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

October 17, 2019

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

Dear Mr. Warzecha:

On September 24, 2019, the Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States Liaison to the MRB, met to consider the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Wisconsin Agreement State Program. The MRB found the Wisconsin program adequate to protect public health and safety, and compatible with the NRC program.

The enclosed final report documents the IMPEP team's findings and summarizes the results of the MRB meeting (Section 5.0). Based on the results of the current IMPEP review, the next full review of the Wisconsin Agreement State Program will take place in approximately 5 years, with a periodic meeting in approximately 2.5 years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/
K. Steven West
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, Compliance, Administration,
and Human Capital Programs
Office of the Executive Director for Operations

Enclosure:
Wisconsin Final IMPEP Report

cc: Earl Fordham, CHP, Eastern Deputy Director
Department of Health, State of Washington
Organization of Agreement States
Liaison to the MRB

SUBJECT: WISCONSIN FY2019 INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM FINAL REPORT - DATED: OCTOBER 17, 2019

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE WISCONSIN PROGRAM

July 8-12, 2019

FINAL REPORT

Enclosure 1

EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Wisconsin Agreement State Program (Wisconsin) are discussed in this report. The review was conducted during the period of July 8-12, 2019 by a team composed of technical staff from the U.S. Nuclear Regulatory Commission (NRC) and the State of Florida.

Based on the results of this review, Wisconsin's performance was found satisfactory for all six of the performance indicators reviewed. The team did not make any recommendations.

Accordingly, the team recommended, and the Management Review Board (MRB) agreed, that Wisconsin's program is adequate to protect public health and safety and is compatible with the NRC's program. Since this was the second consecutive IMPEP with all performance indicators being found satisfactory, the team recommended and the MRB agreed, that the next IMPEP review take place in approximately 5 years with a periodic meeting in approximately 2.5 years.

1.0 INTRODUCTION

The Wisconsin Agreement State Program (Wisconsin) review was conducted during the week of July 8-12, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Florida. Team members are identified in Appendix A. The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* on October 18, 2017 (82 FR 48535), and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of July 19, 2014 to July 12, 2019, were discussed with Wisconsin managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and the applicable non-common performance indicator was sent to Wisconsin on May 29, 2019. Wisconsin provided its response to the questionnaire on June 20, 2019. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML19176A496.

A draft of this report was issued to Wisconsin on August 7, 2019, for factual comment (ADAMS Accession Number ML19218A154). Wisconsin responded to the draft report by electronic mail on September 5, 2019, from Mark Paulson, Supervisor, Radioactive Materials Licensing and Inspection Unit (ADAMS Accession Number ML19252A007). The Management Review Board (MRB) convened on September 24, 2019, to discuss the team's findings.

Wisconsin is administered by the Radiation Protection Section (the Section). The Section is part of the Bureau of Environmental and Occupational Health (the Bureau) within the Division of Public Health (the Division). The Division is part of the Department of Health Services (the Department). Organization charts for the Department and the Bureau are available in ADAMS using Accession Number ML19218A123.

At the time of the review, Wisconsin regulated approximately 277 specific licenses authorizing the possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Wisconsin.

The 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 Wisconsin's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on July 18, 2014. The final report is available in ADAMS using Accession Number ML14288A110. The results of the review are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory
Recommendation: None

Technical Quality of Incident and Allegation Activities: Satisfactory
Recommendation: None

Compatibility Requirements: Satisfactory
Recommendation: None

Overall finding: Adequate to protect public health and safety and compatible with the NRC's program.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the 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

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs and could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

The team used the guidance in State Agreements procedure SA-103, “Reviewing the Common Performance Indicator: Technical Staffing and Training,” and evaluated Wisconsin’s performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to NRC Inspection

Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."

- Qualification criteria for new technical staff are established and are followed, or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

When fully staffed, Wisconsin is comprised of nine technical staff members which contribute 7.5 FTE for the radioactive materials program. At the time of the review, there were no vacancies. During the review period eight staff members left the program and eight staff members were hired. The positions were vacant from two to four months.

