

August 22, 2013

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 July 15, 2013, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on North Dakota Agreement State Program for the followup review conducted in April 2013. The MRB found the North Dakota Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with the U.S. Nuclear Regulatory Commission's program. The MRB agreed that the period of Heightened Oversight of the North Dakota Agreement State Program be discontinued and that a period of Monitoring be initiated to allow additional time for the Program to demonstrate a period of sustained performance, especially with the impending vacancy of the Program Manager position.

Section 5.0, page 10, of the enclosed final report contains a summary of the IMPEP team's findings and recommendations. The review team made one new recommendation regarding the full qualification of inspection staff and kept one recommendation open from the previous IMPEP regarding staff retention and depth. The review team recommended closing the remaining 10 recommendations from the 2011 IMPEP review. We request your evaluation and response to the one new recommendation in the report within 30 days from receipt of this letter. 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 2 years, with a periodic meeting tentatively scheduled for April 2014.

T. Dwelle

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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 by Cathy Haney 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 w/encl: Cheryl Rogers, WI  
Organization of Agreement States  
Liaison to the MRB

T. Dwelle

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

April 22-26, 2013

**FINAL REPORT**

Enclosure

## EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) followup review of the North Dakota Agreement State Program. The review was conducted during the period of April 22-26, 2013, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Washington.

Based on the results of this followup 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. The remaining indicators, Technical Staffing and Training, and Compatibility Requirements, were discussed with North Dakota as part of the Periodic Meeting conducted concurrently with the IMPEP followup review.

The review team made one new recommendation regarding the full qualification of inspection staff and kept one recommendation open from the previous 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, are 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, but needs improvement, and is compatible with the NRC's program. The review team recommended, and the MRB agreed, that the period of Heightened Oversight of the North Dakota Agreement State Program be discontinued and that a period of Monitoring be initiated to allow additional time for the North Dakota Program to demonstrate a period of sustained performance, especially with the impending vacancy of the Program Manager position. The review team recommended, and the MRB agreed, that a Periodic Meeting be held in approximately one year and the next IMPEP review take place in approximately two years.

## 1.0 INTRODUCTION

This report presents the results of the followup Integrated Materials Performance Evaluation Program (IMPEP) review of the North Dakota Agreement State Program. The followup review was conducted during the period of April 22-26, 2013, by a review team composed of technical staff members from the U. S. Nuclear Regulatory Commission (NRC) and the State of Washington. Team members are identified in Appendix A. The followup review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and the NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the followup review, which covered the period of April 9, 2011 to April 26, 2013, were discussed with North Dakota managers on the last day of the review.

A draft of this report was provided to North Dakota for factual comment on May 31, 2013. The State responded by letter dated June 24, 2013. A copy of the State's response is included as an Attachment to this report. A Management Review Board (MRB) met on July 15, 2013, to consider the proposed final report. The MRB found the North Dakota Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program.

The North Dakota Agreement State Program is administered by the Radiation Control Program (the Program), in the Division of Air Quality (the Division). The Division is part of the Environmental Health Section under the North Dakota Department of Health.

At the time of the review, the North Dakota Agreement State Program regulated 102 specific licenses authorizing byproduct, source, and certain special nuclear materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of North Dakota.

As part of the Heightened Oversight process, the NRC conducted quarterly conference calls with the Program to discuss the State's progress in implementing the Program Improvement Plan (the Plan). The State submitted the Plan on August 17, 2011, and the NRC approved the Plan on October 3, 2011. A Periodic Meeting was held with the Program on March 8, 2012. Quarterly conference calls to review progress on the Plan were held on November 17, 2011, June 6, 2012, September 13, 2012, December 6, 2012, and February 5, 2013. A listing of correspondence and summaries from the Periodic Meeting and the quarterly calls is included as Appendix C. The Program's actions and its status, as documented in the Plan and subsequent status updates, were reviewed in preparation for this followup review.

