

### UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20555-0001

August 20, 2014

Charles Warzecha, Deputy Administrator Division of Public Health Wisconsin Department of Health Services 1 West Wilson Street, Room 250 Madison, WI 53701-2659

Dear Mr. Warzecha:

The U.S. 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 July 14–18, 2014. 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 the NRC's program.

NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with the NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess Agreement States' and NRC Regional Offices' radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. The final determination of adequacy and compatibility of each Agreement State program, based on the review team's report, is 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 your review and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks 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. The Management Review Board meeting is scheduled for Thursday, October 9, 2014, from 1:00–4:00 p.m. (EST). The NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. The NRC has video conferencing capability if it is more convenient for the State to

C.Warzecha - 2 -

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 301-415-2598.

Thank you for your cooperation.

Sincerely,

/RA/

Duncan White, Chief Agreement State Programs Branch Division of Materials Safety and State Agreements Office of Federal and State Materials and Environmental Management Programs

Enclosure: Wisconsin Draft IMPEP Report

cc: Paul Schmidt, Chief Radiation Protection Section

Cheryl Rogers, Supervisor Radioactive Materials Unit

C.Warzecha - 2 -

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Cheryl Rogers, Supervisor Radioactive Materials Unit

<u>Distribution</u>: (SP07) PLouden, RIII JGiesnner, RIII LDudes, FSME SAbraham, FSME MBeardsley, FSME JLynch, RIII/RSAO LRoldenOtero, RIV Riley, AL OAS Board

#### ML14231A164

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DATE	08/19/14	08/20/14	08/20/14

OFFICIAL RECORD



## INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF THE WISCONSIN AGREEMENT STATE PROGRAM

JULY 14-18, 2014

**DRAFT REPORT** 

#### **EXECUTIVE SUMMARY**

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Wisconsin Agreement State Program. The review was conducted during the period of July 14-18, 2014, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Alabama

Based on the results of this review, Wisconsin's performance was found satisfactory for all six of the performance indicators reviewed.

The review team did not make any recommendations. The review team identified a "Good Practice" by the Section for implementing the use of a Pre-Inspection Plan by each inspector to ensure that all required information is addressed during special or follow up inspections. The review team determined that the use of these plans contributed to the consistent, high technical quality of inspections during the period of high staff turnover experienced during the review period (Section 3.3).

Accordingly, the review team recommends that the Wisconsin Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The review team recommends that the next IMPEP review take place in approximately five years.

#### 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 14-18, 2014, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Alabama. 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 July 18, 2009, to June 30, 2014, were discussed with Wisconsin managers on the last day of the review.

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 Department and the Bureau are included as Appendix B.

At the time of the review, the Wisconsin Agreement State Program regulated approximately 306 specific licenses authorizing possession and use of radioactive 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 the 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 28, 2014. The Section provided its response to the questionnaire on July 1, 2014. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML14182A620.

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 database, (4) technical review of selected regulatory actions, (5) field accompaniments of five 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.

There were no recommendations made during the previous review.

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 indicator, and Section 5.0 summarizes the review team's findings.

#### 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, this concluded on July 17, 2009, the review team made no recommendations regarding the Wisconsin Agreement State Program's 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 <u>Technical Staffing and Training</u>

Considerations 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 workload backlogs.

The Section, managed by the Section Chief, has approximately 9.5 full-time equivalents (FTE) assigned to the radioactive materials program with 7.5 FTE allotted for inspection and licensing which is comparable with other programs of similar size and scope. The remaining FTE include program management, administrative support, and a half-time training coordinator.

The Section experienced significant turnover in technical staff during the review period in which eight staff members left the Section and eight new staff members were hired. The Section was able to manage this turnover due to the hiring of two additional staff in 2010, the staggered departure and hiring of staff where there was never a period during the four year review period that the staff level was below full strength, and the recruitment of highly qualified, experienced and capable staff for all positions (B.S. and M.S. degrees in nuclear/civil engineering and nuclear medicine). All but three staff members are currently fully qualified. As noted in Sections 3.3 and 3.4 the team found that the technical quality of inspections and licensing was not substantially impacted during the review period due to staff turnover. This can be attributed to the Section's successful use of mentoring, peer review, and consistent management oversight. In addition, the Section routinely uses inspection plans which are approved by the Group Leader. Additionally, peer reviews of licensing casework are performed to maintain continuity.

