September 22, 2009

MEMORANDUM TO: Martin J. Virgilio
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Joseph R. Gray, Associate General Counsel
for Licensing and Regulation
Office of the General Counsel

George Pangburn, Deputy Director
Office of Federal and State Materials
and Environmental Management Programs

Charles A. Casto, Deputy Regional Administrator
Region IV

FROM: Aaron T. McCraw, IMPEP Project Manager ***/RA/***
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) REVIEW OF THE WISCONSIN AGREEMENT STATE PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Enclosure 1) documenting the IMPEP review of the Wisconsin Agreement State Program. The review was conducted by an interoffice team during the period of July 13-17, 2009. The review team issued a draft report to the State on August 6, 2009, for factual comment. Wisconsin responded to the findings and conclusions of the review by e-mail dated August 31, 2009, from Cheryl Rogers, Supervisor, Radioactive Materials Program. The State provided one clarifying comment and one correction, both of which were incorporated into the proposed final report.

The review team is recommending that Wisconsin's performance be found "satisfactory" for all performance indicators reviewed. The review team made no recommendations regarding program performance. Overall, the review team is recommending 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 is recommending that the next full IMPEP review take place in approximately 4 years.

The MRB meeting to consider the Wisconsin report is scheduled for **Tuesday, October 6, 2009, from 10:30 a.m. - 11:30 a.m. EDT, in Two White Flint North, Room 8-A1**. In accordance with Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, the meeting is open to the public. The agenda for the meeting is enclosed (Enclosure 2).

If you have any questions prior to the meeting, please contact me at 630-829-9650.

Enclosures:
As stated

cc w/encl: Thomas Sieger, Deputy Administrator
Wisconsin Division of Public Health

Paul Schmitt, Chief
Wisconsin Radiation
Protection Section

Shawn Seeley, Maine
Organization of Agreement States
Liaison to the MRB

The MRB meeting to consider the Nevada report is scheduled for **Tuesday, October 6, 2009, from 10:30 a.m. - 11:30 a.m. EDT, in Two White Flint North, Room 8-A1**. In accordance with Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, the meeting is open to the public. The agenda for the meeting is enclosed (Enclosure 2).

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DATE	09/22/09							

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U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE WSCONSIN AGREEMENT STATE PROGRAM

JULY 13-17, 2009

PROPOSED FINAL REPORT

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 July 13-17, 2009, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas. 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 NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of August 26, 2005, to July 17, 2009, were discussed with Wisconsin managers on the last day of the review.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

The Wisconsin Agreement State Program is administered by the Radiation Protection Section (the Section). The Section is part of the Bureau of Environmental and Occupational Health within the Division of Public Health (the Division). Organization charts for the State, the Department, and the Division are included as Appendix B.

At the time of the review, the Wisconsin Agreement State Program regulated 330 specific licenses authorizing byproduct, source, and certain special nuclear materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between NRC and the State of Wisconsin.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Section on April 9, 2009. The Section provided its response to the questionnaire on June 11, 2009, with an update dated July 16, 2009. A publicly available version of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML092180388.

The review team's general approach for conduct of this review consisted of: (1) examination of the Section's response to the questionnaire; (2) review of applicable Wisconsin statutes and regulations; (3) analysis of quantitative information from the Section's databases; (4) technical review of selected regulatory actions; (5) field accompaniments of four inspectors; and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicator and made a preliminary assessment of the Wisconsin Agreement State Program's performance.

Section 2.0 of this report covers the State's actions in response to any recommendations made during previous reviews. Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on August 25, 2005, the review team made no recommendations in regard to program performance.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC Regional and Agreement State radioactive materials programs. These indicators are: (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.

3.1 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 managers and staff, reviewed job descriptions and training records, and considered any workload backlogs.

The Section, headed by the Section Chief, devotes approximately 9 full time equivalents (FTE) to the radioactive materials program, of which 5.8 are allotted for licensing and inspection. The remaining 3.2 FTE include program management, administrative support 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.

Since the last review, six individuals left the program, one of which transferred to a different position in the Section. During the review period, five new staff members were hired, three of which are still with the program. At the time of the review, the radioactive materials program had two vacancies. One position became vacant December 2008 and the other was a new position that was recently transferred to the Section. The position under which licensing and inspection efforts are hired is entitled Nuclear Engineer; after 3 years of experience, an individual is designated a Senior Nuclear Engineer. Currently, there are three Nuclear Engineers, and four Senior Nuclear Engineers in the Unit. Two recently hired staff members were not fully qualified to independently perform licensing or inspection activities at the time of the review; however, applications for required courses were submitted to complete their full qualification.