The followup review focused on the Program's performance in regard to the common performance indicators: Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, and Technical Quality of Incident and Allegation Activities. The followup review also included evaluation of the actions taken by the Program to address the recommendations made during the 2011 IMPEP review. Other aspects of the Program not fully evaluated as part of the followup review were discussed at a Periodic

Meeting held in conjunction with the followup review. The Periodic Meeting summary is included as Appendix B.

In preparation for the followup review, a questionnaire addressing the applicable performance indicators was sent to the Program on January 23, 2013. The Program provided its response to the questionnaire on April 6, 2013. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML13105A022.

The review team's general approach for conduct of this followup review consisted of (1) examination of the Program's response to the questionnaire, (2) review of applicable North Dakota statutes and regulations, (3) analysis of quantitative information from the Program's database, (4) technical review of selected regulatory actions, (5) field accompaniments of two 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 North Dakota Agreement State Program's performance.

Section 2.0 of this report covers the State's actions in response to recommendations made during previous reviews.

Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings.

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on April 8, 2011, the review team made 11 recommendations regarding the North Dakota Agreement State Program's performance. The status of each recommendation is as follows:

1. "The review team recommends that the State (1) 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 (2) examine options to increase staff retention and/or develop sufficient depth in staffing to effectively implement the program. (Section 2.1 of 2011 IMPEP Report)"

Status: The State 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. Although staffing has stabilized since the last IMPEP review, and efforts have been made to increase depth in staffing by providing some cross training to X-ray inspectors, this recommendation remains open in order to monitor sustained performance by the Program in the area of staff training and qualifications.

2. "The review team recommends that the State take measures to ensure that initial inspections are performed at the interval prescribed in Inspection Manual Chapter (IMC) 2800. (Section 2.2 of 2011 IMPEP Report)"

Status: The State has taken measures to ensure that initial inspections are performed in a timely manner. The State improved the tracking of initial inspections and enhanced the associated procedures. No initial inspections were performed beyond the interval prescribed in IMC 2800. This recommendation is closed.

3. "The review team recommends that the State take measures to ensure that inspection findings are communicated to licensees within 30 days of the date of the inspection. (Section 2.2 of 2011 IMPEP Report)"

Status: The State has taken measures to ensure that inspection findings are communicated in a timely manner. The State improved the tracking of inspection reports and related correspondence, and enhanced the associated procedures. For the inspection casework reviewed, all inspection findings were provided to licensees within 30 days. This recommendation is closed.

4. "The review team recommends that the State (1) take measures to ensure that sufficient information pertaining to inspection observations and identified non-compliances is documented in inspection records and in letters to licensees and that these documents are appropriately reviewed by management, prior to issuance, for thoroughness and consistency, and (2) develop and implement a plan to address comments noted in Appendix C related to identified items of non-compliance that were not included in findings dispatched to licensees. (Section 2.3 of 2011 IMPEP Report)"

Status: The State has taken measures to ensure that the identified findings are documented in letters issued to the licensee and appropriately reviewed by management. These measures included elements to ensure all items of non-compliance were included in findings to the licensees. This recommendation is closed.

5. "The review team recommends that the State obtain additional training (formal and on-the-job, as appropriate) for the Program Manager and members of the technical staff to enhance inspection skills, particularly with regards to (1) radiation safety issues associated with cyclotron operations, and (2) proper operations and use of radiation survey and measurement instrumentation. (Section 2.3 of 2011 IMPEP Report)"

