealed sources and devices may be retained by the NRC, unless the State requests assumption of the authority and has in place an adequate and compatible program to implement the authority. Wisconsin has decided not to seek authority for evaluation of sealed sources and devices.

The NRC staff concludes that the Wisconsin program meets the requirements of criterion 13.

References: Wisconsin Statutes s. 254.365, Revision 2001; Chapter HFS s. 157.13 - Wisconsin Radiation Protection Code; Letter dated August 21, 2002, from Governor McCallum to Chairman Meserve, request for Agreement.

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 regulatory guides for various categories of licensed activities.**

The NRC staff review determined that the Wisconsin program has established three main licensing procedure guides and a set of application forms. Wisconsin has developed a series of State developed regulatory guides called WISREGS for use by license applicants. Wisconsin also uses NRC guidance documents, including standard

licensing conditions, and standard deficiency paragraphs. The NRC staff determined that the licensing procedure guides cover the handling of license applications from the point of submittal through issuance of the completed license. The Wisconsin licensing procedures are similar to NRC's procedures.

NRC staff concludes that the criterion 14 is satisfied.

References: Wisconsin Radiation Protection Section Narrative and all associated guidance documents referenced, Section III in Request for an Agreement by Governor McCallum.

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 NRC staff review verified that Wisconsin has adopted 10 CFR Part 35 as published in the Federal Register on April 24, 2002, with the exception of Subpart J. Wisconsin intends to issue a "Legally Binding Requirement" (LBR), which will address the Training and Experience criteria in Subpart J during the 2-year NRC transition period, which ends on October 24, 2004. NRC staff concludes that Wisconsin rules, coupled with the use of the LBR during the 2-year transition period, specify the same requirements. This criterion is satisfied.

References: Chapter HFS s. 157, Subchapter VI - Medical Use of Radioactive Material - Wisconsin Radiation Protection Code.

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 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 NRC staff confirmed that the Wisconsin program has statutory authority to conduct inspections of licensees. Wisconsin has adopted regulations compatible with equivalent parts of 10 CFR containing provisions relating to inspections and tests.

Wisconsin has adopted a schedule for inspection of licensees at least as frequent as the schedule used by NRC. The program staff has developed internal procedures and accompanying forms for the inspection areas which cover scheduling, preparation, performance basis, tracking and documentation of inspection results. The program staff has also developed a procedure for tracking inspection reports and related correspondence. The program procedures specify the actions to be taken and identify (by position) the staff responsible for accomplishing the actions. The program

procedure on performance based inspections contains a Performance Based Inspection Plan and a Performance Evaluation Factor Checklist designed to guide inspectors in conducting performance based inspections. The inspection procedures are similar to NRC procedures.

The NRC staff concludes that the criterion is satisfied.

References: Wisconsin Statutes s. 254.34, Revision 2001; Radioactive Materials Program Procedure No. 3.01, Scheduling Inspections in request for an Agreement by Governor McCallum.

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

The NRC staff review confirmed that Wisconsin law provides authority for radiation control program inspectors to enter public or private property at all reasonable times for the purpose of investigating conditions related to radiation use.

References: Wisconsin Statutes s. 254.34(2), Revision 2001.

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 NRC staff review determined that Wisconsin has adopted procedures to convey a copy of the formal inspection report to the licensees, both when violations are found, and when no violations are found. The procedures identify (by position) the staff responsible and specify the time limit for preparing the inspection report, the process for management review and approval, and provide instructions for distribution of the report to the licensee and to the State's official files.

The NRC staff concludes that the criterion is satisfied.

References: Radioactive Materials Program Procedures No. 3.04 - Documentation of Inspection Results, in request for an Agreement by Governor McCallum.

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 NRC staff review confirmed that the Wisconsin program is authorized by law to enforce the State rules using a variety of sanctions, including the imposition of administrative fines, and the issuance of orders to suspend, modify or revoke licenses,

or to impound materials. The program may assess civil penalties in accordance with State Law and Department regulations. The DHFS' Office of Legal Counsel is available to provide assistance with enforcement actions upon the request of the RPS Chief.