The Section has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." 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 Unit 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.

The review team noted that Section managers encourage and support training opportunities, based on program needs and funding. The review team concluded that the Section's staffing and training is adequate to carry out its regulatory duties.

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.

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Section's questionnaire response relative to this indicator, data gathered from the Section's database, examination of completed inspection casework, and interviews with the Unit Supervisor and staff members.

The review team verified that Wisconsin's inspection frequencies for all types of radioactive material licenses are at least the same frequency as NRC's inspection frequencies, listed in IMC 2800, "Materials Inspection Program." Some categories of licenses were assigned inspection frequencies that prescribe a more frequent inspection schedule than those prescribed in IMC 2800, such as remote afterloader units and nuclear pharmacies.

The Section conducted a total of 251 inspections of Priority 1, 2, and 3 licensees during the review period. The review team identified 11 of these inspections that were conducted overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. IThe review team did not identify any inspections that were overdue at the time of the review. The review team also evaluated the Section's timeliness for conducting initial inspections. The review team noted that the Section conducted 16 initial inspections during the review period, of which 2 were conducted greater than 12 months after license issuance. As required by IMC 2800, initial inspections should be conducted within 12 months of license issuance. One of the Section's overdue initial inspections was conducted 3 months late; the other 1 month late. The review team verified that there were no overdue initial inspections at the time of the review. Overall, the review team calculated that the Section performed 6 percent of all Priority 1, 2, and 3 and initial inspections overdue during the review period.

The review team evaluated the Section's timeliness of issuance of inspection findings. The Section has an effective and efficient process that helps ensure that inspection findings are communicated to licensees in a timely manner. The Section has a goal of completing inspection reports within 30 days of the final date of the inspection. At the conclusion of each inspection, inspectors have the option to send inspection findings from the office or to issue a form similar to NRC's Form 591 that can be left with the licensee at the conclusion of the inspection. The Section uses this form to document both clear inspections and inspections identifying infractions, deficiencies, or recommendations. The inspector can require a written response from the licensee describing corrective actions to address any infractions, deficiencies, or recommendations. The review team determined that inspection findings were

usually issued within 30 days of the inspection. Of the 25 inspection files reviewed by the review team, one inspection summary was issued beyond the 30-day goal.

During the review period, the Section received requests for reciprocity from 78 Priority 1, 2 and 3 licensees, and performed inspections of 49 percent of those licensees. The Section exceeded the criterion in IMC 1220 "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," that requires on-site inspection of 20 percent of candidate licensees operating under reciprocity in each of the 4 years covered by the review period.

The review team determined that the Section adequately planned for, and performed, the initial set of Increased Controls inspections of affected licensees. The review team evaluated the Section's prioritization methodology and found it acceptable. The Section identified 27 licensees that were subject to the Increased Controls and performed all of the initial inspections in a timely manner. The Section adequately evaluated the pertinent aspects of the security measures, including changes in licensee personnel or operations, during subsequent routine inspections of Increased Controls licensees.

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.

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, and inspection notes, and interviewed the responsible inspectors for 26 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by nine current and former inspectors and covered a wide variety of inspection types involving both initial and routine inspections. The casework included inspection of various types of programs, including: service providers, nuclear medicine, high dose-rate remote afterloader, medical broad scope, industrial radiography, self-shielded irradiator, gamma knife, portable gauge, reciprocity, and Increased Controls. Appendix C lists the inspection casework files reviewed and includes case-specific comments.

Based on the evaluation of casework, the review team determined that inspections covered almost all aspects of the licensees' radiation safety and security programs. The review team noted four instances that, during reciprocity and field site inspections, Increased Controls inspections were not performed, or were not completely performed, to ensure licensee compliance with fundamental security aspects of the Increased Controls requirements. In interviews with the Unit Supervisor, the Supervisor provided an explanation regarding the lack of Increased Controls inspections, which included a lack of time, and dispatching inspectors that were not properly trained to inspect the licensees' implementation of the Increased Controls. The Unit Supervisor indicated that more inspectors are being trained. The Unit Supervisor committed to reinforce expectations that will require aspects of the Increased Controls to be inspected, when possible. The review team verified that the Section is also reviewing aspects of the National Source Tracking System (NSTS) program.

With the exception stated in the above paragraph, the review team noted that inspection reports were thorough, complete, consistent, and of high quality with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable.

Inspection report documentation supported violations, recommendations made to licensees, unresolved safety issues, and discussions held with licensees during exit interviews.

