UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 14, 2005

Sheri Johnson, Ph.D., Administrator
Division of Public Health
Wisconsin Department of Health and Family Services
P.O. Box 2659
Madison, WI 53701-2659

Dear Dr. Johnson:

The Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report which documents the results of the Agreement State review held in Wisconsin on August 22-26, 2005. I was the team leader for the review. The review team's preliminary findings were discussed with you and your staff on the last day of the review. The review team's proposed recommendations are that the Wisconsin Agreement State program be found adequate to protect public health and safety and compatible with NRC's program.

NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the hazards associated with the use of radioactive materials and that Agreement State programs are compatible with NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess both Agreement State and NRC Regional Office radioactive materials licensing and inspection programs. All reviews use common criteria in the assessment and place primary emphasis on performance. One additional area has been identified as a non-common performance indicator and is also addressed in the assessment. The final determination of adequacy and compatibility of each Agreement State program, based on the review team's report, will be made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft team report for review prior to submitting the report to the MRB. We welcome your comments on the draft report. We request comments within 30 days from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review the response, make any necessary changes to the report and issue it to the MRB as a proposed final report. Our preliminary scheduling places the Wisconsin MRB meeting in the week of November 7, 2005. We will coordinate with you to establish the date for the MRB review of the Wisconsin report and will provide invitational travel for you or your designee to attend. NRC has video conferencing capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

If you have any questions regarding the enclosed report, please contact me at 610-337-5358.

Thank you for your cooperation.

Sincerely,

/RA/

Sheri Minnick
Regional State Agreements Officer
Division of Nuclear Material Safety

Enclosure:
As stated

cc:
P. Schmidt, WI
C. Rogers, WI

Distribution
S. Minnick, RI
J. Lynch, RIII
B. Parker, RI
B. Taylor, TX
J. Zabko, STP
A. McCraw, STP

SISP Review Complete: SM
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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF WISCONSIN AGREEMENT STATE PROGRAM

August 22-26, 2005

Draft Report

U.S. Nuclear Regulatory Commission

ENCLOSURE 1

1.0 INTRODUCTION

This report presents the results of the review of the Wisconsin Agreement State program. The review was conducted during the period of August 22-26, 2005, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the State of Texas. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of July 3, 2003 to August 26, 2005, were discussed with Wisconsin management on August 26, 2005.

The Radiation Control Program is administered by the Radiation Protection Section (the Section). The Section is part of the Division of Public Health (the Division), within the Bureau of Environmental & Occupational Health. Organization charts for the Division and the Section are included as Appendix B. At the time of the review, the Wisconsin program regulated approximately 363 specific licenses, including naturally occurring or accelerator-produced radioactive material (NARM). The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Wisconsin.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Section on June 9, 2005. The Section provided its response to the questionnaire on July 11, 2005. A copy of the questionnaire response may be found on the NRC's Agencywide Documents Access and Management System (ADAMS) using the accession number (ML051600481).

The review team's general approach for conduct of this review consisted of: (1) examination of Wisconsin's response to the questionnaire; (2) review of applicable Wisconsin statutes and regulations; (3) analysis of quantitative information from the Section's licensing and inspection databases; (4) technical evaluation of licensing and inspection actions; (5) field accompaniments of four Wisconsin inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common indicator and made a preliminary assessment of the radiation control program's performance.

Section 2 below discusses the results of the current review for the IMPEP common performance indicators. Section 3 discusses results of the applicable non-common performance indicators, and Section 4 summarizes the review team's findings.

2.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators include: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

2.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Section's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Section's questionnaire response relative to this indicator; interviewed Division management and staff; and reviewed job descriptions, training plans, and training records. The review team also considered any possible workload backlogs in evaluating this indicator; however, no licensing or inspection casework backlogs were identified.

The Section, headed by the Section Chief, devotes approximately eight full time equivalent (FTE) to the radioactive materials program, of which 6.5 are allotted for licensing and inspection. The program is fully staffed, with no vacancies or turnover since becoming an Agreement State. All technical staff members are fully qualified to perform both licensing and inspection activities and are classified as Nuclear Engineers, or after three years of experience, Senior Nuclear Engineers. All but two inspectors are Senior Nuclear Engineers.

The remaining 1.5 FTE include program management and a half-time training coordinator who assists the program with training needs. The training coordinator conducts in-house courses and coordinates participation in outside training courses. In-house training was conducted on September 6, 2003, on management of allegations, and on October 18, 2004, on timeliness of response to radiological incidents.

