

ATTACHMENT 3

NUCLEAR REGULATORY COMMISSION

State of Wisconsin: NRC Staff Draft Assessment of a Proposed Agreement
Between the Nuclear Regulatory Commission and the State of Wisconsin

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of a Proposed Agreement with the State of Wisconsin.

SUMMARY: By letter dated August 21, 2002, former Governor Scott McCallum of Wisconsin requested that the U. S. Nuclear Regulatory Commission (NRC) enter into an Agreement with the State as authorized by Section 274 of the Atomic Energy Act of 1954, as amended (Act).

Under the proposed Agreement, the Commission would relinquish, and Wisconsin would assume, portions of the Commission's regulatory authority exercised within the State. As required by the Act, NRC is publishing the proposed Agreement for public comment. NRC is also publishing the summary of a draft assessment by the NRC staff of the Wisconsin regulatory program. Comments are requested on the proposed Agreement and the staff's draft assessment which finds the Program adequate to protect public health and safety and compatible with NRC's program for regulation of Agreement material.

The proposed Agreement would release (exempt) persons who possess or use certain radioactive materials in Wisconsin from portions of the Commission's regulatory authority. The Act requires that NRC publish those exemptions. Notice is hereby given that the pertinent

exemptions have been previously published in the Federal Register and are codified in the Commission's regulations as 10 CFR Part 150.

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

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

The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/NRC/ADAMS/index.html>. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr@nrc.gov.

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

Draft Assessment are also available for public inspection in the NRC's Public Document Room - **ADAMS Accession Numbers: ML030160104 and _____.**

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 e-mail LAB@nrc.gov.

SUPPLEMENTARY INFORMATION: Since Section 274 of the Act was added in 1959, the Commission has entered into Agreements with 32 States. The Agreement States currently regulate approximately 16,250 agreement material licenses, while NRC regulates approximately 4,900 licenses. Under the proposed Agreement, approximately 260 NRC licenses will transfer to Wisconsin. NRC periodically reviews the performance of the Agreement States to assure compliance with the provisions of Section 274.

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

I. Background

(a) Section 274d of the Act provides the mechanism for a State to assume regulatory

authority, from the NRC, over certain radioactive materials¹ and activities that involve use of the materials.

In a letter dated August 21, 2002, former Governor McCallum certified that the State of Wisconsin has a program for the control of radiation hazards that is adequate to protect public health and safety within Wisconsin for the materials and activities specified in the proposed Agreement, and that the State desires to assume regulatory responsibility for these materials and activities. Included with the letter was the text of the proposed Agreement, which is shown in Appendix A to this Notice.

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

(1) the possession and use of byproduct materials as defined in Section 11e.(1) of the Act; (2) the possession and use of source materials; and (3) the possession and use of special nuclear materials in quantities not sufficient to form a critical mass, as provided for in regulations or orders of the Commission.

(b) The proposed Agreement contains articles that:

¹The radioactive materials are: (a) byproduct materials as defined in Section 11e.(1) of the Act; (b) byproduct materials as defined in Section 11e.(2) of the Act; (c) source materials as defined in Section 11z. of the Act; and (d) special nuclear materials as defined in Section 11aa. of the Act, restricted to quantities not sufficient to form a critical mass.

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

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

- (c) Wisconsin currently registers users of naturally-occurring and accelerator-produced radioactive materials. The regulatory program is authorized by law in Section 3145, Subsection 254.34 of the revised Wisconsin Statutes. Subsection 254.335(1) provides the authority for the Governor to enter into an Agreement with the Commission. Wisconsin law (Subsection 254.335(2)) contains provisions for the orderly transfer of regulatory authority over affected licensees from NRC to the State. After the effective date of the Agreement,

licenses issued by NRC would continue in effect as Wisconsin licenses until the licenses expire or are replaced by State-issued licenses.

- (d) The NRC staff draft assessment finds that the Wisconsin program is adequate to protect public health and safety, and is compatible with the NRC program for the regulation of agreement materials.

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

NRC staff has examined the Wisconsin request for an Agreement with respect to the ability of the Wisconsin radiation control program to regulate agreement materials. The examination was based on the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (referred to herein as the "NRC criteria"), (46 FR 7540; January 23, 1981, as amended by policy statements published at 46 FR 36969; July 16, 1981 and at 48 FR 33376; July 21, 1983).

- (a) Organization and Personnel. The agreement materials program will be located within the existing Radiation Protection Section (Program) of the Wisconsin Department of Health and Family Services. The Program will be responsible for all regulatory activities related to the proposed Agreement.

The educational requirements for the Program staff members are specified in the Wisconsin State personnel position descriptions, and meet the NRC criteria with respect to formal education or combined education and experience requirements. All current staff members hold at least bachelor's degrees in physical or life sciences, or have a combination of education and experience at least equivalent to a bachelor's degree. Several staff members hold advanced degrees, and all staff members have had additional training plus working experience in radiation protection. Supervisory level staff have more than ten years working experience each, in radiation protection.