The Section has a documented training plan for technical staff that is consistent with the requirements in NRC's Inspection Manual Chapter (IMC) 1248, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." Staff members are assigned increasingly complex duties as they progress through the qualification process. Three recently hired staff members have been authorized to perform independent inspections and reviews of the disciplines for which they had completed training. The rest of the staff has been qualified.

The review team concluded that the Section's training program is adequate to carry out its regulatory duties and noted that Wisconsin management supports the Section's training 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.

#### 3.2 <u>Status of Materials Inspection Program</u>

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 management and staff.

The review team verified that Wisconsin's inspection frequencies for all types of radioactive material licenses are at least as frequent as similar license types listed in IMC 2800, "Materials Inspection Program." Three of the license categories established by the Section were assigned inspection priority codes that prescribe a more frequent inspection schedule than those established in IMC 2800 for similar license types. Medical broad scope programs, high dose rate remote afterloaders, and mobile nuclear medicine licensees are inspected more frequently.

The Section conducted 279 Priority 1, 2, and 3 inspections during the review period, based on the inspection frequencies established in IMC 2800. Fourteen of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800, ranging from several days to 11 months overdue. In addition, the Section performed 37 initial inspections during the review period of which 3 were conducted overdue. As required by IMC 2800, initial inspections should be conducted within 12 months of license issuance. None of the overdue inspections occurred in 2013 or 2014. The overdue inspections decreased as the staff completed qualifications and gained experience. State mandated employee furloughs and staff turnover contributed to the late inspections conducted early in the review period. Overall, the review team calculated that the Section performed 5.7 percent of its inspections overdue during the review period.

The review team evaluated the Section's timeliness in providing inspection findings to licensees. A sampling of 29 inspection reports indicated that 4 of the inspection findings were communicated to the licensees beyond the Section's goal of 30 days after the inspection. All reports were issued to licensees within 74 days post inspection.

During the review period, the Section received 90 reciprocity requests from companies wishing to perform work in Wisconsin. The review team determined that the Section conducted reciprocity inspections of 54 percent of those licensees thus far in 2014, 60 percent in 2013, 47 percent in 2012, 67 percent in 2011, 40 percent in 2010, and 53 percent in 2009. The Section exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the 5 years covered by the review period.

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 <u>Technical Quality of Inspections</u>

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 29 radioactive materials inspections conducted during the review period. The casework reviewed included a cross-section of inspections conducted by 10 current and former inspectors and covered inspections of various license types. The casework included; medical broad scope, high dose rate remote afterloader, portable gauges, industrial radiography, self-shielded irradiators, gamma knife, nuclear pharmacy, nuclear medicine, and Increased Controls for the security of large quantities of radioactive materials. Appendix C lists the inspection casework files reviewed.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of the licensee's radiation safety and security programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health, safety and security were acceptable. The documentation supported violations, recommendations made to licensees, unresolved safety issues, the effectiveness of corrective actions taken to resolve previous violations and discussions held with licensees during exit interviews. The review team verified through interviews that the Section is aware of all aspects of the National Source Tracking System program.

The Section has implemented the use of a Pre-Inspection Plan which is used by each inspector. The plan includes basic information about the licensee, priority areas being reviewed, major elements of the program, documents used during preparation and the type of equipment being used. This is also used to ensure all required information is addressed during special or follow up inspections. The use of these plans contributed to the consistent, high technical quality of inspections during the period of high staff turnover. Their preparation and use were evaluated during the review and inspector accompaniments. Inspectors stated that these were instrumental in assuring a good quality inspection. The review team identified this as a "Good Practice".

The review team evaluated the Section's handling and storing of sensitive information. During the review of the Increased Controls inspection casework, the team observed that the Section sends separate letters for health and safety, and security inspections. The Section maintains two separate color-coded files for licensees subject to increased security. The Section implemented this policy for better control of potential security-related information, as the security file is stored in a locked file cabinet.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. Inspection findings were clearly stated and documented in the reports and sent to the licensees with the appropriate letter detailing the results of the inspection. The Section issues to the licensee, either a letter indicating a clear inspection or a Notice of Violation (NOV), in letter format, which details the results of the inspection. When the Section issues an NOV, the licensee is required to provide a written corrective action plan, based on the violations cited, within 30 days.

