

ATTACHMENT 4

DRAFT ASSESSMENT

of the proposed

WISCONSIN PROGRAM FOR THE REGULATION OF AGREEMENT MATERIALS¹

as described in the

Request for an Agreement

This draft 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 draft 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.

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

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).

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 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 alternate 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 manner in which the essential objectives are addressed need not be the same as 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. 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 uniform 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. As with 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 procedures 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 those in 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 commend, 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 260 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. This position is authorized to be replaced and a position announcement has been posted. 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 (includes one currently vacant technical position).

Wisconsin estimates they will assume responsibility for 420 licenses (260 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 (5.5 FTE + 1 vacancy) of fully qualified technical/professional staff provides an adequate level of staffing to satisfactorily handle anticipated licensing, inspection, reciprocity, allegations and incident response workload. 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 staff 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 very 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. The individual hired to fill the current vacant position 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:**

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

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 allegers, 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.