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



October 20, 2015

Terry Dwelle, M.D., M.P.H.T.M. State Health Officer North Dakota Department of Health State Capitol 600 East Boulevard Avenue Bismarck, ND 58505-0200

Dear Dr. Dwelle:

On September 17, 2015, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the North Dakota Agreement State Program. The MRB found the North Dakota program adequate to protect public health and safety, and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 13, of the enclosed final report contains a summary of the IMPEP team's findings. Based on the results of the current IMPEP review, the next full review of the North Dakota Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for June 2017.

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 Patricia Holahan Acting for/

Michael F. Weber
Deputy Executive Director for Materials,
Waste, Research, State, Tribal, and
Compliance Programs
Office of the Executive Director for Operations

Enclosure: North Dakota Final IMPEP Report

cc: Terry L. O'Clair, Director Division of Air Quality

Dale Patrick, Manager Radiation Control Program

Cindy Becker, FL Organization of Agreement States Liaison to the MRB Terry Dwelle, M.D., M.P.H.T.M. State Health Officer North Dakota Department of Health State Capitol 600 East Boulevard Avenue Bismarck, ND 58505-0200

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DATE	9/25/15	9/28/15	9/24/15	10/6/15	10/7/15	10/13/15	10/20/15

Letter to Dr. Dwelle from M. Weber dated: October 20, 2015

SUBJECT: North Dakota FY2015 FINAL IMPEP REPORT

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE NORTH DAKOTA AGREEMENT STATE PROGRAM

June 22 - 25, 2015

**FINAL REPORT** 

#### **EXECUTIVE SUMMARY**

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the North Dakota Agreement State Program. The review was conducted during the period of June 22 – 25, 2015, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Pennsylvania.

Based on the results of this review, North Dakota's performance was found satisfactory for all six of the indicators reviewed: Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Incident and Allegation Activities, and Compatibility Requirements.

The review team did not make any recommendations and determined that the two open recommendations regarding the staff retention and inspector qualifications should be closed.

Accordingly, the review team recommended, and the Management Review Board (MRB) agreed, that the North Dakota Agreement State Program is adequate to protect public health and safety and is compatible with the NRC's program. The review team recommended, and the MRB agreed, that the next IMPEP review take place in approximately 4 years. The review team recommended, and MRB agreed, that the period of monitoring be discontinued.

## 1.0 INTRODUCTION

This report presents the results of the review of the North Dakota Agreement State Program radioactive materials safety program. The review was conducted during the period of June 22–25, 2015, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Pennsylvania. 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 (MD 5.6), "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of April 9, 2011, to June 25, 2015, for the performance indicators Technical Staffing and Training and Technical Quality of Incident and Allegation Activities, and April 27, 2013, until June 25, 2015, for the remainder of the indicators, were discussed with North Dakota managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the North Dakota on February 9, 2015. North Dakota provided its response to the questionnaire on June 1, 2015. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using using the Accession Number ML15167A136.

A draft of this report was issued to North Dakota on July 24, 2015, for factual comment. North Dakota responded to the findings and conclusions of the review by electronic mail dated September 2, 2015. A copy of North Dakota's response can be found in ADAMS using the Accession Number ML15251A086. The Management Review Board (MRB) met on September 17, 2015, to consider the proposed final report. The MRB found the North Dakota Agreement State Program adequate to protect public health and safety, and compatible with the NRC's program.

The North Dakota Agreement State Program (the Program) is administered by the Department of Health, Division of Air Quality (the Division), Radiation Control Program. Organization charts for North Dakota can be found in ADAMS using the Accession Number ML15167A131.

At the time of the review, the Program regulated 98 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 North Dakota.

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 North Dakota Agreement State Program's performance.

#### 2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

From the 2011 IMPEP review, North Dakota's performance was found unsatisfactory for one performance indicator reviewed; satisfactory, but needs improvement for three performance indicators reviewed: and satisfactory for two performance indicators reviewed. The 2011 review team made 11 recommendations regarding the performance of the North Dakota Agreement State Program. These recommendations included areas for improvement to correct identified performance deficiencies and weaknesses in North Dakota's Agreement State Program. The review team recommended that the State (1) update its procedures to memorialize the policies and practices of the Agreement State program and examine staffing options to effectively implement the program; (2) ensure that initial inspections are performed at the prescribed interval; (3) ensure that inspection findings are communicated to licensees in a timely manner; (4) ensure that sufficient information pertaining to inspections is appropriately documented and that items of noncompliance are appropriately communicated to licensees; (5) obtain additional training to enhance inspection skills; (6) ensure that licensing actions are adequately documented and consistent with the regulations and licensing guidance; (7) provide additional training regarding the technical review of licensing actions and correct deficiencies identified in the licensing casework review; (8) take measures to determine and document the basis of confidence that radioactive materials will be used as intended and as described in applications or amendment requests; (9) take measures to assure that financial assurance requirements are properly implemented; (10) take measures to strengthen its incident response program; and (11) take measures to strengthen its allegation program.