Status: The Program staff has accompanied both NRC and Minnesota inspectors in the past and plan to continue to do so as schedules permit. In particular, the State also continues to work with the State of Minnesota to obtain training on cyclotron inspections. The training consisted of the Program staff observing cyclotron inspections in the State of Minnesota, and a Minnesota inspector accompanying the inspector performing the cyclotron inspection in North Dakota jurisdiction. The State plans to conduct cyclotron inspections either with a State qualified inspector or request the assistance of a qualified inspector from another agency such as another Agreement State or an NRC regional office. Regarding the use of instrumentation, staff from the NRC Technical Training Center (TTC) along with contracted personnel from Oak Ridge Institute for Science and Education (ORISE), provided specific instrumentation training to the technical staff members in North Dakota during the week of October 25-27, 2011. During the inspector accompaniments for the 2011 IMPEP, there were issues identified associated with the use of radiation survey and measurement instrumentation; however, accompaniments for the 2013 IMPEP revealed no similar issues



regarding use of radiation survey and measurement instrumentation. This recommendation is closed.

6. "The review team recommends that the State (1) take measures to ensure that the Program's review of licensing actions are adequately documented and that licensing actions are thorough and consistent with the regulations and appropriate licensing guidance, and (2) take measures to address the licensing deficiencies that were identified in the comments in Appendix D of the 2011 IMPEP Report. (Section 2.4 of 2011 IMPEP Report)"

Status: The State has taken measures to ensure that licensing actions are adequately reviewed and documented using appropriate guidance. These measures included elements to ensure previous deficiencies were addressed. For the licensing casework reviewed no issues with review or documentation of licensing actions were identified. This recommendation is closed.

7. "The review team recommends that the State provide additional training to the Program Manager and technical staff members regarding technical review of licensing actions, including training to ensure that the staff acquires increased familiarity with (1) the regulations under North Dakota's equivalent to 10 CFR Parts 30 through 39, and (2) applicable licensing guidance documents for use authorization and license conditions. (Section 2.4 of 2011 IMPEP Report)"

Status: The State obtained additional training through NRC coursework. Also, the NRC Region IV staff provided specific licensing training to the State on March 5-7, 2012. This training included familiarization with regulations and applicable guidance documentation. License reviewers demonstrated enhanced knowledge and improved licensing performance. This recommendation is closed.

8. "The review team recommends that the Program take measures to determine and document the basis of confidence, through consistent use of the pre-licensing checklist and guidance, that radioactive materials will be used as intended and as described in the application or amendment request, prior to authorizing the material on the license. (Section 2.4 of 2011 IMPEP Report)"

Status: The State obtained additional training through NRC coursework. Also, the NRC Region IV staff provided specific licensing training to the State on March 5-7, 2012. This training included familiarization with regulations and applicable guidance documentation. License reviewers demonstrated enhanced knowledge and improved licensing performance. This recommendation is closed.

9. "Regarding financial assurance, the review team recommends that the State (1) develop a procedure or policy to assess financial assurance requirements as part of a significant licensing actions and during licensing renewals; (2) review all North Dakota licenses to determine whether licenses require financial assurance, and either request financial assurance for licenses that are authorized to process the applicable quantified or revise the license conditions to ensure clear quality limits that will not require provision of financial assurance; and (3) take measure to ensure that any financial assurance instruments received

by the Program are maintained and stored in accordance with State requirements. (Section 2.4 of 2011 IMPEP Report)”

Status: The State has developed procedures to assess financial assurance requirements and has reviewed all North Dakota licenses for financial assurance with appropriate followup. The State has taken measures to ensure that financial instruments are properly maintained and stored. These measures, along with procedural enhancements and staff training, have improved the licensing of financial assurance-related actions. This recommendation is closed.

10. “The review team recommends that the State strengthen its incident response program and take measures to ensure that (1) reported incidents are consistently evaluated to determine the appropriate type and level of Program response; (2) licensee event reports are reviewed by the Program for completeness and appropriate corrective actions; and (3) the Program’s evaluation of licensee events, whether based on a review of licensee reports, onsite reviews or inspection followup, is properly documented to facilitate future followup. (Section 2.5 of 2011 IMPEP Report)”

Status: The State has taken measures to strengthen its incident response program by establishing procedures to consistently evaluate incidents and appropriately respond. These procedures include evaluating corrective actions and documenting followup of events. These measures have improved the State’s response to events during the review period. This recommendation is closed.