The program has adopted policies and procedures to implement the enforcement authority. The Wisconsin enforcement procedures are similar to the NRC procedures with regard to the use of severity levels for violations.

The NRC staff concludes that the criterion is satisfied.

References: Wisconsin Statutes s. 254.33, .34, .37, .365, .38, .45; Chapter HFS s. 157.90, Subchapter XII - Enforcement - Wisconsin Radiation Protection Code, Revision 2001; Radioactive Materials Program Procedures No. 3.05 - Enforcement, Escalated Enforcement and Administrative Actions in request for an Agreement by Governor McCallum.

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 inspections 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 of 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 science, 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 are 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 the 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.

Based on the review of the organizational charts and position descriptions for the Wisconsin program, training and qualification plan and the curricula vitae for the current staff members, the NRC staff concludes that the RPS has a staffing plan that provides a sufficient number of adequately trained and qualified technical staff.

a. Draft Assessment of the Agreement Materials Staffing

There are approximately 267 NRC licenses in Wisconsin, of which NRC staff estimates about 263 will become Wisconsin licensees under the proposed Agreement. The RPS conducts a registration and inspection program for NARM users. Wisconsin plans to start licensing NARM users upon the effective date of the Agreement. The program has adopted and implemented rules comparable to 10 CFR Part 20 which also apply to NARM usage. During CY 2001, the Wisconsin RPS registered 160 NARM users and inspected 77 NARM facilities. The RPS has conducted a registration and inspection program for electronic product radiation equipment since 1966.

The staff of the RPS's RMP will be responsible for implementing the Agreement materials program. The Wisconsin staffing plan allocates a total of 9.5 full time equivalent (FTE) staff for the Agreement materials program, including the program supervisor. Since submittal of the Agreement request, one staff member has left the program. The RMP supervisor plans to devote 100% of her time to the Agreement materials program, including management review of licensing and inspection actions, personnel responsibilities, rules development, accompaniment of inspectors for annual management review, general supervision, and other management duties. Other staff, depending on assigned responsibilities, will devote between 50 - 100% of their time to Agreement State program activities.

Based on the RPS staffing allocation of 9.5 technical and administrative FTE for the RMP, and subtracting program supervision and administrative assistants, the technical/professional staffing level devoted to the Agreement State program is 6.5 FTE.

Wisconsin estimates they will assume responsibility for 420 licenses (263 from NRC and 160 existing NARM registrants). The RMP Staff Resource Analysis projects that approximately 243 licensing actions will be processed each year. This projection is based on CY 2001 data from the NRC Region III Office of 18 licensing actions per month and an additional 2 NARM licensing actions per month. The staffing analysis indicates an average inspection workload of 137 inspections per year. This level of inspection effort will keep the inspection program current. An analysis of the anticipated actual inspection workload for the first year of the Agreement, however, indicates a total of only 55 inspections will be due.

The Wisconsin Training and Qualification Plan has been used to evaluate and fully qualify the technical staff. Based on the workload analysis, NRC staff concludes the initial 6.5 FTE of fully qualified technical/professional staff provides an adequate level of staffing to handle anticipated licensing, inspection, reciprocity, allegations and incident response workload satisfactorily. The program has also allocated 1.0 FTE for direct supervision of the RMP staff, 1.5 FTE for Administrative Program Support activities and an additional 0.5 FTE for training and ongoing development of regulations and procedures.

Based on the information provided, the NRC staff concludes that the proposed Wisconsin Agreement materials program has an adequate number of staff. Wisconsin has met the criterion to have an adequate number of personnel to meet the anticipated program needs.

b. Draft Assessment of Staff Qualifications

The NRC staff review considered the qualifications of the individuals currently on the RPS's professional/technical staff that would be involved in the Agreement materials program, and the RPS's procedures for training and qualifying new staff members.

Under the proposed Agreement, the RMP Supervisor would direct the Agreement materials program and would be primarily responsible for the program's administration. The program supervisor will provide the immediate day-to-day supervision of the

Agreement materials program. The RMP Supervisor holds a Bachelor's and a Master's degree in Geology. She has been with the Wisconsin RPS as RMP supervisor since 2001. She has extensive Agreement material program experience from another State dating back to 1983. This includes health physics and supervisory experience (10.5 years).

