

July 18, 2002

Mr. Paul S. Schmidt, Manager
Radiation Protection Section
Division of Public Health
Wisconsin Department of Health
and Family Services
P.O. Box 2659
Madison, WI 53701-2659

Dear Mr. Schmidt:

We have conducted a completeness review of your draft request for an Agreement dated May 30, 2002. The review was conducted by an inter-office staff team identified in Enclosure 1. The review was based on a Commission Policy Statement that provides criteria for new agreements, and an Office of State and Tribal Programs (STP) procedure for processing new agreements, described in further detail below.

The completeness review was conducted to determine whether the draft application contained sufficient information to enable staff to conduct a detailed review of the application. The team found that the draft application provided information on all major program elements and reflected significant effort on the part of your staff. The team also identified several areas where additional clarifying information or documentation is needed. Our comments are contained in Enclosure 1. Please note that our comments only address those elements where additional information is needed. The team concluded that the other elements contained sufficient information to support a detailed review. The Commission's Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States through Agreements," specifies the criteria the Commission will apply in making its finding that a proposed State Agreement program is adequate to protect public health and safety and compatible with NRC's regulatory program, as required by the Atomic Energy Act [Effective January 23, 1981 (46 FR 7540), and amended by Policy Statements published July 16, 1981 (46 FR 36969) and July 21, 1983 (48 FR 33376)]. Under this process, the staff prepares a written assessment of the State's program, based on a review of the State's request against the criteria, to support the Commission's finding.

A procedure has been developed to provide guidance for preparation and review of a request for an Agreement. The STP Procedure SA-700 and Handbook, "Processing an Agreement," is based on the above policy criteria, the performance indicators set out in Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," and staff experience in reviewing previous Agreement requests. A copy of the procedure and handbook is enclosed (Enclosure 2).

The SA-700 Handbook, which identifies the necessary documentation for a complete application, was used by staff to identify any additional information and documentation necessary to complete your request for an Agreement. For your reference, the comments are correlated to the pertinent sections of your draft application. We would also appreciate any comments you might have on the usefulness of the procedure and handbook. After you have an opportunity to review our comments, we would welcome an opportunity to meet with you to review the comments, and answer any questions concerning the review, the

Paul S. Schmidt

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July 18, 2002

information needed, or steps involved in processing the Agreement. Please contact me at (301) 415-3340 or Lloyd Bolling at (301) 415-2327 to arrange the meeting.

Sincerely,

/RA/

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosures:
As stated

After you have an opportunity to review our comments, we would welcome an opportunity to meet with you to review the comments, and answer any questions concerning the review, the information needed, or steps involved in processing the Agreement. Please contact me at (301) 415-3340 or Lloyd Bolling at (301) 415-2327 to arrange the meeting.

Sincerely,

/RA/
Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosures:
As stated

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DATE	7/8/02		7/9/02		7/16/02		7/11/02		7/16/02		7/16/02		7/18/02	

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STATE OF WISCONSIN COMPLETENESS REVIEW TEAM

Lloyd Bolling, Project Manager
Office of State and Tribal Programs

Staffing\Training, Organization, Regulatory
& Events\Allegations Elements

James Lynch, Regional State
Agreements Officer, Region-III

Inspection & Enforcement Elements

David Cummings
Office of the General Counsel

Legal & Regulatory Elements

J. Bruce Carrico
Office of Nuclear Material Safety
and Safeguards

Licensing Elements

Richard Jolliffe
Incident Response Operations

Events & Allegations Elements

ENCLOSURE 1

STATE OF WISCONSIN DRAFT APPLICATION COMMENTS

1. Agreement State Program Internal Procedures

The Working Group (WG) noted that Wisconsin internal program procedures covering Licensing, Inspections, Response to Radiological Incidents and the Management of Allegations lacked specific guidance on when to seek referrals for legal assistance (i.e., for possible criminal cases) and where such assistance is available (i.e., Dept. of Health and Family Services- Legal Division).