The Section requires licensees to respond to violations within 30 days of report issuance. Violations are considered the most severe type of finding and are usually only dispatched from the office after management review and approval. During the review of the Increased Controls inspection casework, the review team noted that the Section did not issue violations of the Increased Controls requirements. If deficiencies were identified during the first inspection, the Section performed several inspections of the same facility and followed up on those deficiencies until full compliance was achieved. For subsequent inspections, the Section issued violations if deficiencies were identified.

While on site, the review team evaluated the Section's handling and storing of sensitive information. The Section maintains two separate color-coded files for licensees subject to the Increased Controls: one that contains the routine licensing and inspection information and a second file that pertains to the inspection of the licensee's implementation of the Increased Controls. The Section implemented this policy for better control of potential security-related information, as the second file is stored in a locked file cabinet. Documents observed were sufficiently marked as sensitive information to be withheld from public disclosure.

The Section has a policy to accompany all staff performing radioactive materials inspections on an annual basis. The review team verified that the Unit Supervisor performed staff accompaniments annually of all staff performing materials inspections. A record of each accompaniment was noted on the inspection report and placed in the staff member's training record.

The review team verified that the Section maintains an adequate supply of appropriately calibrated survey instruments to support the inspection program, as well as to respond to radioactive materials incidents and emergency conditions. Instruments used to support the materials inspection program are sent to an authorized entity for calibration. The Section recently purchased a mobile laboratory that can be used for routine inspections or emergency events.

The review team accompanied four of the Section's inspectors in April and June 2009. The inspectors conducted inspections at a source material manufacturer, an industrial radiographer, a nuclear medicine clinic, and a research facility. The inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspectors held entrance and exit meetings with the appropriate level of licensee management. The review team determined that the inspections were adequate to assess radiological health, safety, and security 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 Inspection, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 35 licensing actions for 21 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of 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 review team also reviewed casework files 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, peer/supervisory review, and proper signatures.

The review team selected licensing casework to provide a representative sample of licensing actions that were completed during the review period. Licensing actions selected for evaluation included 3 new licenses, 10 renewals, 20 amendments, and 2 license terminations. Files reviewed included a cross-section of license types, including: medical and academic broad scope, medical institution - limited, private practice, mobile nuclear medicine, nuclear pharmacy, permanent radiography, radiography - temporary jobsite, portable gauge, fixed gauge, and self-shielded irradiator. A listing of the licensing casework reviewed 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, safety, and security issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and were inspectible. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were 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 (named RAMPROD). The status of all actions is tracked by RAMPROD. The Supervisor assigns each action to one of seven 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. 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. All completed actions are reviewed and signed by the Supervisor. The administrative staff conducts an administrative review and final processing before mailing out to the licensee. New and renewed licenses are issued for a 5-year term. After the 5-year term, licensees are required to submit a complete renewal application to maintain current information in the file.

The Section uses templates to generate most correspondence and licenses, and 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.

The review team examined the Section's licensing practices in regard to the Increased Controls and Fingerprinting requirements. The review team noted that the Section added legally binding license conditions to the licenses that met the criteria for implementing the Increased Controls, including fingerprinting, as appropriate. The review team analyzed the Section's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team verified that the Section has a process in place for identifying new or amended licenses that meet the criteria to implement the Increased Controls.

The review team evaluated the Section's efforts to impose the National Source Tracking System (NSTS) requirements on certain licensees. The Section amended affected licenses by adding legally binding license conditions, which were approved by NRC in September 2008. Most sealed source inventories were loaded into the system by the January 31, 2009 deadline. Staff demonstrated proficiency in using the NSTS database system.

The review team noted the use of a pre-licensing checklist and that the Section follows the implementation guidance provided in NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Letter RCPD-08-020, dated September 22, 2008, to enhance the basis for confidence that radioactive materials will be used as specified on a license. The review team observed that pre-licensing site visits were documented on the license review sheet. If a pre-licensing site visit was not required, the Section included a description of why a visit was not performed (e.g., the applicant was not a new entity or they were licensed in another state) on the license review sheet.

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.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Section's actions in responding to incidents and allegations, the review team examined the Section's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Wisconsin in the Nuclear Material Events Database (NMED) against those contained in the Section's files, and evaluated the casework for 21 of 48 reported radioactive materials incidents. A listing of the casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Section's response to five allegations involving radioactive materials, including the two allegations that NRC forwarded to the State during the review period.