Based on the NRC staff review, all non-supervisory staff members except one have at least a bachelor's degree or equivalent in physical/life sciences or engineering. Among the six members of the technical staff, there are individuals with an associate degree in radiation science and an undergraduate degree in management, an associate degree in management, a bachelor's degree in radiation science, a bachelor's degree in animal science, a bachelor's degree candidate (senior) in nuclear engineering, and a master's degree in nuclear engineering.

The full time technical/professional RMP staff, including the supervisor, have extensive radiation science experience. This includes work in health physics and nuclear power in private industry, the military and in State regulatory agencies. All of the technical staff have completed the NRC recommended core courses or have received waivers from the RPS manager, based on their training and prior experience. These courses include the 5-week Applied Health Physics course, the licensing & inspection courses, the diagnostic & therapeutic medical courses, the industrial radiography course and other use-specific courses. The technical staff have had on-the-job training working with NRC license reviewers in the NRC Region III Office and have accompanied NRC staff on inspections of NRC licensees in Wisconsin. Several of the technical staff have also spent time in neighboring Agreement States receiving licensing and inspection training. One staff member, with completion of the inspection for performance course, will have completed all core courses. A newly hired staff member is scheduled to complete training and qualification requirements by the effective date of the Agreement. An individual was recently hired to fill a vacant position. She will attend the core courses or, based on education and experience, receive waivers.

The RPS has adopted a written program for training and qualification of staff members, which covers both new staff members and the continuing qualification of existing staff. The RPS maintains a qualifications journal and a training plan for each of the current staff. Each milestone in the qualifications journal requires a signature by both the trainee and the RMP supervisor. One of the Integrated Materials Performance Evaluation Program (IMPEP) criterion addresses staff training and qualification plans. NRC staff reviewed the plan and concluded that it satisfies the IMPEP criterion element.

Based upon review of the information provided in the staffing analysis, consideration of their current NARM program, prior regulatory program experience, training and qualification plan and staff education and training, NRC staff concludes that overall the program has an adequate number of technically qualified staff.

Based on the above, the NRC staff review concluded that the technical staff identified by the State to participate in the Agreement materials program are trained and qualified in accordance with the RPS plans, have sufficient knowledge and experience in radiation protection, the use of radioactive materials, the standards for the evaluation of

applications for licensing, and the techniques of inspecting licensed users of Agreement materials to satisfy the criterion.

References: Radioactive Materials Program Procedures No. 6.01 - Qualifications and Training and Program Narrative Description in request for an Agreement by Governor McCallum.

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.**

Wisconsin also adopted appropriate portions of 10 CFR Part 150 by reference to the Atomic Energy Act to further inform persons of the exemptions and reservations of NRC authority under the Agreement. The NRC staff concludes that the criterion is satisfied.

Reference: Wisconsin Statutes s. 254.34

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 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:**

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams PU)}}{200} = 1$$

The NRC staff review verified that Wisconsin has adopted rules compatible with the appropriate portions of 10 CFR 150, including the definition of the terms "special nuclear material in quantities not sufficient to form a critical mass." Staff concludes that the criterion is satisfied.

Reference: Chapter HFS s. 157.03(351) - Wisconsin Radiation Protection Code.

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 process and use radioactive materials, and**
- c. **Taking disciplinary actions against licensees.**

The NRC staff review confirmed that the Wisconsin RPS is bound by general statutory provisions with respect to providing the opportunity for public participation in rulemaking, licensing actions, and disciplinary actions. These general statutory provisions also apply to the protection of personnel radiation exposure records from public disclosure, maintaining the confidentiality of alleged, and administrative and judicial requirements for requesting and holding hearings on enforcement matters.

NRC staff has reviewed the pertinent references and determined that the criterion is satisfied.

References: Wisconsin Statutes ss. 19.35(1), 153.50, and Chapter 227. Wisconsin Radiation Protection Section Narrative in the request for an Agreement by Governor McCallum.

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 NRC staff review confirmed that the Wisconsin DHFS is designated by law to be the State's radiation control agency. The law also allows other State agencies to promulgate rules, which may be enacted by local government. However, no rule or ordinance may be enacted which differs from rules required under the Atomic Energy Act for the Agreement.