The Section has a documented training plan that is consistent with the guidance in the NRC/Organization of Agreement States Training Working Group Report and NRC's Manual Chapter (MC) 1246. The Section also has on-the-job training to supplement the coursework so that individuals may broaden their work areas. Newer staff members are assigned increasingly complex licensing duties under the direction of the Radioactive Materials Licensing and Inspection Unit Supervisor (the Supervisor) and accompany more experienced inspectors during increasingly complex inspections. Inspectors are assigned independent inspections after demonstrating competence during accompaniment evaluations by the Supervisor. The review team confirmed the qualifications of all staff through review of qualification journals, training records, and documentation of supervisory accompaniments.

In preparation for taking over the licensing functions as an Agreement State, four staff members received one-on-one training with an NRC Region III license reviewer. The NRC reviewer spent approximately one week per person providing "hands-on" training for reviewing licensing actions and writing various types of licenses.

The Section Chief indicated that upper-level management has been very supportive of staff training opportunities as well as staff participation in working groups. Training records demonstrate that the Section is committed to a high degree of training. All but two staff members have gone to the five-week Health Physics course taught by Oak Ridge Institute of Science and Education. The remaining two staff members were exempted due to extensive experience in the field of radiation. Several staff members have been to supplementary training courses such as Radiological Emergency Response Operations (RERO), Health Physics in Radiation Accidents, Multi-Agency Radiation Survey and Site Investigations Manual (MARSSIM), and Root Cause/Incident Investigation. The Supervisor and two staff members

are scheduled to attend the NRC Security course in September 2005, in Albuquerque, New Mexico.

The review team noted that the Section had stable funding during the review period. The Section collects 100 percent of the budget from materials fees, which goes into a dedicated fund.

The State of Wisconsin does not have an oversight board or committee to provide direction to the Agreement State program.

Based on the IMPEP evaluation criteria, the review team recommends that Wisconsin's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

2.2 Status of Materials Inspection Program

The team focused on five factors in reviewing this indicator: inspection frequency; overdue inspections of Priority I, II, and III licensees; initial inspection of new licenses; timely dispatch of inspection findings to licensees; and the performance of reciprocity inspections. The review team's evaluation is based on the Section's response to the questionnaire relative to this indicator, data gathered independently from the Section's licensing and inspection data tracking system, the examination of completed inspection casework, and interviews with managers and staff.

The review team's evaluation of the Section's inspection priorities verified that inspection frequencies for various types or groups of licenses are as frequent, or more frequent, than similar license types listed in NRC MC 2800. The Section requires more frequent inspections in some license categories. Medical broad scope programs, gamma knives, high-dose rate remote after loaders, nuclear pharmacies and fixed industrial radiographers are inspected on a one-year frequency compared with the NRC two-year frequency. Mobile nuclear medicine licenses are inspected on a two-year frequency compared with the NRC three-year frequency. Small source material licenses, small medical programs, teletherapy licenses, and self-shielded irradiators are inspected on a three-year frequency compared with the NRC five-year frequency. The Section tracks all inspection activities in a computer database. The database can easily be queried by program management and staff to determine inspection status for any licensed facility.

In response to the questionnaire, the Section indicated that there was only one inspection currently overdue by more than 25 percent of the NRC frequency. That inspection was completed prior to the on-site review. No other inspections were overdue at the time of the IMPEP review. Initial inspections were scheduled and conducted within one year of license issuance.

The timeliness of the issuance of inspection findings was evaluated by the team's review of inspection casework. Letters to licensees regarding inspection results were sent within 30 days of the inspection date. Field inspection forms (similar to NRC 591 forms) are sometimes issued in the field by inspectors when only minor violations are identified during an inspection.

Reciprocity was granted to 20 licensees in 2004 and to 25 licensees thus far in 2005. The Section reciprocity inspection goals are: 100 percent of source exchange service providers, 50 percent of Priority I and II licensees, 30 percent of Priority III licensees, and 10 percent of Priority V licensees. The team verified that the Section had met their reciprocity goals, which are more aggressive than NRC MC 1220 reciprocity inspection requirements.

The team also reviewed the Section's work on general licensees. The Section has completed a large effort to verify the general license database transferred to them from the NRC, since becoming an Agreement State. The program currently has approximately 150 registered general licensees. Each year, the Section requires a self-inspection and fee from registrants. They have been successful in obtaining 100 percent response, after some staff persistence. Of the registered general licensees, the Section has identified approximately 50 higher risk general licensees, of which they perform on-site inspections. They accomplish this task by having each inspector perform a small number of general license inspections each year, in addition to their normal inspection workload.