When notified of an incident or an allegation, the Unit Supervisor and staff discuss the initial response and the need for an on-site investigation, based on the safety significance. The Section maintains a database for tracking the status of all incidents and allegations. If the incident meets the reportability thresholds, as established in the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events," the Section promptly notifies the NRC Headquarters Operations Center and NRC Region III. If the investigation is complex and extends over a period of time, NMED is appropriately updated, using the NMED software. Of the incidents evaluated by the review team, all had been reported to the NRC within the required time frame and been properly completed in NMED.

The incidents selected for review included medical events, lost or stolen radioactive material, contamination events, a leaking source, a transportation event, and equipment failures. The review team determined that the Section's responses to incidents were thorough, complete, and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. The Section immediately dispatched inspectors to the site when the possibility of an immediate threat to public health and safety existed. When no immediate threat was present and the Section determined that the licensee had qualified, competent individuals investigating the incident, the Section generally responded telephonically with an on-site follow-up inspection at a later date. The review team noted that at the conclusion of investigations, inspectors generated narrative reports that thoroughly documented the investigations. Records were stored in the Section's license files and electronic filing system and were marked appropriately.

In evaluating the effectiveness of the Section's response to allegations, the review team evaluated the casework for five allegations. The review team concluded that the Section consistently took prompt and appropriate action in response to concerns raised. The review team noted that the Section thoroughly documented the investigations and retained all necessary documentation to appropriately close the allegations. The Section notified the allegers of the conclusion of the investigations. The review team determined that the Section adequately protected the identity of allegers.

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.

4.0 NON-COMMON PERFORMANCE INDICATORS

4.1 Compatibility Requirements

4.1.1 Legislation

Wisconsin became an Agreement State on August 11, 2003. Legislative authority to create an agency and enter into an Agreement with the NRC is granted in Wisconsin Statue, Section 254.43. Current effective legislation that affects the radiation control program is contained in Sections 254.31 through 254.45.

Chapter DHS 157, Wisconsin Administrative Code, details the licensing requirements and fees. DHS 157 is divided into 14 subchapters, relating to the regulation of radioactive materials and other sources of radiation. Along with their response to the questionnaire, the Section provided the review team with the opportunity to review copies of proposed legislation that affects the radiation control program.

4.1.2 Program Elements Required for Compatibility

The Wisconsin regulations governing radiation protection requirements are found in various subchapters of the Department of Health Services Section 157 of the Wisconsin Administrative Code. These rules apply to all ionizing radiation, whether emitted from radioactive materials or

produced by machines. Section 254.365 of the Wisconsin Statures requires a license for the possession, use, manufacture, transport, storage or transfer of radioactive material.

For each rulemaking initiative, Division staff develops a rulemaking plan that provides overview information (reason for rule changes, potential cost, stakeholder involvement, goals in completing rulemaking, etc), and details of the changes of the existing rule. The Division staff then submits all rulemaking documents, which include the rulemaking change language, to the Office of Legal Counsel for review. Upon completion of the Office of Legal Counsel review, the rulemaking document is submitted to the Office of the Secretary for release to the public for comment. At the time of publication for public comment, the Section sends the proposed rule to NRC for compatibility review. Regulatory action takes between 1 to 2 years to process and incorporate changes to DHS 157, the Chapter on Radiation Protection. The Section Chief is responsible for the entire radiation protection rule process. The Section has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

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 State Regulation Status Sheet that FSME maintains.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after the effective date of NRC's regulations. At the time of this review, the following 4 amendments were overdue:

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, 32 amendment (65 FR 79162), that was due for Agreement State implementation on February 16, 2004.

  Status: Nine of 10 comments listed in NRC's August 31, 2006 letter, commenting on amendment proposals, needed to be addressed by the State. The State's proposed regulation changes are being reviewed by the Office of Legal Services, prior to publication for public comment.

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that was due for Agreement State implementation on October 10, 2007.

  Status: Four comments, pertaining to this NRC amendment, listed in NRC letter dated January 9, 2007, needed to be addressed by the State. The State's proposed regulation changes are being reviewed by the Office of Legal Services, prior to publication for public comment.

- "Medical Byproduct Material – Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336), that was due for Agreement State implementation on April 29, 2008.

Status: Four comments, pertaining to this NRC amendment, listed in NRC letter dated March 13, 2007, needed to be addressed by the State. The State's proposed regulation changes are being reviewed by the Office of Legal Services, prior to publication for public comment.

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70amendment (71 FR 15005), that was due for Agreement State implementation on March 27, 2009.