NRC staff concludes that the criterion is satisfied.

References: Wisconsin Statutes ss. 254.34 - Powers and Duties, 166.03(2)(b)6., 293.15(8) and 293.25; Wisconsin Radiation Protection Section Narrative in the request for an Agreement by Governor McCallum.

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 recognized 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 NRC staff review confirmed that Wisconsin laws contain a provision that deems the holder of an NRC license on the effective date of the proposed Agreement to possess a like license under the Wisconsin Radiation Protection Code. The license will expire 90-days after receipt by the licensee of a notice from the State or on the expiration date on the NRC license, whichever is earlier.

NRC staff concludes that the Wisconsin program satisfies criterion 25.

References: Wisconsin Statutes s. 254.335(2).

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 review verified that the proposed Agreement commits Wisconsin 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 Wisconsin's program will continue to be compatible with the Commission's program for the regulation of Agreement materials.

In a revised policy statement on Adequacy and Compatibility of Agreement State Programs (published 9/3/97 at 62 FR 46517), the Commission determined that providing reports to NRC of Agreement State licensee incidents, accidents and other significant events is a matter of compatibility. Wisconsin has adopted procedures to provide such reports to NRC. NRC staff concludes that the criterion is satisfied.

References: Proposed Agreement between the State of Wisconsin and the Nuclear Regulatory Commission, Article VI; Wisconsin Statutes s. 254.33; Chapter HFS ss. 157.13(17) & 157.32 - Wisconsin Radiation Protection Code; Radioactive Materials Program Procedure No. 4.02 - Radiological Incident Response.

27. Coverage, Amendments, Reciprocity. **An amendment 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 material,**
 - 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 NRC staff review verified that the proposed Agreement provides for the Commission to discontinue, and the State of Wisconsin to assume, regulatory authority over the types of material defined in categories a, c, and d above.

Since this criterion was adopted, the Commission has determined that the Agreement States may assume the authority to evaluate the safety of sealed sources and devices to be distributed in interstate commerce as a separate portion of the Agreement, or to allow NRC to retain that authority. Wisconsin has chosen not to assume that authority.

References: Proposed Agreement between the State of Wisconsin and the Nuclear Regulatory Commission, Articles I, II and III in the request for an Agreement by Governor McCallum.

The proposed Agreement stipulates the desirability or reciprocal recognition of NRC and other Agreement State licenses, and commits the Commission and the State to use their best efforts to accord such reciprocity. Wisconsin has adopted a 10 CFR Part 150 compatible rule which provides for the reciprocal recognition of licenses from other jurisdictions.

The NRC staff concludes that the criterion is satisfied.

References: Proposed Agreement between the State of Wisconsin and the Nuclear Regulatory Commission, Articles VII in the request for an Agreement by Governor McCallum; and Chapter HFS s. 157.14 - Wisconsin Radiation Protection Code.

28. NRC and Department of Energy Contracts. **The State should provide exemptions for NRC and DOE contracts which are substantially equivalent to the following exemptions:**
- a. **Prime contractors performing work for the DOE at U.S. Government-owned or controlled site;**
 - 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 verified that Wisconsin has adopted 10 CFR Parts 30, 40 and 70 compatible rules including §§ 30.12, 40.11 and 70.11 wherein the specified exemptions are contained. Based on this, the NRC staff concludes that the Wisconsin regulations do provide for exemptions from the State's requirements for licensing of sources of radiation for NRC and DOE contractors or subcontractors in accordance with the criterion.

NRC staff concludes that the criterion is satisfied.

Reference: Chapter HFS s. 157.04 - Wisconsin Radiation Protection Code.

STAFF CONCLUSION

Section 274d of the Atomic Energy Act of 1954, as amended, states that "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 material, and that the State program is adequate to protect the public health and safety with respect to the materials covered by the proposed amended."