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 noted that the Section has an adequate supply of survey instruments to support its inspection program, as well as to respond to radioactive materials incidents and emergency conditions. Instruments used to support the radioactive materials inspection program are sent to an authorized entity for calibration. The Section uses a database to track each instrument, and its next calibration date.

Accompaniments of five Section inspectors were conducted by an IMPEP team member during the week of June 9-13, 2014. The inspectors were accompanied during health and safety inspections of industrial radiography, medical therapy including high dose rate remote afterloader/gamma knife, medical diagnostic license and a portable gauge. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well-prepared for the inspection, 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 inspections were adequate to assess radiological health and 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 Inspections, be found satisfactory.

#### 3.4 <u>Technical Quality of Licensing Actions</u>

The review team examined completed licensing casework and interviewed license reviewers for 35 specific licensing actions. 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 license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 5 new licenses, 9 renewals, 3 decommissioning or termination actions, and 17 amendments. Files reviewed included a cross-section of license types including: medical and academic broad scope, medical diagnostic and therapy including high dose rate remote afterloader, temporary/permanent implant brachytherapy, and gamma knife, industrial radiography for permanent and temporary jobsites, research and development, nuclear pharmacy, gauges, manufacturers, and panoramic and self-shielded irradiators. The casework sample represented

work from 13 license reviewers. A list of the licensing casework evaluated is provided 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 and were supported by information contained in the file. 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. License reviewers use the Section's licensing guides and/or NRC NUREG-1556 series guidance documents, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses.

The administrative staff receives all licensing actions and enters all pertinent information into the Section's database, which tracks the status of all actions. 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 NRC. Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the Section's licensing procedures. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

The Section performs pre-licensing checks of all new applicants. The Section's pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All new licensees receive a pre-licensing site visit which includes an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

The review team examined the Section's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the Section uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, 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 confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Section requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The review team examined the Section's implementation of its procedure for the control of sensitive information. This procedure addresses the identification, marking, control, handling, preparation, transportation, transmission, and destruction of documents that contain sensitive information related to the Increased Controls.

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 11 radioactive materials incidents. A list of the incident casework examined may be found in Appendix E. The review team also evaluated the Section's response to all seven of their allegations involving radioactive materials, including three allegations referred to the State by the NRC during the review period.

The incidents selected for review included the following categories: stolen or missing radioactive material, potential overexposure, medical event, damaged equipment, and leaking sources. The review team determined that the Section's response to incidents was 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 dispatched inspectors for on-site investigations in five of the cases reviewed and took suitable enforcement and followup actions for the remainder. The follow up actions consisted of monitoring licensee progress and review during the next inspection. If the incident met the reportability thresholds, as established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events," the State notified the NRC Headquarters Operations Center and entered the information into NMED, in a prompt manner. The review team examined the Section's implementation of its incident and allegation processes, including written procedures for handling allegations and incident response, file documentation, notification of incidents to the NRC Headquarters Operations Center, and the use of NMED software. When notification of an incident or an allegation is received, the Unit Supervisor determines the appropriate level of initial response.

In evaluating the effectiveness of the Section's response to allegations, the review team evaluated the completed casework for all seven allegations received during the review period, including three that NRC referred to the State during the review period. The review team concluded that the Section took prompt and appropriate actions in response to concerns raised. The review team noted that the Section documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. The Section notified the concerned individuals of the conclusion of their investigations. The review team determined that the Section adequately protected the identity of concerned individuals.

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

Four non-common performance indicators are used to review 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. The NRC's Agreement with Wisconsin does not relinquish regulatory authority for a sealed source and device evaluation, low level radioactive waste disposal, or uranium recovery program; therefore, only the first non-common performance indicator applied to this review.

#### 4.1 Compatibility Requirements

#### 4.1.1 <u>Legislation</u>

Wisconsin became an Agreement State on August 11, 2003. The current effective statutory authority is contained in Wisconsin Statutes, Chapter 254, Sections 254.31 through 254.45. The Department is designated as the State's radiation control agency. The Section implements the radiation control program. The review team noted that no legislation affecting the radiation control program was passed during the review period.