11. “The review team recommends that the State strengthen its allegation program and take measures to ensure that (1) allegations are promptly evaluated to determine the appropriate type and level of Program response; (2) the Program’s evaluation of allegation and any actions taken in response to allegations is properly documented to facilitate future followup; and (3) processes are in place to provide a response to allegeders as appropriate. (Section 2.5 of 2011 IMPEP Report)”

Status: The State has taken measures to strengthen its allegation program by establishing procedures to consistently evaluate allegations and appropriately respond. These procedures include evaluating the circumstances and documenting followup, including responding to allegeders as appropriate. These measures have improved the State’s response to allegations during the review period. This recommendation is closed.

### 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. The indicator, Technical Staffing and Training, was found satisfactory in the 2011 IMPEP and therefore, not reviewed in this followup IMPEP. Technical staffing and training was discussed under the Periodic Meeting held concurrently (Appendix B).

### 3.1 Status of Materials Inspection Program

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

The review team verified that North Dakota's inspection frequencies for all types of radioactive material licenses are as frequent or in some cases (i.e. Type A broad scope, medical institution-no written directive required and well logging) more frequent as similar license types listed in IMC 2800, "Materials Inspection Program."

The Program conducted approximately 28 Priority 1, 2, and 3 inspections during the review period. None of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. In addition, the Program performed five initial inspections during the review period, none of which was conducted overdue. Overall, the review team determined that the Program performed none of its inspections overdue during the review period.

The review team evaluated the Program's timeliness in providing inspection findings to licensees. A sampling of 10 inspection reports (see Appendix D) indicated that none of the inspection findings were communicated to the licensees beyond the Program's goal of 30 days after the inspection.

During the review period, the Program granted 18 reciprocity permits in calendar year (CY) 2011, 15 of which were candidate licensees based upon the criteria in IMC 1220. The Program granted 24 reciprocity permits in CY 2012, 23 of which were candidate licensees. The review team determined that the Program inspected 7 percent of the CY 2011 reciprocity candidates, and 22 percent of the CY 2012 reciprocity candidates during the two years covered by the review period. The review team noted that the lower percentage of reciprocity inspections in 2011 was due in part to resource allocation and lacking inspector qualifications.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

### 3.2 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 10 of the 28 radioactive materials inspections and seven reciprocity inspections conducted during the review period. The casework reviewed included inspections conducted by two program inspectors and covered inspections of various license types, including: medical institutions-therapy, high dose rate remote afterloader, unsealed radioiodine therapy, permanent or temporary implant brachytherapy, medical-diagnostic, portable gauges, and industrial radiography. Appendix D lists the inspection casework files reviewed, as well as the results of the inspector accompaniments.

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

The inspection procedures utilized by the Program are consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector which is then reviewed and signed by the accompanying inspector and the Radiation Control Program Manager. Per the North Dakota Radiation Control Program Administrative Policies and Procedures Manual issued April 15, 2013, supervisory accompaniments by the Radiation Control Program Manager or the Division Director are required for 10 percent of all inspections. Of the 28 inspections identified in the IMPEP questionnaire, the Radiation Control Program Manager accompanied the inspection team on four of those inspections (14 percent). The Radiation Control Program Manager also accompanied the inspection team on two of the seven reciprocity inspections conducted of the available candidates during the evaluation period (28 percent).

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 Program issues to the licensee, either a letter indicating a clear inspection or a Letter of Apparent Non-Compliance (LOAN), in letter format, which details the results of the inspection. When the Program issues a LOAN, the licensee is required to provide a written corrective action plan, based on the apparent non-compliances cited, within 30 days. All findings are reviewed by the Radiation Control Program Manager.

The review team noted that the Program has an adequate supply of survey instruments to support its inspection program. Appropriate, calibrated survey instrumentation, such as Geiger-Mueller meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors, was observed to be available. Instruments are appropriately calibrated at least annually.