  Status: The State's proposed regulation changes are being reviewed by the Office of Legal Services, prior to publication for public comment. The State will submit the proposed regulation changes to NRC for a compatibility review during the public comment period.

The review team identified the following regulation amendments that will be needed in the future. The Section indicated that the Wisconsin regulations are currently proposed and progressing through the rule promulgation process:

- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendment (72 FR 45147, 54207), that is due for Agreement State adoption by October 29, 2010.

- "Requirements for Expanded Definition of Byproduct Material,"10 CFR Parts 20, 30, 31, 32, 33, 35, 61, 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.

- "Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material; Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.

- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19, 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.

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

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 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. Overall, 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 IMPEP review take place in approximately 4 years.

LIST OF APPENDIXES AND ATTACHMENT

Appendix A	IMPEP Review Team Members
Appendix B	Wisconsin Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Attachment	August 31, 2009 E-mail from Cheryl Rogers Wisconsin's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Joseph DeCicco, FSME	Team Leader Compatibility Requirements
James Harris, KS	Technical Staffing and Training Technical Quality of Licensing Actions
James Lynch, Region III	Status of Materials Inspection Program Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Michael LaFranzo, Region III	Technical Quality of Inspections

APPENDIX B

WISCONSIN ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML092100344

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: Metaltek International License No.: 133-1181-01
Inspection Type: Routine/Special, Unannounced Priority: 1
Inspection Dates: 3/27/07, 4/19/07, 7/18/07 Inspectors: PC, CR

File No.: 2
Licensee: Aurora Health Care Metro, Inc. License No.: 079-1281-01
Inspection Type: Routine/Special, Unannounced Priority: 1
Inspection Dates: 6/12/07, 8/13/07 Inspector: JH

File No.: 3
Licensee: Great Lakes Testing, Inc. License No.: 009-1116-01
Inspection Type: Routine/Special, Unannounced Priority: 1
Inspection Dates: 6/19-20/06, 8/31/06 Inspectors: MW, JH

File No.: 4
Licensee: Community Blood Center, Inc. License No.: 087-1067-01
Inspection Type: Routine/Special, Unannounced Priority: 5
Inspection Date: 10/4/06 Inspectors: JH, PC

File No.: 5
Licensee: Shaw Pipeline Services, Inc. License No.: 035-1236-01
Inspection Type: Routine/Special, Unannounced Priority: 1
Inspection Date: 6/27/08 Inspectors: CR, CD

File No.: 6
Licensee: Metaltek International License No.: 133-1181-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 6/8/09 Inspector: KP

File No.: 7
Licensee: Conam Inspections License No.: NRC 12-16559-02
Inspection Type: Reciprocity, Initial Priority: 1
Inspection Date: 7/13/06 Inspectors: MW, MM

File No.: 8
Licensee: Great Lakes Testing License No.: 009-1116-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 7/9/08 Inspector: PC

File No.: 9
Licensee: Cardinal Health License No.: 141-1306-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 11/26/08 Inspectors: CT, JH

File No.: 10
Licensee: Mercy Hospital License No.: 105-1176-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 1/29/09 Inspectors: DS, JH

File No.: 11
Licensee: Lafayette Testing Services License No.: 079-1147-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 4/1/08 Inspector: PJC

File No.: 12
Licensee: Aurora Health Care Southern Lakes, Inc. License No.: 127-1023-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/3/08 Inspector: JH

File No.: 13
Licensee: CERAC, Inc. License No.: 079-1055-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 6/9/09 Inspector: MS

File No.: 14
Licensee: St. Michael's Hospital License No.: 097-1301-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 7/6/09 Inspector: LD

File No.: 15
Licensee: Team Industrial Services License No.: 079-2005-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 1/31/07 Inspector: MM

File No.: 16
Licensee: Wisconsin Medical Cyclotron License No.: 079-1366-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 3/14/08 Inspector: RS

File No.: 17
Licensee: Dane Co. Sanitary Landfill Site No. 2 License No.: 025-1082-01
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 7/11/07 Inspector: SM

File No.: 18
Licensee: Varian Medical Systems License No.: 45-30957-01
Inspection Type: Reciprocity. Announced Priority: 1
Inspection Date: 5/11/09 Inspector: DS

File No.: 19
Licensee: Mayo Clinic License No.: MN-1047-201-55
Inspection Type: Reciprocity, Announced Priority: 3
Inspection Date: 5/25/07 Inspector: RS

File No.: 20
Licensee: JANX License No.: 21-16560-01
Inspection Type: Reciprocity, Unannounced Priority: 1
Inspection Date: 7/16/08 Inspector: KP