#### 4.1.2 <u>Program Elements Required for Compatibility</u>

The regulations governing radiation protection requirements are located in Chapter DHS 157 of the Wisconsin Administrative Code and apply to all ionizing radiation. Wisconsin requires a license for possession and use of all radioactive material. Wisconsin also requires registration of all equipment designed to produce x-rays or other ionizing radiation.

For each rulemaking initiative, Division staff develops a rulemaking plan that provides overview information (reason for rule changes, potential costs, stakeholder involvement, etc.), and details of the existing rule. Once approved, the plan is submitted to the Office of Legal Counsel for review and Department approval. A Statement of Scope is then submitted by the Office of the Secretary to the Governor's office. After approval, the Statement of Scope is published in the Wisconsin Register. The rulemaking package is developed and published for public comment. At the same time, the Section sends the proposed rule to the NRC for a compatibility review. A public hearing is required for all rulemaking packages. After the hearing process, a resolution of comments document is prepared and sent to the Governor's office for approval of the final proposed rules package. The rulemaking process, as recently modified by State lawmakers, is expected to take a minimum of two years to complete.

The review team noted that the State's rules and regulations are not subject to sunset laws. The State may adopt the regulations of another agency by reference and also has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective. In the event that Wisconsin's security regulations equivalent to 10 CFR 37 are not adopted by the March 2016 compatibility deadline, the State developed a license condition, approved by the NRC, to add to licenses.

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.

During the review period, Wisconsin submitted 11 final regulation amendments and 1 legally binding license condition to the NRC for a compatibility review. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than 3 years after they become effective. Five of the amendments were overdue for State adoption at the time of submission. No regulation amendments were overdue at the time of the IMPEP review. The NRC's compatibility review resulted in seven comments, which will need to be addressed by the State. According to the Section Chief, who is responsible for oversight of rulemaking activities, the Section is addressing the comments in a rulemaking package that is in process.

The five amendments adopted overdue are as follows:

- "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 adoption by October 1, 2007. (RATS 2004-1)
- "Medical Use of Byproduct Material Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that was due for Agreement State adoption by September 28, 2012. (RATS 2005-2)
- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40 and 70 amendment (71 FR 15005), that was due for Agreement State adoption by March 27, 2009. (RATS 2006-1)
- "National Source Tracking System Serialization Requirements," 10 CFR Part 32 with reference to Part 20 Appendix E amendment (71 FR 65685), that was due for Agreement State adoption by February 6, 2007. (RATS 2006-2)
- "National Source Tracking System," 10 CFR Part 20 amendment (71 FR 65685 and 72 FR 59162), that was due for Agreement State adoption by January 31, 2009. (RATS 2006-3)

A complete list of regulation amendments may be found on the NRC website at the following address: <a href="http://nrc-stp.ornl.gov/rss">http://nrc-stp.ornl.gov/rss</a> regamendents.html.

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, Wisconsin's performance was found satisfactory for all of the performance indicators reviewed. The review team did not make any recommendations. The review team identified a "Good Practice" by the Section for implementing the use of a Pre-Inspection Plan by each inspector to ensure that all required information is addressed during special or follow up inspections. The review team determined that the use of these plans may have contributed to the consistent, high technical quality of inspections during the period of high staff turnover experienced during the review period. Accordingly, the review team recommends that the Wisconsin Agreement State Program be found adequate to protect public health and safety and compatible with the 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 five years.

#### LIST OF APPENDICES

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

#### APPENDIX A

#### IMPEP REVIEW TEAM MEMBERS

Area of Responsibility

**Technical Quality of Inspections** 

**Technical Quality of Licensing Actions** 

# Orysia Masnyk Bailey, Region I Team Leader Technical Quality of Incident and Allegation Activities Staffing and Training Inspector Accompaniments Jim Lynch, Region III Compatibility Requirements Status of Materials Inspection Program

Name

Myron Riley, Alabama

Lizette Roldán-Otero, Ph.D., Region IV

#### APPENDIX B

WISCONSIN ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML14182A609

#### APPENDIX C

#### **INSPECTION CASEWORK REVIEWS**

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Cardinal Health License No.: 141-1306-01