In 2011, North Dakota was found adequate, to protect public health and safety, but needs improvement, and compatible with the NRC's program. The NRC initiated a period of heightened oversight for North Dakota.

A follow-up IMPEP was conducted in 2013 to review the indicators found less than satisfactory in 2011. Based on the results of this follow-up review, North Dakota's performance was found satisfactory for the indicators Status of Materials Inspection Program, Technical Quality of Licensing Actions, and Technical Quality of Incidents and Allegations, and satisfactory, but needs improvement for the indicator, Technical Quality of Inspections.

In 2013, the review team made one new recommendation regarding the full qualification of inspection staff and kept one recommendation open from the 2011 IMPEP regarding staff retention and depth. The remaining 10 recommendations from the 2011 IMPEP review, regarding policies and procedures, inspection scheduling, timeliness of inspection report issuance, inspection documentation, training, documentation of licensing actions, financial assurance matters, and evaluation of incidents and allegations, were closed in 2013.

In 2013, North Dakota was found adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program. The period of heightened oversight was discontinued and a period of monitoring was initiated to allow additional time for North Dakota to demonstrate a period of sustained performance.

The final reports for the 2011 and 2013 reviews are available in ADAMS using the Accession Numbers ML111780525 and ML13204A355, respectively. The results of the 2011 and 2013 reviews and the status of the open recommendations from the 2013 review are as follows:

## Technical Staffing and Training:

(1) 2011 Satisfactory; (2) 2013, Not evaluated, but discussed during the 2013 and 2014 periodic meetings

**Open Recommendation**: (2011) The review team recommends that the State (a) update its existing procedures and develop new procedures as necessary, to memorialize the policies and practices of the Agreement State program, to serve as a knowledge management tool, and (b) examine options to increase staff retention and/or develop sufficient depth in staffing to effectively implement the program.

Status: (a) North Dakota has updated existing procedures and established new procedures to memorialize the policies and practices of the Program and serve as a knowledge management tool. The staff demonstrated familiarity with and use of these policies and procedures.

Status: (b) North Dakota elevated the promotion potential of inspector positions from Environmental Scientist two positions to Environmental Scientist three positions. The plan is to eventually have two Environmental Scientist three positions and three Environmental Scientist two positions. This will result in higher salary incentives for the newer staff. North Dakota also has the ability to provide "roll-up" dollars, which incrementally increases the staff's pay when another staff person leaves with more seniority. North Dakota also increased staffing with the hiring of two additional inspectors, with one additional position posted. The two additional new hires and two X-ray inspectors have started training to become qualified materials inspectors.

The review team recommended, and the MRB agreed, that both parts of this recommendation be closed.

#### Status of Materials Inspection Program:

(1) 2011 Satisfactory, but needs improvement; (2) 2013 Satisfactory

Recommendation: (2013) None.

#### Technical Quality of Inspections:

(1) 2011 Unsatisfactory; (2) 2013 Satisfactory but needs improvement

**Open Recommendation**: (2013) The review team recommends that the State develop and implement a plan to ensure that inspectors become qualified to conduct inspections in all radioactive material program areas licensed by the State.

Status: North Dakota has developed and implemented a written training and qualification plan to ensure that inspectors become qualified to conduct inspections in all radioactive material program areas licensed by the State. One inspector is now fully qualified to conduct inspections in all program areas, and all other inspectors are making progress towards becoming fully qualified. To make progress in qualifications as quickly as the inspection schedule allows, the program sends multiple inspectors out on nearly all inspections.

The review team recommended, and the MRB agreed, that this recommendation be closed.

#### Technical Quality of Licensing Actions:

(1) 2011 Satisfactory, but needs improvement; (2) 2013 Satisfactory

Recommendation: (2013) None

Technical Quality of Incident and Allegation Activities: (1) 2011 Satisfactory, but needs

improvement; (2) 2013 Satisfactory

Recommendation: (2013) None.