File No.: 21
Licensee: JANX License No.: 21-16560-01
Inspection Type: Reciprocity, Unannounced Priority: 1
Inspection Date: 4/23/07 Inspector: MM

File No.: 22
Licensee: Dean Medical Center License No.: 025-1083-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 3/22/06 Inspector: MW

File No.: 23
Licensee: St. Mary's Hospital License No.: 025-1293-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/4/07 Inspector: RS

File No.: 24
Licensee: AITEC USA Investments, Inc. License No.: TX L05718
Inspection Type: Reciprocity, Announced Priority: 1
Inspection Date: 4/4/07 Inspector: MM

File No.: 25
Licensee: Seaman Nuclear Corporation License No.: 079-1257-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 1/29/08 Inspectors: MS, PC

File No.: 26
Licensee: University of Wisconsin
Madison Safety Department
License No.: 025-1323-01
Inspection Type: Routine, Unannounced
Priority: 1
Inspection Dates: 11/13-20/07
Inspectors: MS, LD, JH, SM

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Molecular Biology Resources, Inc.
License No.: 079-1195-01
Inspection Type: Routine, Unannounced
Priority: 5
Inspection Date: 4/27/09
Inspector: CT

Accompaniment No.: 2
Licensee: Wheaton Franciscan Medical Group, Inc.
License No.: 079-1352-01
Inspection Type: Routine, Unannounced
Priority: 5
Inspection Date: 4/28/09
Inspector: DS

Accompaniment No.: 3
Licensee: MetalTek International
License No.: 133-1181-01
Inspection Type: Special, Unannounced
Priority: 1
Inspection Date: 6/8/09
Inspector: KP

Accompaniment No.: 4
Licensee: CERAC, Inc.
License No.: 079-1055-01
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Date: 6/9/09
Inspector: MS

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Great Lakes Testing — License No.: 009-1116-01
Type of Actions: Renewal, Amendment — Amendment Nos.: 04, 05, 06
Dates Issued: 5/12/08, 11/14/08, 12/10/08 — License Reviewer: MS

File No.: 2
Licensee: Community Blood Center — License No.: 087-1067-01
Types of Action: Renewal, Amendment — Amendment Nos.: 03, 04, 05, 06
Dates Issued: 10/09/07, 5/12/08, 11/14/08, 12/23/08 — License Reviewers: LD,MS

File No.: 3
Licensee: Aurora Health Care Metro — License No.: 079-1281-01
Type of Action: Amendment — Amendment Nos.: 08, 14
Dates Issued: 9/30/05, 12/22/08 — License Reviewers: PC, LD

File No.: 4
Licensee: Shaw Pipeline Service — License No.: 035-1236-01
Type of Action: New — Amendment No.: 0
Date Issued: 12/18/07 — License Reviewer: KP

File No.: 5
Licensee: BayCare Clinic — License No.: 139-1309-01
Types of Action: Renewal, Amendment — Amendment Nos.: 02, 03
Dates Issued: 11/5/07, 5/29/09 — License Reviewers: KP, LD

File No.: 6
Licensee: Appleton Medical Center — License No.: 087-1014-01
Type of Action: Amendment — Amendment Nos.: 06, 08, 12
Dates Issued: 10/14/05, 10/27/06, 10/6/08 — License Reviewers: MW, RS, MS

File No.: 7
Licensee: Northern Shared Medical Service — License No.: 025-1209-01
Type of Action: Amendment — Amendment Nos.: 24, 30, 31
Dates Issued: 1/22/07, 7/1/08, 4/1/09 — License Reviewers: RS, JH, DS

File No.: 8
Licensee: Community Memorial Hospital — License No.: 133-1069-01
Types of Action: Renewal, Amendment — Amendment Nos.: 16, 17
Dates Issued: 12/12/08, 1/21/09 — License Reviewer: DS

File No.: 9
Licensee: ECS Illinois
Type of Action: New
Date Issued: 2/4/08
License No.: 105-1221-01
Amendment No.: 0
License Reviewer: KP

File No.: 10
Licensee: Community Memorial Hospital
Type of Action: Renewal
Date Issued: 2/7/07
License No.: 083-1068-01
Amendment No.: 01
License Reviewer: MS

File No.: 11
Licensee: Chosen Valley Testing
Type of Action: Amendment
Date Issued: 5/19/08
License No.: 063-2009-01
Amendment No.: 04
License Reviewer: LD