Based on the IMPEP evaluation criteria, the review team recommends that Wisconsin's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

2.3 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and interviewed staff members for 20 radioactive materials inspections conducted during the review period. The casework included work performed by all of the Section's materials license inspectors, and covered a variety of license types including: academic; medical; nuclear pharmacy; industrial radiography; mobile nuclear medicine; service provider; manufacturing and distribution; and research and development. Appendix C lists the inspection casework reviewed for completeness and adequacy with case-specific comments, as well as the results of the inspection accompaniments.

Based on the casework reviewed, the review team noted that the inspections covered all aspects of the licensees' radiation programs. The review team determined that inspection reports were generally very thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed for larger and complex licensees and for training purposes.

Supervisory accompaniments were conducted annually for all inspectors in 2004 and are on track to be completed in 2005. Accompaniments are documented on a review checklist which is placed in the inspector's qualification and training file.

The team identified that inspection findings were appropriate, and prompt regulatory actions were taken, as necessary. All inspection findings were clearly stated and documented in the reports, and reviewed by the Supervisor. The Section has the ability to require enforcement conferences and impose civil penalties or orders when it is deemed that a licensee has had a significant breakdown in operations affecting health and safety. The Section's enforcement program is detailed in Radioactive Materials Program Procedure 3.05 "Enforcement, Escalated

Enforcement, and Administrative Actions." Enforcement actions to date appear to have been appropriate and effective.

During the review of reciprocity license files, a team member noticed that an NRC-issued security order, marked as *Safeguards Information-Modified Handling*, was in the file cabinet drawer with the reciprocity files. The cabinet was accessible to Section staff members who did not have a "need-to-know" for access to the information contained therein. The inappropriate storage of the document was discussed with the Section Chief who immediately moved the document to an approved, secure location. The normal storage location is a locked and secured cabinet. The Section Chief discussed the need to properly control *Safeguards Information-Modified Handling* documents with the individual who placed the document in the cabinet. The review team determined that this was an isolated incident. The individual, and two other staff members, are scheduled to attend NRC-sponsored security training in September 2005.

The Section has adequate numbers and types of radiation survey instruments to support their radiation control program efforts. Instruments are calibrated by the manufacturer or the University of Wisconsin Radiation Calibration Laboratory. The laboratory is accredited by National Voluntary Laboratory Accreditation Program (NVLAP) and uses sources directly traceable to National Institute of Standards and Technology (NIST) primary standards. Appropriate, calibrated survey instruments such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, micro-R-meters, and neutron meters were observed. Portable multi-channel analyzers are used in response to incidents and recycling facility alarms. The Section maintains calibrated equipment to analyze environmental samples and samples of unknown radioactive materials for isotopic identification and quantification.

The team performed an on-site review of the Section's waste storage facility located within the campus of the University of Wisconsin, Madison. The Section collects radioactive material that has been abandoned within the State and holds it in storage until they can dispose of it at an authorized low-level radioactive waste disposal facility. The storage area was found to be secure, appropriately posted, well maintained and inventoried.

Four Section inspectors were accompanied during inspections by review team members in July 2005. Inspection accompaniments included: an industrial radiographer; a mobile nuclear medicine service; an academic research program and a hospital medical license, as identified in Appendix C. During the accompaniments, each inspector demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspectors were trained, prepared, and thorough in their audits of the licensees' radiation safety programs. Each inspector utilized good health physics practices during the inspections. Interviews with licensee personnel were performed in an effective manner, and the inspections were adequate to assess radiological health and safety at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends that Wisconsin's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

2.4 Technical Quality of Licensing Actions

The review team interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 21 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of the license conditions, and overall technical quality. The casework files were also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions which were completed during the review period. The sampling included the following types: medical and academic broad scope, manufacturing and distribution, medical institution - limited, private practice, mobile nuclear medicine, nuclear pharmacy, permanent radiography, radiography - temporary jobsite, portable gauge, fixed gauge, veterinarian, special nuclear material (pacemaker), and self-shielded irradiator. Types of licensing actions selected for evaluation included two new licenses, four renewals, nine amendments to existing licenses, four license terminations, and several licenses that were converted from NRC to Wisconsin. A listing of the casework licenses evaluated with case specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectible. Deficiency letters clearly state regulatory positions, are used at the proper time, and identify substantive deficiencies in the licensees' documents. Terminated licensing actions are well documented, showing appropriate transfer and survey records.