Inspection Type: Routine, Unannounced Priority: 1

Inspection Date: 2/14/14 Inspectors: KW, LJ

File No.: 2

Licensee: Aspirus-Wausau Hospital License No.: 073-1342-01

Inspection Type: Initial, Announced Priority: 1
Inspection Date: 5/2/14 Inspector: CT

File No.: 3

Licensee: ECS Midwest, LLC License No.: 101-2041-01

Inspection Type: Initial, Announced Priority: 5

Inspection Date: 9/26/12 Inspectors: AT, LJ

File No.: 4

Licensee: Divine Savior Healthcare, Inc. License No.: 021-1380-01

Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 10/24/13 Inspector: AT

File No.: 5

Licensee: NDT Specialists, Inc. License No.: 079-1199-01

Inspection Type: Routine, Unannounced Priority: 1

Inspection Date: 6/19/14 Inspectors: KK, MP

File No.: 6

Licensee: Great Lakes Testing License No.: 009-1116-01

Inspection Type: Routine, Unannounced Priority: 1

Inspection Date: 9/18/13 Inspector: MP

File No.: 7

Licensee: Team Industrial Services, Inc. License No.: 079-2005-01

Inspection Type: Routine, Unannounced Priority: 1

Inspection Date: 11/30/11 Inspectors: CT, RN

File No.: 8

Licensee: Aurora Medical Center of Washington County, Inc. License No.: 131-1024-01

Inspection Type: Special, Announced Priority: 3

Inspection Date: 8/31/11 Inspectors: KK, PC

Inspector: PC

File No.: 9

Licensee: Howard Young Medical Center License No.: 085-1126-01

Inspection Type: Routine, Unannounced Priority: 3

Inspectors: LJ, KK Inspection Date: 11/18/12

File No.: 10

Licensee: Acuren Inspection, Inc. License No.: 133-2008-01

Inspection Type: Routine, Announced-Field Priority: 1

Inspection Date: 6/10/14 Inspectors: EE, KK

File No.: 11

Licensee: Wisconsin Medical Cyclotron, LLC License No.: 079-1366-01

Inspection Type: Routine, Unannounced Priority: 1

Inspection Date: 3/12/14 Inspector: MP

File No.: 12

Licensee: Aurora Medical Center Grafton, LLC License No.: 089-1392-01

Inspection Type: Routine, Unannounced Priority: 3 Inspector: KW

Inspection Date: 2/26/14

File No.: 13

Licensee: Scott Construction License No.: 111-1021-01

Inspection Type: Routine, Announced Priority: 5 Inspection Date: 8/17/10 Inspector: SZ

File No.: 14

Licensee: Medi-Physics, Inc. License No.: 079-1168-01

Inspection Type: Routine, Unannounced Priority: 1 Inspection Date: 1/15/14 Inspectors: LJ, EE

File No.: 15

Licensee: Community Blood Center, Inc. License No.: 087-1067-01

Inspection Type: Routine, Unannounced Priority: 5 Inspector: MS

Inspection Date: 11/4/09

File No.: 16

Licensee: Fort Memorial Hospital License No.: 055-1105-01

Inspection Type: Announced, Special Priority: 3

Inspection Date: 10/12/09

File No.: 17

Licensee: Appleton Medical Center License No.: 087-1014-01

Inspection Type: Initial, Announced, Reactive Priority: 1

Inspection Date: 2/22/12 Inspectors: MS, LJ Wisconsin Draft IMPEP Report **Inspection Casework Reviews** 

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License No.: 063-1121-01

File No.: 18

Licensee: Gunderson Clinic, Ltd.