Accompaniments of both program inspectors were conducted by one IMPEP team member during the week of March 19-22, 2013. The inspectors were accompanied during health and safety inspections of medical therapy including high dose rate remote afterloader/unsealed radioiodine therapy/permanent implant brachytherapy, medical diagnostic licenses, fixed and portable gauges. The accompaniments are identified in Appendix D. 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.

One weakness noted in the Program was that none of the technical staff are fully qualified to inspect all radioactive material program areas licensed by the State. This is partly due to the

small number of staff and the significant staff turnover in years prior to this IMPEP followup review. This is also due to a relatively small number of licensees in the State which leads to fewer opportunities to gain experience in certain areas. For example, there are only two broad scope licensees and one cyclotron licensed in North Dakota. Therefore, it has been difficult for technical staff to gain inspection experience in these areas. Another area is well-logging which has recently become a potential area of growth in both numbers of licensees and reciprocity applicants due to the oil and gas industry boom. 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.

Based on the IMPEP evaluation criteria, 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, but needs improvement.

### 3.3 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 11 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 seven amendments, three new licenses, and one termination. Files reviewed included a cross-section of license types, including medical diagnostic and therapy including high dose rate remote afterloader, unsealed radioiodine therapy, industrial radiography, and portable and fixed gauges. The casework sample represented work from two license reviewers. A listing of the licensing casework evaluated is provided in Appendix E.

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 NRC NUREG-1556 series guidance documents or equivalent, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses.

The Program Director performs a supervisory review on all licensing actions before issuance to the licensee. Licenses are issued for a 10 year period under a timely renewal system.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the Program licensing procedures, the State's regulations, and

good health physics practices. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

The Program performs pre-licensing checks of all new applicants. The Program's pre-licensing review methods incorporate the essential elements of the 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 Program's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the State uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, including fingerprinting, as appropriate. The review team analyzed the Program'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 Program 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 Program's 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. The review team noted that the Program maintains adequate controls to access its licensing and inspection files. Files that contained sensitive information were further secured in locked file cabinets.

Based on the IMPEP evaluation criteria, 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.

### 3.4 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Program's actions in responding to incidents and allegations, the review team examined the Program's response to the questionnaire relative to this indicator, evaluated selected incidents reported for North Dakota in the Nuclear Material Events Database (NMED) against those contained in the Program's files, and evaluated the casework for two radioactive materials incidents. A list of the incident casework examined may be found in Appendix E. The review team also evaluated the Program's response to three allegations involving radioactive materials, including one allegation referred to the State by the NRC during the review period.

The review team identified two radioactive material incidents in NMED for North Dakota during the review period. The review team reviewed both radioactive material incidents. The incidents involved an equipment failure that led to an inability to retract a radiography source, and a procedural failure that led to a radiography source disconnect.

The review team determined that the Program'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. Followup actions were taken and

additional review of each event was made during the next inspections. 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. As a policy, the State reports all incidents in NMED regardless of reportability.

The review team examined the Program'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 Program Manager, with staff input, determines the appropriate level of initial response.

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

Based on the IMPEP evaluation criteria, 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 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, low level radioactive waste disposal, or uranium recovery program. Therefore, only the first non-common performance indicator for compatibility would apply. The indicator, Compatibility Requirements, was found satisfactory in the 2011 IMPEP and therefore, not reviewed in this followup IMPEP. Compatibility Requirements was discussed under the Periodic meeting held concurrently (Appendix B).

#### 5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, 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. The review team made one recommendation regarding qualification of staffing and kept one recommendation open from the 2011 IMPEP review. The review team determined the 10 other recommendations from the 2011 IMPEP review should be closed.