The administrative staff receives all licensing actions and enters all pertinent information into the Section’s database (RAMPROD). The status of all actions is tracked by RAMPROD. The Supervisor assigns each action to one of six reviewers based on workload and experience. For reviewers with less experience in a given area, the Supervisor provides additional oversight and/or assigns another experienced reviewer as a mentor. All completed actions are reviewed and signed by the Supervisor. Deficiency letters are reviewed and signed by the reviewers. When the reviewer completes a licensing action, a second technical review is performed by another reviewer or the Supervisor. The administrative staff conducts an administrative review and final processing before mailing out to the licensee.

While the Section does not yet use templates to generate correspondence and licenses, there are standard formats and license conditions for each license type. The Section utilizes licensing guides based on NRC licensing guides (NUREG-1556 series), as appropriate and maintains other licensing guidance (i.e., Technical Assistance Requests, regulatory guides) that are the same or similar to those used by the NRC.

After Wisconsin became an Agreement State, the Section began converting licenses transferred from NRC Region III to Wisconsin licenses. The conversions were performed over

many months to distribute the workload. Licenses were converted "as is" from the NRC licenses, using existing expiration dates, unless the expiration period was greater than five years. In those cases, the expiration date was five years from the date of conversion. For licenses at or near expiration, a renewal was performed following the Section's renewal procedures. All licenses have been converted. New and renewed licenses are issued for a five-year term. After the five-year term, licensees are required to submit a complete renewal application to maintain current information in the file.

The Section appropriately requires certain licensees to maintain financial assurance for decommissioning. Applicable financial assurance documents are maintained in a locked cabinet. The Section has converted 16 of 17 financial surety instruments from NRC to Wisconsin as the beneficiary. The Section continues to work with NRC Region III to complete the one outstanding instrument which is partially converted.

Based on the IMPEP evaluation criteria, the review team recommends that Wisconsin's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

2.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Section's actions in responding to incidents, the review team examined the Section's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Wisconsin in the Nuclear Materials Events Database (NMED) against those contained in the Section files, evaluated the casework and supporting documentation for radioactive materials incidents and accompanied staff on an incident investigation. A list of the incident casework examined, with case-specific comments, is included in Appendix E. The team also reviewed the Section's response to allegations involving radioactive materials including allegations referred to the State by NRC during the review period. Incident and allegation policies, file documentation, the Branch's incident and allegation tracking system, NMED, and notification of incidents to the NRC Operations Center were discussed with the Section Chief and staff.

When notified of an incident, the State Radiological Coordinator (SRC) determines the approach to be taken regarding the incident. Individuals designated as SRCs are the Supervisor and trained Senior Nuclear Engineers. The SRC can be contacted by beeper if necessary, when a notification of an incident is received. The SRC assumes the lead role and assigns appropriate staff to assist with the initial response and follow-up actions.

The Section responded to 20 radioactive material incidents as reported to NMED during the review period. Monthly reports and follow-up information are submitted electronically using the NMED software. One designated staff member manages the submissions to NMED. A sample of 11 incidents was selected for review. The incidents included: unauthorized removal of a gauge, damage to equipment, release of radioactive material, contamination, loss and recovery of radioactive material, three equipment malfunctions, a medical event and two abnormal occurrences.

During the June 10, 2004, orientation meeting held between Wisconsin and the NRC, the Section Chief stated that additional efforts would be directed to future incident response to assure an appropriate level of response is coordinated. The review team noted that following

the meeting, incident response training was conducted, close coordination with the NRC was maintained, and the Section's response to incidents was commensurate with the health and safety significance of the event. Inspectors were dispatched for investigations when appropriate and the enforcement action was taken when indicated. Incident reports were thorough and well-documented. All incident reports were reviewed and signed by the appropriate level of management.

The Section responded to two incidents resulting from a MICK® Applicator malfunction. Staff researched the issue through NMED. They discussed the issue with the relevant hospitals, the device manufacturer, Agreement States and the NRC. They concluded that the malfunction was a generic issue and issued an Information Notice (IN) on June 9, 2005. The IN informs Wisconsin medical licensees of the incidents and alerts them to problems associated with the applicator. The information was shared with the NRC, and shortly thereafter, on June 23, 2005, the NRC issued IN 2005-17: Manual Brachytherapy Source Jamming, using Wisconsin's IN as an attachment. The review team recommends the issuance of Wisconsin's IN as a good practice.