Inspection Type: Announced, Special Priority: 1

Inspection Date: 10/3/12 Inspectors: EE, CT

File No.: 19

Licensee: Marshfield Clinic License No.: 141-1162-01

Inspection Type: Routine, Unannounced Priority: 1 Inspectors: KK, MS

Inspection Date: 4/29-30/14

File No.: 20

Licensee: Aurora Health Care Metro, Inc. License No.: 079-1281-01

Inspection Type: Routine, Unannounced Priority: 1

Inspection Date: 8/14-15/13 Inspectors: MS, KK

File No.: 21

Licensee: University of Wisconsin-Madison License No.: 025-1323-01

Inspection Type: Routine, Announced Priority: 1

Inspection Date: 2/18-20/14 Inspectors: EE, CT, KK, AT, MP

File No.: 22

Licensee: RAM Services, Inc. License No.: 071-1234-01

Inspection Type: Routine, Announced Priority: 2

Inspection Date: 11/12/13 Inspectors: CT, EE, LJ

File No.: 23

Licensee: Foss Therapy Services License No.: CA-6875-19

Inspection Type: Reciprocity-Routine, Unannounced Priority: 2

Inspection Date: 7/10/13 Inspectors: LJ, MP

File No.: 24

Licensee: Best Theratronics, Ltd. License No.: NRC-45-31299-01

Inspection Type: Reciprocity-Routine, Unannounced Priority: 5

Inspection Date: 6/7/14 Inspector: KK

File No.: 25

Licensee: Viewray, Inc. License No.: OH-0321480085

Inspection Type: Reciprocity-Routine, Unannounced Priority: 2

Inspection Date: 7/9/13 Inspector: MS

File No.: 26

Licensee: McNDT Leasing, Inc. License No.: IL-01875-01

Inspection Type: Reciprocity-Routine, Unannounced Priority: 1

Inspection Date: 2/2/12 Inspectors: CT, LJ, RN Wisconsin Draft IMPEP Report **Inspection Casework Reviews** 

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File No.: 27

Licensee: Varian Medical Systems, Inc. License No.: NRC-45-30957-01

Inspection Type: Reciprocity-Routine, Unannounced Priority: 1

Inspectors: CT, AT Inspection Date: 5/15/14

File No.: 28

Licensee: Lawrence University License No.: 087-1153-01

Inspection Type: Routine, Announced Priority: 5 Inspection Date: 6/17/14 Inspector: CT

File No.: 29

Licensee: Pharmasan Labs, Inc. License No.: 095-1223-01

Inspection Type: Reactive, Announced Priority: 5

Inspection Date: 8/15/13 Inspector: MP

#### INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Lakeshore Medical Center License No.: 079-1307-01

Inspection Type: Routine Priority: 3 Inspection Date: 6/12/14

Inspector: LJ

Accompaniment No.: 2

Licensee: Dane County Sanitary Landfill License No.: 025-1082-01

Inspection Type: Reactive Priority: 5

Inspection Date: 6/9/14 Inspector: KW

Accompaniment No.: 3

Licensee: Acuren License No.: 133-2008-01

Inspection Type: Routine Priority: 1

Inspection Date: 6/10/14 Inspectors: KK, EE

Accompaniment No.: 4

Licensee: West Allis Memorial Hospital License No.: 079-1347-01

Inspection Type: Routine Priority: 1

Inspection Date: 6/11/14 Inspector: MP

#### APPENDIX D LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Green Bay Packaging, Inc.

Type of Action: Renewal

Date Issued: 6/4/12

License No.: 009-1119-01

Amendment No.: 02

License Reviewers: KK

File No.: 2

Licensee: Green Bay Packaging, Inc.

Type of Action: Termination

Date Issued: 10/30/13

License No.: 009-1119-01

Amendment Nos.: 03

License Reviewers: MS

File No.: 3

Licensee: NDT Specialist, Inc.

Type of Action: Renewal

Date Issued: 11/18/13

License No.: 079-1199-01

Amendment No.: 08

License Reviewer: KK

File No.: 4

Licensee: Team Industrial Services

Type of Action: Renewal

Date Issued: 8/19/11

License No.: 079-2005-01

Amendment No.: 7

License Reviewers: CT

File No.: 5

Licensee: Team Industrial Services

Type of Action: Amendment

Date Issued: 11/12/12

License No.: 079-2005-01

Amendment No.: 8

License Reviewers: CT

File No.: 6

Licensee: Team Industrial Services

Type of Action: Amendment

Date Issued: 5/5/14

License No.: 079-2005-01

Amendment No.: 10

License Reviewers: LJ

File No.: 7

Licensee: Great Lakes Testing, Inc.