Wisconsin has a training and qualification program compatible with the NRC's IMC 1248. Five of the employees hired during the review period had a bachelor's degree in science and/or engineering and three members of the staff had master's degrees in science. Wisconsin management is very supportive of the training program, and the staff is encouraged to attend NRC training courses. Continuing education and professional development are promoted and tracked by the supervisor. The training qualification records that are used to track qualification milestones are comprehensive and includes self-study, in-house training, on-the-job training, and formal courses. A mentoring program has been implemented where the supervisor, senior inspectors and license reviewers provide on-the-job training for the junior staff. The fully qualified staff also receive support for the 24-hour refresher training that is detailed in IMC 1248.

c. Evaluation

The team determined that, during the review period, Wisconsin met the performance indicator objectives listed in Section 3.1.a. Based on the criteria in MD 5.6, the team recommends that Wisconsin's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Wisconsin's performance with respect to this indicator, satisfactory.

3.2 Status of Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good

safety practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated Wisconsin's performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3 licensees are performed at the frequency prescribed in IMC 2800.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections, or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports").

b. Discussion

Wisconsin performed 329 Priority 1, 2, 3, and initial inspections during the review period. Wisconsin's inspection frequencies are the same for similar license types in IMC 2800. Wisconsin conducted 2.7 percent of Priority 1, 2, 3, and initial inspections overdue, well below the target of no more than 25 percent overdue. Specifically, 1 out of the 273 Priority 1, 2, 3 inspections and 8 out of the 56 initial inspections were conducted overdue.

The one Priority 1, 2, or 3 inspection that was performed late was of a licensee located on the far west side of the state and presented inspection scheduling challenges due to the distance. This inspection was performed late in 2015, and since then, Wisconsin has made adjustments in its inspection scheduling to ensure future inspections are performed on time.

For the eight initial inspections that were overdue, Wisconsin chose to prioritize the Priority 1, 2, and 3 inspections over the initial inspections. All the late initial inspections were due to the timing of the licensees acquiring radioactive materials or initiating licensed activities. Wisconsin postponed the initial inspections until they were sure that

the licensee had acquired its material and/or initiated its activities. These inspections were late between 7 and 294 days.

A sampling of 45 inspection reports indicated that five of the inspection findings were communicated to the licensees beyond Wisconsin's goal of 30 days after the inspection exit. These reports were late between 5 and 20 days. Two of the late reports contained minor violations.

Each year of the review period, Wisconsin performed greater than 20 percent of candidate reciprocity inspections.

c. Evaluation

The team determined that, during the review period, Wisconsin met the performance indicator objectives listed in Section 3.2.a. Based on the criteria in MD 5.6, the team recommends that Wisconsin's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Wisconsin's performance with respect to this indicator, satisfactory.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing inspections, and the critical evaluation of inspection records, are used to assess the technical quality of an Agreement State's inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated Wisconsin's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- The Program Supervisor, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, procedures are

established and followed to provide feedback information to license reviewers.
- Inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The casework reviewed included inspections conducted by 14 inspectors, who conducted work during the review period, and covered medical, industrial, commercial, academic, research, and service licenses.

The team determined that the inspection plans, and inspection reports generated by the inspectors were exceptional. The team found that inspection documents were thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed. Inspection findings were well-founded, clearly communicated to the licensee and violations were written with direct link to a regulation or license condition. In the casework reviewed, every inspection addressed previously identified open items and violations. In addition, the team determined that supervisory accompaniments were conducted annually for all inspectors, except for three inspectors. The three inspectors were not accompanied because they left the program early in the year.

Team members accompanied four program inspectors in June of 2019. No performance issues were noted during the inspection accompaniments. The inspectors were well prepared, and thorough, and assessed the impact of licensed activities on health, safety, and security. The inspector accompaniments are identified in Appendix B.

An adequate supply of calibrated instruments is available to support the program and are calibrated at the required frequency. Calibration records for the instruments are maintained on file.

c. Evaluation

The team determined that, during the review period, Wisconsin met the performance indicator objectives listed in Section 3.3.a. Based on the criteria in MD 5.6, the team recommends that Wisconsin's performance with respect to the indicator, Technical Quality of Inspections be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Wisconsin's performance with respect to this indicator, satisfactory.