The review team recommended, and the MRB agreed, that the North Dakota Agreement State Program is adequate to protect public health and safety, but needs improvement, and is compatible with the NRC's program. The review team recommended, and the MRB agreed, that the period of Heightened Oversight of the North Dakota Agreement State Program be discontinued and that a period of Monitoring be initiated to allow additional time for the Program to demonstrate a period of sustained performance, especially with the impending vacancy of the Program Manager position. The review team recommended, and the MRB agreed, that a Periodic Meeting be held in approximately one year and the next IMPEP review take place in approximately two years.

Below are the review team's recommendations, as mentioned in the report, for evaluation and implementation by the State:

#### RECOMMENDATIONS

1. The review team recommends that the State (1) 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 (2) examine options to increase staff retention and/or develop sufficient depth in staffing to effectively implement the program. (Section 2.1 of 2011 IMPEP Report)
2. 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. (Section 3.2)



## LIST OF APPENDICES

|            |   |
|------------|---|
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## APPENDIX A

### IMPEP REVIEW TEAM MEMBERS

| <b>Name</b>                           | <b>Area of Responsibility</b>   |
|---------------------------------------|---|
| Bryan Parker, Region III              | Team Leader<br>Technical Quality of Incident and Allegation Activities<br>Status of Materials Inspection Program<br>Inspection Accompaniments |
| Randy Erickson, Region IV             | Technical Quality of Inspections<br>Compatibility Requirements<br>Technical Staffing and Training   |
| Stephen Matthews, State of Washington | Technical Quality of Licensing Actions  |

Marti Poston-Brown, Region IV, supported the team with the review of Status of Materials Inspection Program and Technical Quality of Inspections

## APPENDIX B

### PERIODIC MEETING SUMMARY

A Periodic Meeting was held with the Program Manager by Randy Erickson, Team Member and Regional State Agreements Officer, during the followup IMPEP review pursuant to the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-116, "Periodic Meetings between IMPEP Reviews." Topics normally documented during Periodic Meetings that were reviewed and documented as part of the followup IMPEP review are not discussed in this Appendix. The following topics were discussed:

#### Status of Recommendations from Previous IMPEP Reviews

See Section 2.0 for details on the status of recommendations identified during the previous IMPEP review.

#### Program Strengths

During the last IMPEP review period there were significant turnovers within the Radiation Control Program, which impacted the program and contributed to the number of recommendations identified by the IMPEP review team. Since the last IMPEP review, there has been stability in the staffing of the Radiation Control Program. The two technical staff members have completed most of the required training courses and some of the specialized training courses necessary to support the program. The Program Manager indicated that the staff has gained significant confidence in implementing program requirements. The Program Manager indicated that as the staff gains more experience and confidence it will only further enhance the program. The Program Manager stated that another major strength of the program is that they are well funded and that resources are sufficient to support the program.

#### Program Weaknesses

The Radiation Control Program went through a cycle of significant turnover during the last IMPEP review period. The Radiation Control Program is fully staffed with two technical staff members and one supervisor to support a growing radiation control program. The Program Manager indicated that minimum staffing levels could potentially be a weakness in the event the program experiences any additional turnover. As a result, additional personnel in the Air Quality Division are being trained to support the Agreement State Program and provide the additional man-power support in areas such as medical inspections.

#### Feedback on NRC's Program

The Program indicated that the IMPEP process was a very beneficial program and the review team provided good recommendations that focused the Radiation Control Program on areas that needed improvement. The IMPEP process guided the Radiation Control Program to develop policies and procedures to promote knowledge management transfer and minimize the impacts from any future, potential turnover in personnel.

The Program also stated that they have had little trouble getting into NRC courses and that they appreciate NRC paying for their attendance at the training courses.

### Staffing and Training

It was noted during the 2011 IMPEP review that several staff had left the Program for various reasons causing the Program to fall behind in many program areas. However, since that time the staff has remained stable. At the present time the Program is composed of a working supervisor and two technical staff members. The Program Manager and one of the technical staff members are considered qualified to perform most inspection types, and the second staff member is considered qualified to only perform fixed and portable gauge inspections at the present time. Additionally, staff from the X-ray program are being sent to NRC training courses as a means to develop depth in staffing to support the Radiation Control Program primarily with medical inspections of small facilities.