Type of Action: Amendment

Date Issued: 11/18/13

License No.: 09-1116-01

Amendment No.: 11

License Reviewer: MP

File No.: 8

Licensee: Arrowhead-Madison

Type of Action: New

Date Issued: 10/05/09

License No.: 025-2027-01

Amendment No.: NA

License Reviewer: CT

File No.: 9

Licensee: Arrowhead-Madison

Type of Action: Amendment

Date Issued: 5/31/11

License No.: 025-2027-01

Amendment No.: 02

License Reviewer: CT

File No.: 10

Licensee: Aurora Medical Center Grafton, LLC

Type of Action: New

Date Issued: 10/1/10

License No.: 089-1392-01

Amendment No.: NA

License Reviewers: EE

File No.: 11

Licensee: Aurora Medical Center Grafton, LLC

Type of Action: Amendment

Date Issued: 7/13/11

License No.: 089-1392-01

Amendment No.: 01

License Reviewers: MP

File No.: 12

Licensee: Comprehensive Genetic Services, S.C.

Type of Action: Renewal

Date Issued: 11/24/09

License No: 079-1071-01

Amendment No.: 01

License Reviewers: RN

File No.: 13

Licensee: Comprehensive Genetic Services, S.C.

Type of Action: Termination

Date Issued: 12/29/11

License No: 079-1071-01

Amendment No.: 02

License Reviewers: DMS

File No.: 14

Licensee: University of Wisconsin

Type of Action: Amendment

Date Issued: 6/23/09

License No.: 025-1323-01

Amendment No.: 18

License Reviewers: PC

File No.: 15

Licensee: University of Wisconsin

Type of Action: Renewal

Date Issued: 1/8/14

License No.: 025-1323-01

Amendment No.: 29

License Reviewers: EE

File No.: 16

Licensee: Cardinal Health
Type of Action: Amendment
Date Issued: 5/3/12

License No.: 079-1311-01
Amendment No.: 13
License Reviewer: KK

File No.: 17

Licensee: Appleton Medical Center

Type of Action: Amendment

Date Issued: 5/23/14

License No.: 087-1014-01

Amendment No.: 24

License Reviewers: KW

File No.: 18

Licensee: Appleton Medical Center

Type of Action: Amendment

Date Issued: 5/23/14

License No.: 087-1014-01

Amendment No.: 25

License Reviewers: PS

File No.: 19

Licensee: GZA GeoEnvironmental, Inc.

Type of Action: New

Date Issued: 4/8/13

License No: 133-2040-01

Amendment No.: NA

License Reviewer: LNE

File No.: 20

Licensee: Promega Corporation

Type of Action: Renewal

Date Issued: 12/2/13

License No.: 025-1231-01

Amendment No.: 07

License Reviewer: LNE

File No.: 21

Licensee: Kendrick Laboratories, Inc.

Type of Action: Renewal

Date Issued: 9/7/11

License No.: 025-1139-01

Amendment No.: 03

License Reviewer: KK

File No.: 22

Licensee: Kendrick Laboratories, Inc.

Type of Action: Amendment

Date Issued: 11/29/11

License No.: 025-1139-01

Amendment No.: 04

License Reviewer: KK

File No.: 23

Licensee: Bio-Technical Resources

Type of Action: Renewal

Date Issued: 3/26/10

License No.: 071-1037-01

Amendment No.: 02

License Reviewer: KP

File No.: 24

Licensee: Lucigen Corporation

Type of Action: Renewal

Date Issued: 6/16/10

License No.: 025-1047-01

Amendment No.: 04

License Reviewer: EE

File No.: 25

Licensee: MD Imaging, LLC

Type of Action: Amendment

Date Issued: 7/15/14

License No.: 079-1190-01

Amendment No.: 19

License Reviewer: MS

File No.: 26

Licensee: J.T. Roofing Inc.

Type of Action: Termination

Date Issued: 5/1/12

License No.: 089-1132-01

Amendment No.: 05

License Reviewer: LJ

File No.: 27

Licensee: St. Mary's Hospital

Type of Action: Amendment

Date Issued: 7/15/14

License No.: 025-1293-01

Amendment No.: 09

License Reviewer: KK

File No.: 28

Licensee: Wheaton Franciscan Healthcare License No.: 079-1288-01

- St. Joseph, Inc.