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the Wisconsin licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Wisconsin's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements are consistent with current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk-significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Wisconsin performed 1,250 radioactive materials licensing actions. The team evaluated 25 of those licensing actions. The licensing actions selected for review included 4 new applications, 10 amendments, 4 renewals, 6 terminations, and 1 financial assurance. The team evaluated casework which included the following license types and actions: broad scope, medical diagnostic and therapy, accelerator, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, self-shielded irradiators, service providers, waste processor, financial assurance, and notifications. The casework sample represented work from 14 license reviewers.

The team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. A second

technical review is performed on all licensing actions. License tie-down conditions were clearly stated 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. Wisconsin maintains financial assurance instruments for eight licenses; all are secured in a lock box inside a secured file cabinet.

Wisconsin uses templates to generate most correspondence and licenses, and there are standard formats and license conditions for each license type. Wisconsin uses licensing guides based on NRC licensing guidance (NUREG-1556 series), as appropriate, and maintains licensing guidance that is the same or similar to guidance used by NRC. Based on the casework evaluated, the team concluded that the licensing actions were of high quality and consistent with Wisconsin's licensing procedures. The team attributed the consistent use of templates and quality assurance reviews to the overall quality in the casework reviews.

Wisconsin performs pre-licensing checks of all new applicants. Wisconsin's pre-licensing guidance checklist was updated February 4, 2019, and incorporated the essential elements of NRC's revised pre-licensing guidance (issued August 2018) to verify that the applicant will use requested radioactive materials, as intended. All new licensees not meeting the exclusion criteria of Wisconsin's pre-licensing checklist 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 team confirmed that Wisconsin used the most up to date Risk Significant Radioactive Material (RSRM) checklist, which they revised and implemented on February 4, 2019, to be consistent with the current NRC RSRM checklist. The team found that the implementation was thorough and accurate. The team also confirmed that license reviewers evaluated new license applications and license amendments using the same criteria contained in Wisconsin's RSRM checklist. Wisconsin requires full implementation of 10 CFR Part 37 prior to issuance of a new license or license amendment that meets the established criteria contained in Wisconsin's RSRM checklist.

The team examined Wisconsin'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 10 CFR Part 37. The team found Wisconsin's implementation of the procedure to be thorough and complete.

c. Evaluation

The team determined that, during the review period, Wisconsin met the performance indicator objectives listed in Section 3.4.a. Based on the criteria in MD 5.6, the team recommends that Wisconsin's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Wisconsin's performance with respect to this indicator, satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and follow-up actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Wisconsin's performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety, or security significance.
- Appropriate follow-up actions are taken to ensure prompt compliance by licensees.
- Follow-up inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database.
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 36 incidents were reported to Wisconsin. The team evaluated 28 radioactive materials incidents which included two lost/stolen radioactive materials, eight damaged equipment, six leaking sources, one leaking electron capture device, three industrial radiography source retrieval incidents, one industrial radiography incident where the extremity dose for one individual exceeded the annual dose limit of 50 rem, one gamma knife incident, four Yttrium-90 under doses, one blood irradiator incident, and one incident involving a radioactive water spill at the La Crosse Power Station.

When an incident is reported to Wisconsin, staff and management collectively evaluate the information and make a health and safety determination for an appropriate response.

For incidents that Wisconsin determines to be health and safety significant, Wisconsin immediately responds, which includes a thorough written investigation plan. All responses to incidents during the review period were done with regard to established program procedures.

The team found that inspectors properly evaluated each incident, interviewed involved individuals, and thoroughly documented their findings. Although the enforcement program is not evaluated as part of the IMPEP process, the team noted that enforcement actions were taken when Wisconsin determined it was appropriate. Enforcement actions were taken for 11 of the incidents reviewed.

The team evaluated Wisconsin's reporting of events to the NRC's Headquarters Operations Officer (HOO). The team determined that in each case evaluated where HOO notification was required, Wisconsin reported all events within the required timeframe.