Training and qualification requirements are found in the Administrative Procedures Manual. Training and documentation of inspector activities (observation of and participation in inspections) is recorded on a Training Regimen Checklist which is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."

During the review, the Program Manager discussed with the review team the qualification process used in North Dakota. The Program Manager self-identified that he was not formally signed-off to perform inspections. Over the previous six years he attended NRC training courses, supported multiple inspection accompaniments with both NRC and Minnesota inspectors, and had performed inspections in the presence of Minnesota inspectors, but he did not receive any type of formal sign-off confirming he had the skills necessary to perform an inspection independently. In addition, he has been training the current inspection staff and confirming they had the skills necessary to perform certain inspections.

The team discussed this situation with the Program Manager and then with North Dakota senior management. Collectively, it was determined that the Program Manager will document his classroom training in addition to his work history on the Training Regimen Checklist after which time the Division Director would sign off formally qualifying the Program Manager. Once this is completed, then the Program Manager can continue to qualify the staff.

### Program Reorganizations

There has not been a program reorganization since the IMPEP review.

### Changes in Program Budget/Funding

The Program has not been impacted by the recession or a reduction in revenue as a number of other state economies have experienced. The state is poised to continue to successfully meet their budget obligations based on the strong state economy as a result of the oil and gas industry and fiscally conservative agenda in the state programs. The Program evaluated their

fee structure and set up a six-year program which automatically increased fees by fourteen percent annually. After the sixth year, the fee structure will be adjusted automatically based on the Consumer Price Index (CPI). When this fee increase is completed in 2016, the Program will be at 54.62 percent of 2011 NRC fees. They also have a small entity fee that will remain at 60 percent of normal fee amounts.

#### Status of the Materials Inspection Program

See Sections 3.2 and 3.3 for details on the Materials Inspection Program.

#### Materials Licensing Program

See Section 3.4 for details on the Licensing Program.

#### Regulations and Legislative Changes

The Program has not had any legislation passed that affected the program. The following amendments will need to be addressed by the Radiation Control Program in future rulemakings or by adopting alternate generic legally binding requirements:

- "Decommissioning Planning," 10 CFR Parts 20, 30, 40, and 70 amendment (76 FR 35512) that is due for Agreement State adoption by December 17, 2015
- "Licenses, Certifications, and Approvals for Materials Licensees," 10 CFR Parts 30, 36, 40, 70, and 150 (76 FR 56951) that is due for Agreement State adoption by November 14, 2014

#### Response to Incidents and Allegations

See Section 3.4 for details on the Incident and Allegations Program.

#### Status of Allegations and Concerns Referred by the NRC for Action

See Section 3.4 for details on the Incident and Allegations Program.

#### Emerging Technologies

None Reported

#### Large, Complicated, or Unusual Authorizations for use of Radioactive Materials

None Reported

#### Current State Initiatives

None Reported

### State's Mechanisms to Evaluate Performance

The Radiation Control Program uses management review of inspection reports and licensing actions to ensure the quality of regulatory products. The Radiation Control Program holds a meeting every two weeks to track metrics and ensure communications are sufficient for any large or complicated actions. The Radiation Control Program Supervisor performs accompaniments of the technical staff members during inspections.

### Current NRC Initiatives

NRC staff discussed ongoing Office of Federal and State Materials and Environmental Management Programs (FSME) initiatives with the North Dakota representatives. This included a review of strategic FSME and RCPD letters, as well as proposed rulemaking and Regulatory Issues Summaries.