The NRC staff has reviewed the proposed Agreement, the certification by Wisconsin in the application for an Agreement submitted by Governor McCallum on August 21, 2002, and the supporting information provided by the staff of the Radiation Protection Section of the Wisconsin Department of Health and Family Services, and concludes that, the State of Wisconsin satisfies the criteria in the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement," and therefore meets the requirements of Section 274 of the Act. The proposed Wisconsin program to regulate Agreement materials, as comprised of statutes, regulations, and procedures, is compatible with the program of the Commission and is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

ATTACHMENT 3

STAFF ANALYSIS OF PUBLIC COMMENTS

STAFF ANALYSIS OF PUBLIC COMMENTS

INTRODUCTION:

NRC staff received two comment letters in response to the notice that the Governor of Wisconsin has proposed to enter into an Agreement with the Commission under Section 274b of the Atomic Energy Act. The notice was published in the Federal Register (FR) on April 8, April 15, April 22, and April 29, 2003. The notice contained a summary of the staff's draft assessment of the proposed Wisconsin program. In the FR notice, comments were requested in two categories: (a) the proposed Agreement; and (b) the NRC staff's assessment of the Wisconsin radiation control program.

(1) COMMENTS ON THE PROPOSED AGREEMENT

Comments regarding the proposed Agreement have been grouped into three principal areas: (a) Supporting the Agreement; (b) Opposing the Agreement; and (c) Other.

(a) Comments Supporting the Agreement

Commenter: **Affiliation:**

Ronald Fraass Executive Director - Conference of Radiation Control Program Directors, Inc.

Summary of Comments:

A letter received from the Executive Director of the Conference of Radiation Control Program Directors, Inc. (CRCPD) strongly supported the proposed Agreement between the Nuclear Regulatory Commission and the State of Wisconsin. The letter stated that the CRCPD members and staff worked with the State of Wisconsin for several years while they prepared to become an Agreement State. It was further stated that the CRCPD will continue to work with Wisconsin, other Agreement States, the Organization of Agreement States, and the Commission to maintain coordinated and compatible programs for protection against radiation hazards.

NRC staff response:

The comments encouraging approval of the Agreement support the NRC staff's plan to complete the staff assessment documenting that the Commission's criteria for entering into an Agreement are satisfied, and then to request the Commission to approve the Agreement and to place it into effect. These comments are supportive of the Commission's process for approval of an Agreement.

(b) Comments Opposing the Agreement (None received)

(c) Other

Summary of Comments:

Commenter:

Affiliation:

Clayton Bradt

Principal Radiophysicist - Radiological Health Unit, New York State
Department of Labor

1. Sealed Source and Device Review and Registration -

The proposed Agreement reserves the review and registration of sealed sources and devices (SS&D) to the Commission. This would appear to be in violation of the provisions of §274 of the Atomic Energy Act (AEA).

Contrary to the assertion by Commission staff, the term "categories of materials" is not meant to encompass "activities." Section 274 of the AEA is quite explicit about both. In general, the assumption of regulatory authority over "categories of materials" under Chapters 6, 7, & 8 and §161, means the assumption of authority over all activities involving those materials as enumerated in the specified chapters and section, with certain expressly stated exceptions: e.g., the licensing of fuel cycle/utilization facilities, the licensing of the distribution of radioactive devices, and the protection of national security/safeguards information under §161 b and i. Section 274 provides no authorization for the Commission to reserve activities from State authority under an Agreement save for those expressly enumerated. Consequently, the AEA does not permit the Commission to reserve the safety reviews of SS&D from State regulatory authority. In fact, since the AEA does not even mention such reviews, they cannot properly be considered as part of an Agreement.

The proposed Agreement will establish a system of dual regulation of manufacturers and distributors of radioactive devices in Wisconsin, a result which the Agreement State program was intended to avoid. Regardless of who reviews SS&D registrations, the State of Wisconsin must still license the manufacture and distribution of radioactive devices within its borders. And, since it is the license which is legally enforceable, not the SS&D registration certificate, any requirements, restrictions or special procedures needed to ensure the safety of such devices must be included in the conditions of the license in order to be enforced. The effect of such an Agreement unfairly burdens manufacturers/distributors of radioactive devices in the State of Wisconsin, vis-à-vis those located in other States, and could arguably be viewed as an unauthorized restriction of trade by the State of Wisconsin - ironically operating against its own citizens.