A review team member accompanied staff members on an incident investigation that occurred during the review week. The incident investigation involved response to tritium exit signs that ended up at a non-licensed facility. Staff were prepared and assessed the radiological hazard quickly. Wipe tests were performed and sent for analysis. The radiological hazard and proper disposal of the material was explained to members of that facilities staff, which are non-radiation workers.

The SRC also evaluates each allegation and determines the proper level of response. The review of casework files indicated that prompt and appropriate action was taken in response to the concerns raised. Allegers requesting anonymity are informed that every effort will be made to protect his/her identity, but cannot be guaranteed. Each of the allegations reviewed were appropriately closed, and the allegers were informed of the results either verbally or in writing. Staff were knowledgeable of the allegation procedure. There were no performance issues identified from the review of the allegation casework documentation.

Based on the IMPEP evaluation criteria, the review team recommends that Wisconsin's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

3.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. Only the first non-common performance indicator was applicable to this review.

3.1 Compatibility Requirements

3.1.1 Legislation

Wisconsin became an Agreement State on August 11, 2003. Along with their response to the questionnaire, the Section provided the review team with the opportunity to review copies of

legislation that affect the radiation control program. Legislative authority to create an agency and enter into an Agreement with the NRC is granted in Wisconsin Revised Statue, Section 254.34. The Division is designated as the State's radiation control agency.

3.1.2 Program Elements Required for Compatibility

The Wisconsin regulations governing radiation protection requirements are found in various subchapters of the Department of Health and Family Services Section 157 of the Wisconsin Administrative Code. These rules apply to all ionizing radiation, whether emitted from radionuclides or produced by machines. Wisconsin requires a license for the possession and use of all radioactive material including naturally occurring materials, and accelerator-produced radionuclides. Wisconsin also requires registration of all machines designed to produce x-rays or other ionizing radiation.

The review team examined the State's rulemaking process and found that the process takes approximately one year after preparation of a draft rule. The Section Chief is responsible for the radiation protection rule promulgation process. Every step in the process is tracked on the State of Wisconsin Administrative Rules website. The first step in the process begins with a "Statement of Scope of Proposed Rules" submitted to the Office of Legal Counsel which is the Agency's public notice that it intends to begin the development of a permanent rule. Draft rule language is developed with input from staff. Wisconsin has used an ad hoc Advisory Group to comment on the draft language. The group is comprised of a cross section of the regulated community who will be effected by the new regulations and has been helpful in identifying controversial issues before the rule process gets underway. Depending on the scope of the draft language, the group is given a minimum of 90 days to comment. Comments from the group are incorporated in the draft rule, or a justification for not changing the rule is provided.

The proposed draft rules are sent to the Legislative Counsel Rules Clearinghouse, and posted on the Division web site. The public comment period is a minimum of 30 days and at least one public hearing is held. At the same time, the proposed rule is submitted to the NRC for compatibility review. Following the hearing, the Division may modify the rule based on the Clearinghouse and public comments.

The final proposed rule is sent to the Senate and Assembly for legislative review, then to the Secretary of State for rule publication in the Wisconsin Administrative National Register. Normally, the rule will take effect 30 days later.

The review team evaluated Wisconsin's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the Office of State and Tribal Programs' State Regulation Status Sheet.

At the time of their Agreement, the program had in place, State-specific regulations that are compatible with the NRC. The Section has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they are effective. All regulations required to be adopted, including amendments, are currently in effect.

The review team verified that 33 NRC comments on proposed Wisconsin Regulations have been incorporated into their rules and are currently in the rule promulgation process. The review team also identified the following regulation adoptions that will be needed in the future, and Section management indicated that the regulations are currently proposed and going through the rule promulgation process:

- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 amendment 68 FR 57327, that became effective December 3, 2003.

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment 69 FR 3697, that became effective on October 1, 2004.

- "Security Requirements for Portable Gauges Containing Byproduct Material, 10 CFR 30, amendment 70 FR 2001, that became effective on July 11, 2005.

- "Medical Use of Byproduct Material - Recognition of Speciality Boards, 10 CFR 30, amendment 70 FR 16336, that became effective on April 29, 2005.

Based on the IMPEP evaluation criteria, the review team recommends that Wisconsin's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.0 SUMMARY

As noted in Sections 2 and 3 above, the review team found Wisconsin's performance to be satisfactory for all performance indicators reviewed. The review team made no recommendations regarding the performance of the Wisconsin Agreement State program and identified one potential good practice. Accordingly, the review team recommends that the Wisconsin Agreement State program be found adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full review should take place in approximately four years.