Compatibility Requirements: (1) 2011 Satisfactory; (2) 2013, Not evaluated, but

discussed during the 2013 and 2014 periodic meetings

Recommendation: (2013) None

#### 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 thus could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires a 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 review team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated North Dakota'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 the 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 being followed or that 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

The Program is composed of six staff members which equals five full-time equivalents for the radioactive materials program including any vacancies in the Program. Currently, there is one vacancy. Since the 2011 IMPEP, the Program's staffing has increased by three positions. North Dakota has a training and qualification manual compatible with the NRC's IMC 1248. During the review period, the radiation control program manager retired and was replaced. The previous and current manager's time in the Program overlapped by 1 month which provided continuity in the Program. In addition, one staff member left the Program for the private industry, three staff members were hired, and one additional position had been posted at the time of the review.

#### c. Evaluation

The team determined that during the review period the North Dakota program met the performance indicator objectives listed in Section 3.1.a.

#### d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

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

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 review team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated North Dakota'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. <u>Discussion</u>

The Program's inspection frequency is the same for similar license types in IMC 2800. North Dakota performed 64 priority 1, 2, 3, and initial inspections during the review period. All inspections were conducted timely.

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

# c. Evaluation

The team determined that during the review period North Dakota met the performance indicator objectives listed in Section 3.2.a.

# d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Status of the Materials Inspection Program, be found 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 a program's inspection capability.

#### a. Scope

The review team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated North Dakota'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.
- Supervisors conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, to verify that procedures are established and followed to provide feedback information to license reviewers.
- For Agreement States, to determine if inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

#### b. Discussion

The review team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 20 materials inspections conducted during the review period. The team reviewed casework for inspections led by each of the program's qualified inspectors, and covered inspections of medical, industrial, commercial, and academic licenses.

A review team member accompanied the program's two qualified inspectors on June 8-11, 2015. The inspector accompaniments are identified in Appendix B. The review team also evaluated the performance of supervisory accompaniments of the Program's qualified inspectors. All qualified inspectors were accompanied at least annually.

Within the scope of this indicator, the Program continued a trend of improved performance consistent with the 2013 follow-up IMPEP review. The review team found that the program's inspectors were well-prepared, used appropriate and calibrated survey instruments effectively, and placed appropriate emphasis on the risk significance of observations and findings. All inspections were well documented, reviewed thoroughly by management, and resulted in appropriate and prompt regulatory action in response to non-compliances.

## c. Evaluation

The team determined that during the review period, North Dakota met the performance indicator objectives listed in Section 3.3.a.

#### Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Technical Quality of Inspections, be found 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, and security. An assessment of licensing procedures, actual implementation of these procedures, and documentation of communications and associated actions between the North Dakota licensing staff and regulated community will be a significant indicator of the overall quality of the program.

#### a. Scope

The review team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated North Dakota'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 meet 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 are inspectable.
- 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. <u>Discussion</u>

During the review period, North Dakota completed 309 radioactive materials licensing actions. The review team evaluated 17 radioactive materials licensing actions. The licensing actions selected for review included four new applications, nine amendments, one renewal, and three terminations. The review team evaluated casework which included the following license types and actions e.g., broad scope, medical diagnostic and therapy, accelerator, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, panoramic and self-shielded irradiators, well-logging, service providers, waste brokers, financial assurance, and bankruptcies. The casework sample represented work from five license reviewers.

## c. Evaluation

The team determined that during the review period, North Dakota met the performance indicator objectives listed in Section 3.4.a.

#### d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

# 3.5 <u>Technical Quality of Incident and Allegation Activities</u>

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 procedures and actions will be a significant indicator of the overall quality of the program.

#### a. Scope

The review team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated North Dakota'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. <u>Discussion</u>

During the review period, seven radioactive materials incidents were reported to North Dakota. The review team evaluated all seven incidents, which included two damaged fixed and portable gauges, four defective radiography devices, and one abandoned well logging source.

During the review period, nine allegations were received by North Dakota. The review team evaluated all nine allegations, including four allegations that the NRC referred to the State.

#### c. Evaluation

The team determined that during the review period, North Dakota met the performance indicator objectives listed in Section 3.5.a.