NRC staff response:

This issue was addressed in Commission Paper SECY-95-136 entitled, "Options to Improve and Standardize the Evaluation and Approval of Sealed Sources and Devices Manufactured in Agreement States." By approving Option 2 and with the issuance of Management Directive 5.8 entitled "Proposed 274b Agreements with States," the Commission determined that this activity could be considered as a separate activity which States could choose to address in a Section 274 Standard Agreement. Under this policy, Agreement States have the option whether or not to seek authority to perform sealed source and device evaluations. In our view, this is consistent with the discretion provided the Commission in the last sentence of Section 274c of

the AEA. The Governor of Wisconsin chose not to request this authority in the State's request for an Agreement with the NRC.

2. Cooperation with Other Agencies -

The Commission staff state that the proposed Agreement commits Wisconsin "to use its best efforts to cooperate with the NRC and other Agreement States" (emphasis added) in the formulation of standards and regulations "and to assure that Wisconsin's program will continue to be compatible ..." They further state that the proposed Agreement "commits the Commission and Wisconsin to use their best efforts" (emphasis added) to accord reciprocity to each other's licensees and the licensees of other States. This language echoes the bi-lateral commitments first introduced in the Commission's Agreement with the State of New York, in 1962. The intent of this wording, as expressed in then Governor Nelson A. Rockefeller's letter to the Commission, was to better reflect the fact that the relationship between the Commission and the State was to be a cooperative one. In the New York Agreement both the Commission and the State commit to "use their best efforts" to cooperate for the desired result of maintaining compatible regulatory programs. They did not commit themselves to obtaining the desired result, but only to use their "best efforts" to do so. Clearly, for either party to commit to do more than use its best efforts to achieve the mutual goal would place it under the authority of the other - something that a sovereign could never do.

It is curious that the Commission staff use this language in Section II to describe the commitments in the Agreement, when in the text of the Agreement itself this "best efforts" language is replaced by a much more one-sided set of commitments. In Article VI of the proposed Agreement, the Commission agrees that it "will cooperate" to formulate standards and regulations and that it will cooperate to assure the coordination and compatibility of the State and Commission programs. Wisconsin also agrees to cooperate in the formulation of standards and regulations but then agrees that it "will assure" that the State's program will continue to be compatible - a much stronger (and unwise) commitment.

Thus by signing this proposed Agreement, the State of Wisconsin will place itself under the ultimate authority of the Commission. For in practice, the Commission has reserved to itself the sole authority for determining the meaning of "compatibility." By committing itself to obtain the result, Wisconsin commits itself to operate its regulatory program in whatever manner the Commission tells it to. A sovereign cannot commit itself to the achievement of a result, the metric of success for which is controlled by another, and remain sovereign.

The proposed Agreement thus short-changes the residents of the State of Wisconsin, relegating them to a second-class status vis-à-vis those of other States such as New York, as well as violates the provisions and intent of the Atomic Energy Act.

NRC staff response:

The commenter has expressed a different opinion from the policy approved by the Commission in 1997. The Policy on Adequacy and Compatibility of Agreement State Programs and the accompanying implementation procedures were developed cooperatively with the States, over a period of several years, and are detailed in SECY-97-054 and Management Directive 5.9. The ultimate interpretation of this policy rests with the Commission. The proposed Wisconsin

Agreement is consistent with Commission policy and thus meets the criteria for an Agreement with the Commission. It is also consistent with the Standard Agreement which was previously developed and set out in Management Directive 5.8 "...to establish a system for an orderly transition in the discontinuance of certain regulatory authority by the NRC with assumption thereof by the State through a standard agreement."

In our view, whether or not the phrase "best efforts" is used, the State has agreed to seek continued compatibility. Thus, in our view the difference pointed out by the commenter is not significant. It should be noted that the inconsistency with use of the phrase "best efforts" has been previously recognized in SECY-97-145 (July 11, 1997) which evaluated the language in past agreements against the standard agreement. This evaluation concluded that modifications to the Agreements were not necessary. However, the staff intends to delete the phrase "best efforts" from the Federal Register Notice in the future and make a conforming change to Management Director 5.8.