GOOD PRACTICE:

> The Section responded to two incidents resulting from a MICK® Applicator malfunction. Staff researched the issue through NMED. They discussed the issue with the relevant hospitals, the device manufacturer, Agreement States and the NRC. They concluded that the malfunction was a generic issue and issued an IN to medical licensees of the incidents to alert them to problems associated with the applicator. The review team recommends that Wisconsin's issuance of an IN following two incidents resulting from a MICK® Applicator malfunction be identified as a good practice. (See Section 2.5)

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Sheri Minnick, STP	Team Leader Technical Staffing and Training Inspector Accompaniments
James Lynch, RIII	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Bryan Parker, RI	Technical Quality of Licensing Actions
Barbara Taylor, TX	Technical Quality of Incident and Allegation Activities Compatibility Requirements

APPENDIX B

WISCONSIN ORGANIZATION CHARTS

ADAMS: ML051600481

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Metal Tek International — License No.: 133-1181-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 5/12/05 — Inspectors: MM, RS

File No.: 2
Licensee: NDT Specialists, Inc. — License No.: 079-1199-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 10/7/04 — Inspectors: MW, RS

File No.: 3
Licensee: Froedtert Memorial Lutheran Hospital. — License No.: 079-1104-01
Inspection Type: Routine, Announced — Priority: 1
Inspection Dates: 5/10-12/05 — Inspectors: JH, LD, PC

Comment:
The inspection did not address a contaminated medical waste incident reported by the licensee in September 2004.

File No.: 4
Licensee: Seaman Nuclear Corporation — License No.: 079-1257-01
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 9/30/04 — Inspectors: MM, PC, CR

File No.: 5
Licensee: Marquette University — License No.: 079-1161-01
Inspection Type: Follow-up, Announced — Priority: 3
Inspection Date: 7/18/05 — Inspector: LD

File No.: 6
Licensee: Covance Clinical Research Unit, Inc. — License No.: 025-1075-01
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 2/8/05 — Inspectors: MS, PC

File No.: 7
Licensee: Cardinal Health-Wauwatosa — License No.: 079-1311-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 5/6/04 — Inspectors: MS, CR

File No.: 8
Licensee: Mercy Hospital — License No.: 105-1176-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Dates: 3/8-15/05 — Inspectors: MS, PC, PS

File No.: 9
Licensee: Team Cooperheat-MQS, Inc. License No.: 079-2005-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 10/26/04 Inspector: JH

File No.: 10
Licensee: Shared Medical Technology License No.: 005-1271-01
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 7/13/05 Inspector: RS

File No.: 11
Licensee: Medi-Physics, Inc. License No.: 079-1168-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 11/23/04 Inspectors: LD, MS

File No.: 12
Licensee: Sacred Heart Hospital License No.: 035-1253-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 8/5/04 Inspector: MW

Comment:
Inspection letter issued late (35 days).

File No.: 13
Licensee: WOS Testing License No.: 035-1358-01
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 11/25/03 Inspector: JH

File No.: 14
Licensee: Columbia-St. Mary's Hospital License No.: 079-1064-01
Inspection Type: Initial, Announced Priority: 1
Inspection Date: 3/22/04 Inspectors: PC, MS

File No.: 15
Licensee: Waukesha Memorial Hospital License No.: 133-1339-01
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 12/15/04 Inspectors: LD, MM

File No.: 16
Licensee: Lafayette Testing License No.: 079-1147-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 12/12/03 Inspectors: MW, MM

File No.: 17
Licensee: MNC License No.: 079-1194-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 2/15/05 Inspector: RS

File No.: 18
Licensee: Elmbrook Memorial Hospital
License No.: 079-1092-01
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Date: 7/19/05
Inspector: PC

File No.: 19
Licensee: JANX
License No.: 21-16560-01 (NRC)
Inspection Type: Reciprocity, Unannounced
Priority: 1
Inspection Date: 8/8/05
Inspector: MM

File No.: 20
Licensee: Nucletron
License No.: MD-27-035-01 (Maryland)
Inspection Type: Reciprocity, Unannounced
Priority: 3
Inspection Date: 5/5/05
Inspector: RS

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1
Licensee: Twin Ports Testing, Inc.
License No.: 31-1317-02
Inspection Type: Routine
Priority: 1
Inspection Date: 7/12/05
Inspector: JH