File No.: 12
Licensee: CGC
Type of Action: Renewal, Amendment
Dates Issued: 2/28/08, 9/24/08
License No.: 025-1056-01
Amendment Nos.: 06, 07
License Reviewers: MW, PC

File No.: 13
Licensee: Standard Imaging
Type of Action: Amendment
Date Issued: 12/17/07
License No.: 025-1304-01
Amendment No.: 06
License Reviewer: LD

File No.: 14
Licensee: Ripon College
Type of Action: Termination
Date Issued: 7/19/06
License No.: 039-1240-01
Amendment No.: 02
License Reviewer: MW

File No.: 15
Licensee: Medi-Physics
Type of Action: Amendment
Dates Issued: 5/29/07, 3/4/09
License No.: 079-1168-01
Amendment Nos.: 09, 18
License Reviewer: LD

File No.: 16
Licensee: Kenosha County Div. of Health
Type of Action: Renewal
Date Issued: 8/13/08
License No.: 059-1140-01
Amendment No.: 04
License Reviewer: KP

File No.: 17
Licensee: Domtar A.W.
Type of Action: Renewal
Date Issued: 6/29/09
License No.: 141-1086-01
Amendment No.: 04
License Reviewer: CT

File No.: 18
Licensee: Community Housing Initiative
License No.: 133-1098-01
Type of Action: Termination
Amendment No.: 03
Date Issued: 12/6/07
License Reviewer: KP

File No.: 19
Licensee: The Wisconsin Heart Hospital
License No.: 079-1359-01
Type of Action: Renewal
Amendment No.: 05
Date Issued: 1/29/09
License Reviewer: CT

File No.: 20
Licensee: R H Batterman & Co.
License No.: 105-1233-01
Type of Action: Renewal
Amendment No.: 05
Date Issued: 1/21/09
License Reviewer: CT

File No.: 21
Licensee: Road Runner Consulting
License No.: 025-1336-01
Type of Action: New
Amendment No.: 0
Date Issued: 7/17/07
License Reviewer: SM

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Cardinal Health
Date of Incident: 2/24/06
Investigation Date: 2/27/06
License No.: 079-1311-01
NMED Log No.: 060172
Type of Incident: Contamination Event
Type of Investigation: Telephone

File No.: 2
Licensee: Cardinal Health
Date of Incident: 3/3/06
Investigation Date: 3/9/06
License No.: 079-1311-01
NMED Log No.: 060175
Type of Incident: Contamination Event
Type of Investigation: Telephone

File No.: 3
Licensee: Elmbrook Memorial Hospital
Date of Incident: 5/16/06
Investigation Date: 5/17/06
License No.: 079-1092-01
NMED Log No.: 060610
Type of Incident: Lost Sources
Type of Investigation: Telephone

File No.: 4
Licensee: University of Wisconsin
Date of Incident: 12/27/06
Investigation Date: 1/8/07
License No.: 025-1323-01
NMED Log No.: 070015
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 5
Licensee: Bristol-Myers Squibb Medical Imaging
Date of Incident: 1/14/07
Investigation Date: 1/17/07
License No.: Non-licensee
NMED Log No.: 070027
Type of Incident: Lost Sources
Type of Investigation: Site

File No.: 6
Licensee: Miller Compressing
Date of Incident: 2/22/07
Investigation Date: 2/22/07
License No.: Non-licensee
NMED Log No.: 070132
Type of Incident: Lost Sources
Type of Investigation: Telephone

File No.: 7
Licensee: Saint Vincent Hospital
Date of Incident: 4/4/07
Investigation Date: 4/6/07
License No.: 09-1303-01
NMED Log No.: 070211
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 8
Licensee: Roofing Consultants, Ltd.
Date of Incident: 4/24/07
Investigation Date: 4/24/07
License No.: Non-license
NMED Log No.: 070250
Type of Incident: Stolen Sources
Type of Investigation: Telephone

File No.: 9
Licensee: Aurora Saint Luke's Medical Center
Date of Incident: 5/31/07
Investigation Date: 5/31/07
License No.: 079-1281-01
NMED Log No.: 070350
Type of Incident: Medical Event
Type of Investigation: Telephone

File No.: 10
Licensee: Wheaton Franciscan Healthcare-St. Francis
Date of Incident: 8/28/07
Investigation Date: 8/28/07
License No.: 079-1285-01
NMED Log No.: 070562
Type of Incident: Lost Source
Type of Investigation: Telephone

File No.: 11
Licensee: Wheaton Franciscan Healthcare-St. Francis
Date of Incident: 9/19/07
Investigation Date: 9/21/07
License No.: 079-1285-01
NMED Log No.: 070689
Type of Incident: Leaking Source
Type of Investigation: Site

File No.: 12
Licensee: Aurora Saint Luke's Medical Center
Date of Incident: 1/31/08
Investigation Date: 1/31/08
License No.: 079-1281-01
NMED Log No.: 080070
Type of Incident: Equipment Failure
Type of Investigation: Telephone

Comment:
The Section did not perform a reactive inspection, as planned.