Type of Action: Amendment No.: 20
Date Issued: 7/23/13

Amendment No.: 20
License Reviewer: MS

File No.: 29

Licensee: Agnesian Healthcare, Inc.

Type of Action: Amendment

Date Issued: 5/20/13

License No.: 039-1282-01

Amendment No.: 09

License Reviewers: EE

File No.: 30

Licensee: Agnesian Healthcare, Inc.

Type of Action: Amendment

Date Issued: 11/11/13

License No.: 039-1282-01

Amendment No.: 10

License Reviewers: LJ

File No.: 31

Licensee: Agnesian Healthcare, Inc.

Type of Action: Amendment

Date Issued: 3/18/14

License No.: 039-1282-01

Amendment No.: 11

License Reviewers: LJ

File No.: 32

Licensee: NorthStar Medical Technologies

Type of Action: New

Date Issued: 1/24/14

License No.: 025-2038-02

Amendment No.: NA

License Reviewer: MP

File No.: 33

Licensee: NorthStar Medical Technologies

Type of Action: Amendment

Date Issued: 4/17/14

License No.: 025-2038-02

Amendment No.: 1

License Reviewer: MP

File No.: 34

Licensee: University of Wisconsin - Madison

Type of Action: New

Date Issued: 11/30/12

License No.: 025-1323-05

Amendment No.: NA

License Reviewer: MS

File No.: 35

Licensee: University of Wisconsin - Madison

Type of Action: Amendment

Date Issued: 1/9/13

License No.: 025-1323-05

Amendment No.: 1

License Reviewer: MS

#### APPENDIX E

#### INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Ansul Inc./Tyco Fire Protection Products

Date of Incident: 6/13/14

Investigation Date: 6/16/12

License No.: 070-4087-01

NMED No.: 140323

Type of Incident: Lost RAM

Type of Investigation: Phone

File No.: 2

Licensee: NewPage Wisconsin Systems License No.: 141-1258-01

Date of Incident: 6/7/14 NMED No.: 140308 Investigation Date: 6/9/14 Type of Incident: Equipment Failure

Type of Investigation: Phone

File No.: 3

Licensee: Bath, Bath, & Beyond

Date of Incident: 9/17/13

Investigation Date: 10/14/13

License No.: General

NMED No.: 130472

Type of Incident: Lost RAM

Type of Investigation: Phone

File No.: 4

Licensee: Monroe Clinic

Date of Incident: 6/13/13

Investigation Date: 7/8/13

License No.: 045-1197-01

NMED No.: 140077

Type of Incident: Medical Event?

Type of Investigation: Phone

File No.: 5

Licensee: Miller Compressing, Inc.

Date of Incident: 3/7/13

Investigation Date: 6/4/13

Type of Incident: Unsecured NORM
Type of Investigation: Site

File No.: 6

Licensee: Acuren Inspection, Inc. License No.: 133-2008-01

Date of Incident: 2/25/13 NMED No.: 130198
Investigation Date: 4/19/13 Type of Incident: Equipment Malfunction
Type of Investigation: Site

File No.: 7

Licensee: University of Wisconsin - Madison License No.: 25-1323-01

Date of Incident: 9/20/12 NMED No.: 120573
Investigation Date: 10/17/13 Type of Incident: Contamination
Type of Investigation: Site

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File No.: 8

Licensee: Frank Jiran Contractor, Inc.

License No.: 021-1255-01M Date of Incident: 5/1/11 NMED No.: 110273 Investigation Date: 6/1/11 Type of Incident: Lost RAM Type of Investigation: Phone

File No.: 9

Licensee: Miller Compressing, Inc. License No.: Non-Licensee

Date of Incident: 1/19/10 NMED No.: 100417 Investigation Date: 6/9/10 Type of Incident: Abandoned RAM Type of Investigation: Site

File No.: 10

License No.: 79-1104-01 Licensee: Froedtert & Medical College of Wisconsin

Date of Incident: 6/9/10 NMED No.: 100305 Investigation Date: 6/10/10 Type of Incident: Medical Event Type of Investigation: Phone

File No.: 11

License No.: 073-1165-01 Licensee: Tetra Tech, Inc.

Date of Incident: 6/28/10 NMED No.: 100417 Investigation Date: 6/28/10 Type of Incident: Damaged Equipment Type of Investigation: Site