Accompaniment No.: 2
Licensee: Shared Medical Technology
License No.: 5-1271-01
Inspection Type: Routine
Priority: 3
Inspection Date: 7/13/05
Inspector: RS

Accompaniment No.: 3
Licensee: Marquette University
License No: 079-1161-01
Inspection Type: Follow-up, Announced
Priority: 3
Inspection Date: 7/18/05
Inspector: LD

Accompaniment No.: 4
Licensee: Elmbrook Memorial Hospital
License No: 079-1092-01
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Date: 7/19/05
Inspector: PC

Comment:
The inspector missed an opportunity to observe handling of licensed material.

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Heart Hospital of Milwaukee — License No.: 076-1376-01
Type of Action: Termination — Amendment No.: 02
Date Issued: 1/10/05 — License Reviewer: MS

File No.: 2
Licensee: Cardinal Health — License No.: 025-1123-01
Type of Action: Renewal — Amendment No.: 04
Date Issued: 1/15/05 — License Reviewer: MS

File No.: 3
Licensee: Longview Inspection — License No.: 133-2008-01
Type of Action: Conversion — Amendment No.: 00
Date Issued: 7/15/04 — License Reviewer: MS, MW

File No.: 4
Licensee: Red Feather, LLC — License No.: 125-1387-01
Type of Action: New — Amendment No.: 00
Date Issued: 5/24/05 — License Reviewer: MS

File No.: 5
Licensee: Wisconsin Veterinary Referral Center — License No.: 133-1357-01
Type of Action: Conversion — Amendment No.: 00
Date Issued: 10/1/04 — License Reviewer: MW

File No.: 6
Licensee: Iroquois Foundry — License No.: 045-1130-01
Type of Action: Termination — Amendment No.: 01
Date Issued: 3/11/05 — License Reviewer: MW

File No.: 7
Licensee: Seaman Nuclear Corporation — License No.: 079-1257-01
Type of Action: Amendment — Amendment No.: 01
Date Issued: 4/20/05 — License Reviewer: MW, MS

File No.: 8
Licensee: Aurora Baycare Medical Center — License No.: 009-1017-01
Type of Action: Amendment — Amendment No.: 05
Date Issued: 3/23/05 — License Reviewer: MW

Comment:
An authorized use of gadolinium-153 was inadvertently omitted for one authorized user.

File No.: 9
Licensee: Bellin Memorial Hospital
Type of Action: Renewal
Date Issued: 3/23/05
License No.: 009-1033-01
Amendment No.: 02
License Reviewer: RS

File No.: 10
Licensee: Advanced Healthcare, S.C.
Type of Action: Amendment
Date Issued: 6/27/05
License No.: 079-1001-01
Amendment No.: 02
License Reviewer: RS

File No.: 11
Licensee: Northern Shared Medical Services
Type of Action: Amendment
Date Issued: 2/11/05
License No.: 025-1209-01
Amendment No.: 05
License Reviewer: RS

File No.: 12
Licensee: St. Joseph Hospital
Type of Action: Termination
Date Issued: 3/12/04
License No.: 079-1288-02
Amendment No.: 01
License Reviewer: PC

File No.: 13
Licensee: Appleton Medical Center
Type of Actions: Renewal, Amendment
Dates Issued: 11/30/04, 3/30/05
License No.: 087-1014-01
Amendment Nos.: 04, 05
License Reviewer: PC

File No.: 14
Licensee: MD Imaging
Type of Action: Amendment
Date Issued: 10/8/04
License No.: 079-1190-01
Amendment No.: 03
License Reviewer: PC

File No.: 15
Licensee: Shared Medical
Type of Action: Conversion
Date Issued: 6/15/04
License No.: 005-1271-01
Amendment No.: 00
License Reviewer: LD

Comment:
Two locations of use were properly requested, but inadvertently omitted from this action.

File No.: 16
Licensee: Bay Area Medical Center
Type of Action: Conversion
Date Issued: 3/23/04
License No.: 075-1030-01
Amendment No.: 00
License Reviewer: LD

File No.: 17
Licensee: Prevea Clinic, Inc.
Type of Action: New
Date Issued: 7/15/05
License No.: 009-1174-01
Amendment No.: 00
License Reviewer: LD

File No.: 18
Licensee: Waukesha Foundry Co.
License No.: 133-1337-01
Type of Action: Conversion
Amendment No.: 00
Date Issued: 11/1/04
License Reviewer: JH

File No.: 19
Licensee: Milwaukee Cardiac Nuclear Imaging
License No.: 079-1378-01
Type of Action: Termination
Amendment No.: 01
Date Issued: 3/9/05
License Reviewer: JH

Comment:
This termination was completed without written confirmation from the licensee that radioactive material was no longer possessed.