# d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that North Dakota'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 (LLRW) Disposal Program, and (4) Uranium Recovery Program. The NRC's Agreement with North Dakota does not relinquish regulatory authority for a Sealed Source and Device Evaluation Program or a Uranium Recovery Program. Additionally, in 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption thereof by States through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need for an amendment.

Although North Dakota has such authority to regulate a LLRW disposal facility, the NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW program. Currently, there are no plans for a commercial LLRW disposal facility in North Dakota, so 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 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 review team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated North Dakota's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC Web site at the following address: <a href="https://scp.nrc.gov/rss">https://scp.nrc.gov/rss</a> regamendents.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 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.
- Impact of sunset requirements, if any, on the State's regulations.

#### b. Discussion

North Dakota became an Agreement State on September 1, 1969. The North Dakota Agreement State Program's current effective statutory authority is contained in North Dakota Century Code Chapter 23-20. The North Dakota Century Code designates that the radiation control program is administered by the North Dakota Department of Health. The North Dakota Century Code is sufficiently broad to provide authority for the regulation of source, byproduct, special nuclear material, and other radioactive materials. No legislation affecting the Program was passed during the review period.

The State's administrative rulemaking process takes approximately 6 months from drafting to finalizing a rule. The public, the NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved by the Legislative Rules Committee. The review team noted that the State's rules and regulations are not subject to "sunset" laws.

At the time of this review, the following two amendments were overdue:

- "Licenses, Certifications, and Approvals for Materials Licensees," Parts 30, 36, 39, 40, 70, and 150 (77 FR 56951), which was due for adoption by November 14, 2014.
- "Change of Compatibility of 10 CFR 31.5 and 31.6 in the Withdrawal of Proposed Rule and Closure of Petition For Rulemaking" (77 FR 3640), which was due for adoption by January 25, 2015.

At the time of the IMPEP review, North Dakota was in the process of addressing three NRC comments to the final regulations adopted for the "Requirements for Expanded Definition of Byproduct Material" Parts 20, 30, 31, 32, 33, 35, 61, 150 (72 FR 55864).

Prior to the review period, in January 2011, North Dakota finalized regulations for 10 CFR Part 36, "Licensing and Radiation Safety Requirements for Irradiators," without submitting the final regulations to NRC for a compatibility review. Although North Dakota adopted the regulations, the Program has not had an application for a license that would be subject to 10 CFR Part 36 requirements.

North Dakota management committed to submitting a package addressing all of the above comments and amendments to the NRC for review prior to the Management Review Board meeting. Prior to the MRB, North Dakota did, in fact, follow through on this commitment and submitted the regulations to the NRC for review on September 10, 2015.

## c. Evaluation

The team determined that during the review period North Dakota met the performance indicator objectives listed in Section 3.4.1.a.

#### d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that North Dakota'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, North Dakota's performance was found satisfactory for all six performance indicators reviewed. The review team did not make any new recommendations regarding program performance by the State and determined that two recommendations from the 2011 and 2013 IMPEP reviews should be closed.

Accordingly, the review team recommended, and the MRB agreed, that the North Dakota 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 recommended, and the MRB agreed, that the period of monitoring be discontinued and that the next full IMPEP review take place in approximately 4 years.

# LIST OF APPENDICES

Appendix A IMPEP Review Team Members

Appendix B Inspection Accompaniments

# APPENDIX A

# IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Orysia Masnyk Bailey Region I	Team Lead Technical Staffing and Training Technical Quality of Incidents and Allegations
Ryan Craffey Region III	Technical Quality of Inspections Inspector Accompaniments
Dwight Shearer Commonwealth of Pennsylvania	Technical Quality of Licensing Actions
Binesh Tharakan Region IV	Status of Materials Inspection Program Compatibility Requirements

# APPENDIX B

# INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 33-52122-01
License Type: Industrial Radiography – Temporary Job Sites	Priority: 1
Inspection Date: 06/08/2015	Inspector: KD
Accompaniment No.: 2	License No.: 33-32706-01
License Type: Measuring Systems – Portable Gauges	Priority: 5
Inspection Date: 06/09/2015	Inspector: KD
Accompaniment No.: 3	License No.: 33-43520-01
License Type: Medical Institution – Written Directive	Priority: 2
Required, including High Dose Rate Remote Afterloader	
Inspection Date: 06/10/2015	Inspector: DS
Accompaniment No.: 4	License No.: 33-48922-01
License Type: Radionuclide Production Using an Accelerator	Priority: 2
Inspection Date: 06/11/2015	Inspector: DS