During the review period, Wisconsin received nine allegations. Two of the nine were referred to Wisconsin by the NRC. The team evaluated all the allegations, including the two allegations that the NRC referred to the State. The team found that Wisconsin took prompt and appropriate action in response to the concerns raised. All the allegations were appropriately closed, concerned individuals were notified of the actions taken, and allegers' identities were protected whenever possible in accordance with State law.

c. Evaluation

The team determined that, during the review period, Wisconsin met the performance indicator objectives listed in Section 3.5.a. Based on the criteria in MD 5.6, the team recommends that Wisconsin's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Wisconsin's performance with respect to this indicator, 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 (SS&D) Evaluation Program, (3) Low-Level Radioactive Waste Disposal (LLRW) Program, and (4) Uranium Recovery Program. The NRC's Agreement with Wisconsin retains regulatory authority for sealed source and device evaluations, low-level radioactive waste disposal, and uranium recovery; therefore, only the first non-common performance indicator applied to this review.

4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of the NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by an Agreement State within 6 months following NRC designation.

a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated Wisconsin's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC website at the following address: https://scp.nrc.gov/regtoolbox.html.

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations were not adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.
- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program, have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Sunset requirements, if any, do not negatively impact the effectiveness of the State's regulations.

b. Discussion

The State of Wisconsin became an Agreement State on August 11, 2003. The State of Wisconsin's current effective statutory authority is found in Chapter 254, Sections 254.31 through 254.45, of the Wisconsin Statutes. The Department is designated as the State's radiation control agency and Wisconsin implements the radiation control program. The State's rules and regulations are not subject to sunset laws. A legislative change, entitled 2011 Wisconsin Act 21, was made prior to this review period which increased the number of administrative review steps in the rule adoption process.

Wisconsin Administrative Code, Chapter Department of Health Services (DHS) 157, Radiation Protection contains Wisconsin's regulations that apply to its radioactive material licensees. For each rulemaking initiative under 2011 Wisconsin Act 21, Section 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. In the beginning of the administrative review process, 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 Administrative Register. At that point the rulemaking package is developed, an economic impact analysis is performed, the need for public informational or listening sessions is determined, and an advisory committee is established, if needed. Wisconsin monitors comments received from all sources and submits comments that differ from the Statement of Scope to the Office of the Secretary and Governor's office for review. Revisions to the rulemaking package are made and the draft rule language and summary economic impact analysis are submitted to the Office of the Secretary and Governor's office for approval. Following the approval, the rulemaking package is sent to the Wisconsin Legislative Council for review and filing of a hearing notice. The rulemaking package is subsequently published for public comment.

At the same time, Wisconsin sends the proposed rule to the NRC for a compatibility review. A minimum of one public hearing is required for all rulemaking packages. After the hearing process, a resolution of public and legislative council comments documents is prepared and sent to the Governor's office for approval of the final proposed rules package. Once approved, the final proposed rulemaking package is sent to legislative standing committees for review and approval. After legislative approval, the rulemaking package is sent to the Legislative Reference Bureau for publication in the Wisconsin Administrative Register.

Wisconsin submitted a regulation package to revise DHS 157 during the review period, and it took substantially longer than for previously approved packages. It began in late 2013 and concluded with the newest revision becoming effective February 1, 2018. Several factors contributed to this longer than normal process. These included legislative changes to the administrative rules process which added additional review steps; the large size and scope of the revision, which included the incorporation of 10 CFR Part 37 and non-radioactive materials requirements; and staff turnover at multiple levels including the Department legal rules coordinator.

During the review period, Wisconsin submitted one rule package to NRC for review. This package included a total of 13 amendments. Of those 13 amendments, six were submitted late for review for the reasons previously mentioned; two other amendments were considered health and safety significant by Wisconsin and submitted as license conditions; and the remaining five had later due dates and, while submitted in the same rule package, were not late when submitted. No amendments were overdue for State adoption at the time of the review. As a result of the extended process brought on by 2011 Wisconsin Act 21, Wisconsin instituted changes in committing to work with its Office of Legal Counsel earlier in the process to adopt future amendments within the required time frame. Additionally, legally binding license conditions which have been used in the past, will be implemented earlier in the process, if necessary to maintain compatibility.