File No.: 20
Licensee: Univ. of Wisconsin - Madison
License No.: 025-1323-04
Type of Action: Renewal
Amendment No.: 01
Date Issued: 7/1/05
License Reviewer: JH

Comment:
This action contained multiple typographical errors.

File No.: 21
Licensee: Univ. of Wisconsin - Madison
License No.: 025-1323-01
Type of Actions: Amendments
Amendment Nos.: 05, 06, 07
Dates Issued: 11/29/04, 6/2/05, 6/21/05
License Reviewer: JH

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Wisconsin Public Services Corp. License No.: General Licensee
Date of Incident: 9/25/03 NMED No.: 030825
Investigation Date: 10/14/03 Type of Incident: Unauthorized Removal of Gauge
Type of Investigation: Inspection

File No.: 2
Licensee: Mead & Hunt Inc. License No.: 025-1167-01
Date of Incident: 7/29/04 NMED No.: 040604
Investigation Date: 7/30/04 Type of Incident: Damaged Gauge
Type of Investigation: Inspection

File No.: 3
Licensee: Cardinal Health 414, Inc. License No.: 025-1123-01
Date of Incident: 8/9/04 NMED No.: 040578
Investigation Date: 8/10/04 Type of Incident: Release of Radioactive Material
Type of Investigation: Inspection

File No.: 4
Licensee: University of Wisconsin License No.: 025-1323-01
Date of Incident: 8/30/04 NMED No.: 040643
Investigation Date: 9/3/04 Type of Incident: Loss/Recovery of Radioactive Material
Type of Investigation: Inspection

File No.: 5
Licensee: Aurora Baycare Medical Center License No.: 009-1017-01
Date of Incident: 8/31/04 NMED No.: 040635
Investigation Date: 9/2/04 Type of Incident: Equipment Malfunction
Type of Investigation: Inspection

File No.: 6
Licensee: Memorial Hospital of Burlington License No.: 101-1173-01
Date of Incident: 9/1/04 NMED No.: 050410
Investigation Date: 3/9/05 Type of Incident: Loss of RAM
Type of Investigation: Inspection

Comment:
This incident was discovered during a routine inspection.

File No.: 7
Licensee: Mercy Hospital License No.: 105-1176-01
Date of Incident: 7/13/04 NMED No.: 050353
Investigation Date: 3/15/05 Type of Incident: Other (Abnormal Occurrence)
Type of Investigation: Inspection

Comment:
This incident was discovered during a routine inspection.

File No.: 8
Licensee: University of Wisconsin
License No.: 025-1323-01
Date of Incident: 4/5/05
NMED No.: 050235
Investigation Dates: 4/11-5/3/05
Type of Incident: Medical Event (Abnormal Occurrence)
Type of Investigation: Inspection

Comment:
Enforcement action, including a civil penalty, was issued. This event has not been closed by the state. The Section has retained a medical consultant to review the medical consequences to the patient.

File No.: 9
Licensee: Aurora Baycare Medical Center
License No.: 009-1017-01
Date of Incident: 4/19/05
NMED No.: 050289
Investigation Date: 4/25/05
Type of Incident: Equipment Malfunction, Leaking Source
Type of Investigation: Inspection

Comment:
Information Notice concerning MICK® Applicators was developed and distributed to Wisconsin licensees. This event has not been closed by the state. The manufacturer is currently investigating the cause of the device malfunction.

File No.: 10
Licensee: Gunderson Lutheran Medical Center
License No.: 063-1121-01
Date of Incident: 5/18/05
NMED No.: 050351
Investigation Date: 5/19/05
Type of Incident: Equipment Malfunction, Leaking Source
Type of Investigation: Inspection

Comment:
Information Notice concerning MICK® Applicators was developed and distributed to Wisconsin licensees. This event has not been closed by the state. The manufacturer is currently investigating the cause of the device malfunction.

File No.: 11
Licensee: Aspirus - Wausau Hospital
License No.: 073-1342-01
Date of Incident: 7/6/05
NMED No.: 050451
Investigation Date: 7/11/05
Type of Incident: Medical Event
Type of Investigation: Inspection