Recommendation: The WG recommends that guidance on Legal referrals be specifically mentioned in the Wisconsin Radioactive Materials Program's (RMP) internal procedures. The procedures identified above should also state the location, within State Government, where legal assistance may be obtained.

2. Legal Elements

- a. The draft Wisconsin Agreement document contained a number of changes which were significant departures from the standard Agreement format detailed in SA-700.

Recommendation: While it is not likely that these departures would change the responsibilities or terms of the Wisconsin Agreement with the NRC, the WG recommends that the State utilize the standard language contained in SA-700. A "Redline/Strikeout" version of the Wisconsin draft agreement document was sent to the Radiation Protection Section (RPS) Manager and is enclosed. (See Attachment)

- b. A review of the State's statutes indicated that the draft application contained an earlier (1999) version which had already received NRC review and comment. This review was documented in a letter to Mr. Paul S. Schmidt, Manager, RPS, dated January 9, 2002.

Recommendation: Mr. Schmidt was informed of this and provided the WG with a copy of the 2001 version which incorporated the NRC comments.

- c. The proposed Wisconsin radiation control regulations received NRC review and comment which was documented in a letter to Mr. Paul S. Schmidt dated April 4, 2002. The proposed regulations were sent to the State legislature which approved them and forwarded them to be published in final form in August 2002.

Recommendation: Mr. Schmidt committed to sending NRC a copy of the as published final version of the State's regulations in accordance

with STP Internal Procedure SA-201, entitled "Review of State Regulations" issued November 10, 1998. The final regulations will be reviewed for adequacy and compatibility upon receipt.

3. Events and Allegations

- a. The Radioactive Materials Program Procedure (RMPP) No. 4.02, entitled "Radiological Incident Response" does not include criteria for follow-up inspections.

Recommendation: RMPP No. 4.02 should state what criteria will be used to determine the need for a follow-up or reactive inspection.

- b. RMPP No. 4.02 does not include guidance on the notification of other Wisconsin licensees when generic problems are found.

Recommendation: RMPP No.4.02 should state what procedure will be used to inform other Wisconsin licensees of generic problems.

- c. RMPP No. 4.02 item 2.0 Responsibilities, lacks several requirements when compared to the NRC guidance.

Recommendation: RMPP No. 4.02 should address the following areas:

- i. Assign responsibility for the completion of the reports.
- ii. Assign responsibility for assuring the quality of the reports.
- iii. Specify times for completion of the reports.
- iv. Specify times for submitting the reports to the NRC.
- v. Provide guidance for identifying abnormal occurrences.
- vi. Contain criteria for identifying events as reportable events to the NRC.

It may be appropriate to reference STP Procedure SA-300 and Handbook, entitled "Nuclear Materials Event Reporting in Agreement States."

- d. RMPP No. 4.02 does not contain guidance on forwarding event reports to the NRC for inclusion in the Nuclear Materials Events Database (NMED).

Recommendation: RMPP No. 4.02 should include guidance on forwarding reports to the NRC for inclusion in the NMED. It may be appropriate to reference STP Procedure SA-300 and Handbook, entitled "Nuclear Materials Event Reporting in Agreement States."

- e. Radiation Protection Procedure (RPP) No. 4.01, entitled "Management of Allegations" does not address the protection of (other) sensitive information.

Recommendation: RPP No. 4.01 should provide for the protection of (other) sensitive information.

Attachment:
As stated

ENCLOSURE 1

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 ACTION 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~~ 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 **[date]** 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;

ATTACHMENT

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. 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 ~~control over~~ 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 ~~ensure~~ assure that Commission and State programs for protection against hazards of radiation will be coordinated and compatible. The State ~~will~~ 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 will use their best efforts to keep each other informed of events, accidents, proposed changes in their respective rules, regulations and licensing, inspection and enforcement policies and criteria, 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 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 **[date]** and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at Madison, Wisconsin this **[date]** day of **[month]**, **[year]**.

FOR THE UNITED STATES NUCLEAR
REGULATORY COMMISSION

Richard A. Meserve, Chairman

FOR THE STATE OF WISCONSIN

Scott McCallum, Governor