ATTACHMENT 4

**DRAFT LETTER
FROM
CHAIRMAN NILS DIAZ
TO
GOVERNOR JIM DOYLE**

DRAFT

The Honorable Jim Doyle
Governor of Wisconsin
Madison, WI 53707

Dear Governor Doyle:

I am pleased to inform you that the U. S. Nuclear Regulatory Commission (NRC) has approved the proposed Agreement requested by former Governor McCallum under which the NRC will discontinue and the State of Wisconsin will assume regulatory authority over the acquisition, possession, use, transfer, and disposal of certain byproduct material, source material and special nuclear material in quantities not sufficient to form a critical mass.

Enclosed are three formal copies of the Agreement for your signature. After signature, one copy should be retained by your office, and the other two copies should be mailed to Paul H. Lohaus, Director, Office of State and Tribal Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

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

Sincerely,

Nils J. Diaz

Enclosure:
As stated

ATTACHMENT 5

DRAFT

**FEDERAL REGISTER NOTICE OF
AGREEMENT SIGNING**

DRAFT

U. S. Nuclear Regulatory Commission

State of Wisconsin: Discontinuance of Certain Commission Regulatory Authority Within the State; Notice of Agreement Between the NRC and the State of Wisconsin

Agency: U. S. Nuclear Regulatory Commission.

Agency: Notice of Agreement between the NRC and the State of Wisconsin.

Summary: This notice is announcing that on **June ??, 2003**, Dr. Nils J, Diaz, Chairman of the U. S. Nuclear Regulatory Commission (NRC) and on **July ??, 2003**, Governor Jim Doyle of the State of Wisconsin signed an Agreement as authorized by Section 274b of the Atomic Energy Act of 1954, as amended (Act). The Agreement provides for the Commission to discontinue its regulatory authority and for Wisconsin to assume regulatory authority over the possession and use of byproduct material as defined in Section 11e.(1) of the Act, source material and special nuclear materials (in quantities not sufficient to form a critical mass). Under the Agreement, a person in Wisconsin possessing these materials is exempt from certain Commission regulations. The exemptions have been previously published in the Federal Register (FR) and are codified in the Commission's regulations as 10 CFR Part 150. The Agreement is published here as required by Section 274e of the Act.

FOR FURTHER INFORMATION CONTACT: Lloyd A. Bolling, Office of State and Tribal Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone (301) 415-2327 or email LAB@NRC.GOV.

SUPPLEMENTARY INFORMATION:

The draft Agreement was published in the Federal Register for comment once a week for four consecutive weeks (see, e.g., 68 FR 17086, April 8, 2003) as required by the Act. The public comment period ended on May 8, 2003. The Commission received two comment letters which were addressed by the staff. One letter was supportive and encouraged the Agreement. The other letter raised questions about NRC's authority, under the Act, to transfer certain NRC programs or activities to the States and to require Agreement State compatibility with NRC programs. These are policy questions which were developed cooperatively with the States, over a period of several years. The ultimate interpretation of these policies rests with the Commission. These comments do not affect the NRC staff's assessment which finds that the Wisconsin Agreement materials program is adequate to protect public health and safety and compatible with the NRC's program and thus Wisconsin meets NRC's criteria for an Agreement. The proposed Wisconsin Agreement is consistent with Commission policy and thus meets the criteria for an Agreement with the Commission.

After considering the request for an Agreement by the Governor of Wisconsin, the supporting documentation submitted with the request for an Agreement, and its interactions with the staff of the Wisconsin Department of Health and Family Services, Radiation Protection Section, the NRC staff completed an assessment of the Wisconsin program. A copy of the staff assessment was made available in the NRC's PDR and electronically on NRC's website. Based on the staff's assessment, the Commission determined on **June 27**, 2003, that the proposed Wisconsin program for control of radiation hazards is adequate to protect public health and safety, and that it is compatible with the Commission's program.

Copies of the staff assessment, and the Commission's decision may be reviewed at the NRC website, <http://www.nrc.gov>.

Dated at Rockville, Maryland, this _____ **day of** _____, 2003.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook
Secretary of the Commission