The Program currently has one staff vacancy, which they are actively recruiting to fill. The Program performed, and NRC staff reviewed, an analysis of the expected Program workload under the proposed Agreement. Based on the NRC staff review of the State's staff analysis, Wisconsin has an adequate number of staff to regulate radioactive materials under the terms of the Agreement. The Program will employ a staff of 9.5 full-time professional/technical and administrative employees for the agreement materials program. The distribution of the qualifications of the individual staff members will be balanced to the distribution of categories of licensees transferred from NRC. Each individual on the staff is qualified in accordance with the Program's training and qualification procedure to function in the areas of responsibility to which the individual is assigned.

- (b) Legislation and Regulations. The Wisconsin Department of Health and Family Services (DHFS) is designated by law in Chapter 254 of the Wisconsin Revised Statutes to be the radiation control agency. The law provides the DHFS the authority to issue licenses, issue

orders, conduct inspections, and to enforce compliance with regulations, license conditions, and orders. Licensees are required to provide access to inspectors. The DHFS is authorized to promulgate regulations.

The law requires the DHFS to adopt rules that are compatible with equivalent NRC regulations and that are equally stringent to the equivalent NRC regulations. Wisconsin has adopted HFS 157 Radiation Protection Code effective August 1, 2002. The NRC staff reviewed and forwarded comments on these regulations to the Wisconsin staff. The NRC staff review verified that, with the comments incorporated, 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 DHFS has extended the effect of the rules, where appropriate, to apply to naturally occurring radioactive materials and to radioactive materials produced in particle accelerators, in addition to agreement materials. The NRC staff also concludes that Wisconsin will not attempt to enforce regulatory matters reserved to the Commission.

Wisconsin regulations are different from the NRC regulations with respect to the termination of the license. 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 the future 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 alternate to license termination under restricted release. NRC staff has concluded that this approach is compatible with NRC regulations.

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

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

- (e) Recordkeeping and Incident Reporting. Wisconsin has adopted the sections compatible with the NRC regulations which specify requirements for licensees to keep records, and to report incidents, accidents, or events involving materials.

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

- (g) Inspections and Enforcement. The Wisconsin radiation control program has adopted a schedule providing for the inspection of licensees as frequently as the inspection schedule used by NRC. The Program has adopted procedures for the conduct of inspections, the reporting of inspection findings, and the reporting of inspection results to the licensees. The Program has also adopted, by rule based on the Wisconsin Revised Statutes, procedures for the enforcement of regulatory requirements.

- (h) Regulatory Administration. The Wisconsin Department of Health and Family Services is bound by requirements specified in State law for rulemaking, issuing licenses, and taking enforcement actions. The Program has also adopted administrative procedures to assure fair and impartial treatment of license applicants. Wisconsin law prescribes standards of ethical conduct for State employees.

- (i) Cooperation with Other Agencies. Wisconsin law deems the holder of an NRC license on the effective date of the proposed Agreement to possess a like license issued by Wisconsin. The law provides that these former NRC licenses will expire either 90 days after receipt from the radiation control program of a notice of expiration of such license or on the date of expiration specified in the NRC license, whichever is earlier.

Wisconsin also provides for “timely renewal.” This provision affords the continuance of licenses for which an application for renewal has been filed more than 30 days prior to the date of expiration of the license. NRC licenses transferred while in timely renewal are included under the continuation provision. The Wisconsin Radiation Protection Code provides exemptions from the State's requirements for licensing of sources of radiation for NRC and U.S. Department of Energy contractors or subcontractors. 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. The proposed Agreement stipulates the desirability of reciprocal recognition of licenses, and commits the Commission and Wisconsin to use their best efforts to accord such reciprocity.

III. Staff Conclusion

Subsection 274d of the Act provides that the Commission shall enter into an agreement

under subsection 274b with any State if:

- (a) The Governor of the State certifies that the State has a program for the control of radiation hazards adequate to protect public health and safety with respect to the agreement materials within the State, and that the State desires to assume regulatory responsibility for the agreement materials; and
- (b) The Commission finds that the State program is in accordance with the requirements of Subsection 274o, and in all other respects compatible with the Commission's program for the regulation of materials, and that the State program is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

On the basis of its draft assessment, the NRC staff concludes that the State of Wisconsin meets the requirements of the Act. The State's program, as defined by its statutes, regulations, personnel, licensing, inspection, and administrative procedures, is compatible with the program of the Commission and adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

NRC will continue the formal processing of the proposed Agreement which includes publication of this Notice once a week for four consecutive weeks for public review and comment.

IV. Small Business Regulatory Enforcement Fairness Act

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

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

For the Nuclear Regulatory Commission.

_____, Director
Office of State and Tribal Programs

AGREEMENT
BETWEEN
THE UNITED STATES NUCLEAR REGULATORY COMMISSION
AND
THE STATE OF WISCONSIN
FOR THE
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 the State of Wisconsin 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 Atomic Energy Act of 1954, as amended;

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. 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.

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 **July 1, 2003**, and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at Madison, Wisconsin this ** day of **June, 2003**.

FOR THE UNITED STATES NUCLEAR
REGULATORY COMMISSION

Richard A. Meserve, Chairman

FOR THE STATE OF WISCONSIN

Jim Doyle, Governor