File No.: 13
Licensee: Marshfield Clinic Minocqua Center
Date of Incident: 3/4/08
Investigation Date: 3/4/08
License No.: 141-1162-01
NMED Log No.: 080144
Type of Incident: Lost Sources
Type of Investigation: Telephone

File No.: 14
Licensee: Appleton Medical Center
Date of Incident: 3/6/08
Investigation Date: 3/17/08
License No.: 087-1014-01
NMED Log No.: 080156
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 15
Licensee: Team Industrial Services, Inc.
Date of Incident: 4/15/08
Investigation Date: 5/22/08
License No.: 079-2005-01
NMED Log No.: 080238
Type of Incident: Equipment Failure
Type of Investigation: Site

File No.: 16
Licensee: University of Wisconsin
Date of Incident: 7/14/08
Investigation Date: 7/17/08
License No.: 025-1323-01
NMED Log No.: 080406
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 17
Licensee: University of Wisconsin
Date of Incident: 8/18/08
Investigation Date: 8/20/08
License No.: 025-1323-01
NMED Log No.: 080493
Type of Incident: Contamination Event
Type of Investigation: Site

File No.: 18
Licensee: GE Healthcare
Date of Incident: 12/15/08
Investigation Date: 12/15/08
License No.: Non-licensee
NMED Log No.: 090156
Type of Incident: Contaminated Equipment
Type of Investigation: Telephone

File No.: 19
Licensee: Aurora Health Care Central
Date of Incident: 3/9/09
Investigation Date: 3/12/09
License No.: 117-1022-01
NMED Log No.: 090385
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 20
Licensee: University of Wisconsin
Date of Incident: 3/18/09
Investigation Date: 3/20/09
License No.: 025-1323-01
NMED Log No.: 090398
Type of Incident: Transportation
Type of Investigation: Site

File No.: 21
Licensee: Wheaton Franciscan Healthcare-St. Joseph
Date of Incident: 6/25/09
Investigation Date: 6/29/09
License No.: 079-1288-01
NMED Log No.: 090571
Type of Incident: Medical Event
Type of Investigation: Site

ATTACHMENT

August 31, 2009 E-mail from Cheryl Rogers
Wisconsin's Response to Draft IMPEP Report

ADAMS Accession No.: ML092600596

Agenda for Management Review Board Meeting
October 6, 2009, 10:30 a.m. - 11:30 a.m. (EDT), TWFN-8-A1

1. Announcement of public meeting, request for members of the public to indicate they are participating and their affiliation.

2. MRB Chair convenes meeting. Introduction of MRB members, review team members, State representatives, and other representatives participating remotely. (Organization of Agreement States (OAS) Liaison is Shawn Seeley, Maine.)

3. Consideration of the Wisconsin IMPEP Report.

   A. Presentation of Findings Regarding Wisconsin's Program and Discussion.
      - Technical Staffing and Training
      - Status of Materials Inspection Program
      - Technical Quality of Inspections
      - Technical Quality of Licensing Actions
      - Technical Quality of Incident and Allegation Activities
      - Compatibility Requirements

   B. IMPEP Team Recommendations.
      - Recommendation for Adequacy and Compatibility Ratings
      - Recommendation for Next IMPEP Review

   C. MRB Consultation/Comments on Issuance of Report.

4. Request for comments from Wisconsin representatives, OAS Liaison, and State IMPEP team member. (State member is James Harris, Kansas.)

5. Adjournment.

Invitees:

Martin Virgilio, DEDMRT
Joseph Gray, OGC
George Pangburn, FSME
Chuck Casto, Region IV
Shawn Seeley, Maine
Cheryl Rogers, WI
Robert Lewis, FSME
Terrence Reis, FSME
Mike Franovich, OEDO
Joe DeCicco, FSME
Jim Lynch, Region III
Michael LaFranzo, Region III
James Harris, KS
Aaron McCraw, FSME
Michelle Beardsley, FSME
Karen Meyer, FSME
Duncan White, FSME

Enclosure 2