As a result of the extended times for the approval of rulemaking packages, the rulemaking process was recently modified by State lawmakers. The modified administrative review process is now expected to take between 7.5 to 13 months and is limited to 24 months. The modified process now provides opportunity for Wisconsin to expedite the approval process of the Statement of Scope by being allowed to request status reports and offer assistance during any of the milestones that occur in the review process. Before the process was modified, Wisconsin was not provided any opportunity to inquire with regard to the status or offer any assistance to facilitate the process.

c. Evaluation

The team determined that, except as noted below, during the review period Wisconsin met the performance indicator objectives listed in Section 4.1.a.

- Regulations were not adopted by the Agreement State for purposes of compatibility or health and safety within 3 years after the effective date of the NRC regulation.

Wisconsin did not adopt the final regulation for six NRC amendments within the required 3-year frequency. Legislative changes to the administrative rules process added additional review steps which delayed the implementation of the amendments. In addition, other contributing factors were the large size and scope of the revision (e.g., inclusion of a new part), and staff turnover at multiple levels outside of Wisconsin's program.

The team discussed a finding of Satisfactory but needs improvement for this indicator; however, it concluded that a finding of Satisfactory is more appropriate. The team noted that the legislative change (2011 Wisconsin Act 21) resulting in the additional steps to the regulation adoption process was identified as a concern by Wisconsin during their most recent Periodic Meeting. At that time, they acknowledged that additional time would be needed administratively for rule adoption and that they would need to begin the initial process for rule adoption sooner. The modified administrative review process is now expected to take between 7.5 to 13 months with a limit of 24 months, and provides Wisconsin the opportunity to request an expedited review of packages that are at risk of being overdue.

In addition, when it became apparent to Wisconsin that the regulation package would not be approved in a timely manner, the team noted that Wisconsin evaluated the health and safety significance of each amendment in the regulation package and implemented license conditions for those they believed held a higher health and safety significance. Those with a lower threshold for health and safety significance, or were mostly technical corrections to the rules were allowed to continue in the process. Lastly, Wisconsin has committed to beginning the rule adoption process immediately upon receipt, and to work closely with its Office of General Counsel to ensure that rules are adopted timely. Additionally, Division management indicated that they would work with Wisconsin to ensure that regulation packages would be timely.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommends that Wisconsin's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Wisconsin's performance with respect to this indicator, satisfactory.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Wisconsin's performance was found to be satisfactory for all performance indicators reviewed. The team did not make any recommendations and there were no recommendations from the previous review for the team to consider.

Accordingly, the team recommended, and the MRB agreed, that Wisconsin be found adequate to protect public health and safety**,** and compatible with the NRC's program. Since this was the second consecutive IMPEP with all performance indicators being found satisfactory, the team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 5 years, with a periodic meeting in approximately 2.5 years.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Areas of Responsibility**
Randy Erickson, Region IV	Team Leader Compatibility Requirements Inspector Accompaniments
Darren Piccirillo, Region III	Technical Staffing and Training
Robin Elliott, Region I	Technical Quality of Licensing Actions
Michael Reichard, Region I	Technical Quality of Inspections
Stephen Poy, NRC HQ	Team Leader in Training Status of Materials Inspection Program Inspector Accompaniments
Leo Bakersmith, State of Florida	Technical Quality of Incident and Allegation Activities

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 133-2008-01
License Type: Industrial Radiography	Priority: 1
Inspection Date: 6/3/19	Inspector: DR

Accompaniment No.: 2	License No.: 131-1286-01
License Type: Medical Written Directive Required	Priority: 3
Inspection Date: 6/4/19	Inspector: JR

Accompaniment No.: 3	License No.: 079-1058-01
License Type: Medical Written Directive Required	Priority: 3
Inspection Date: 6/5/19	Inspector: MS

Accompaniment No.: 4	License No.: 079-1055-01
License Type: Manufacturer	Priority: 3
Inspection Date: 6/6/19	Inspector: KW