## APPENDIX C

### HEIGHTENED OVERSIGHT PROGRAM CORRESPONDENCE

#### Summaries of Quarterly Conference Calls:

1. November 17, 2011 Summary (ML120900390)
2. June 6, 2012 Summary (ML12192A689)
3. September 13, 2012 Summary (ML12261A082)
4. December 6, 2012 Summary (ML12348A065)
5. February 5, 2013 Summary (ML13039A277)

#### Letters from/to North Dakota:

1. August 17, 2011 E-mail Letter to R. Browder, RASO, RIV from D. Harman – Submittal of Program Improvement Plan (ML112341233)
2. October 3, 2011 Letter to T. O'Clair from J. Luehman, FSME – NRC Acceptance of Program Improvement Plan (ML112720330)
3. April 6, 2012 Letter to T. O'Clair from R. Browder, RASO, RIV – Summary of Periodic Meeting Held on March 8, 2012 (ML12097A460)

## APPENDIX D

### INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

|   |                              |  |
|---|------------------------------|--|
| File No.: 1                                     |                              |  |
| Licensee: American Sugar Crystal Co – Hillsboro | License No.: 33-05208-01     |  |
| Inspection Type: Routine, Unannounced           | Priority: 5                  |  |
| Inspection Date: 03/22/13                       | Inspectors: LV (lead) and DS |  |
| File No.: 2                                     |                              |  |
| Licensee: Sanford Medical Center                | License No.: 33-10227-02     |  |
| Inspection Type: Routine, Unannounced           | Priority: 2                  |  |
| Inspection Date: 03/20/13                       | Inspectors: DS (lead) and LV |  |
| File No.: 3                                     |                              |  |
| Licensee: Jamestown Regional Medical Center     | License No.: 33-05026-01     |  |
| Inspection Type: Routine, Unannounced           | Priority: 3                  |  |
| Inspection Date: 03/21/13                       | Inspectors: DS (lead) and LV |  |
| File No.: 4                                     |                              |  |
| Licensee: Bismarck Cancer Center                | License No.: 33-41919-01     |  |
| Inspection Type: Routine, Unannounced           | Priority: 2                  |  |
| Inspection Date: 04/02/12                       | Inspectors: DS (lead) and LV |  |
| File No.: 5                                     |                              |  |
| Licensee: Schlumberger                          | License No.: 33-00090-01     |  |
| Inspection Type: Routine, Unannounced           | Priority: 3                  |  |
| Inspection Date: 02/02/13                       | Inspectors: DS (lead) and LV |  |
| File No.: 6                                     |                              |  |
| Licensee: St. Alexis Medical Center             | License No.: 33-11320-01     |  |
| Inspection Type: Routine, Unannounced           | Priority: 3                  |  |
| Inspection Date: 05/16-17 & 22/12               | Inspectors: DS (lead) and LV |  |
| File No.: 7                                     |                              |  |
| Licensee: Team Industrial                       | License No.: 33-48313-01     |  |
| Inspection Type: Routine, Unannounced           | Priority: 1                  |  |
| Inspection Date: 10/16 & 11/02/12               | Inspectors: DS (lead) and LV |  |
| File No.: 8                                     |                              |  |
| Licensee: Steele Testing, Inc.                  | License No.: 33-49619-01     |  |
| Inspection Type: Initial, Announced             | Priority: 1                  |  |
| Inspection Date: 10/05/12                       | Inspectors: LV (lead) and DS |  |



File No.: 9

Licensee: T&K Inspection, Inc.  
Inspection Type: Routine, Announced  
Inspection Date: 04/28/11

License No.: 33-22313-01  
Priority: 1  
Inspectors: DS (lead) and LV

File No.: 10

Licensee: Northern Technologies Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 03/19/13

License No.: 33-32112-01  
Priority: 5  
Inspectors: LV (lead) and DS

### INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Northern Technologies, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 03/19/13

License No.: 33-32112-01  
Priority: 5  
Inspectors: LV (lead) and DS

Accompaniment No.: 2

Licensee: Sanford Medical Center  
Inspection Type: Routine, Unannounced  
Inspection Date: 03/20/13

License No.: 33-10227-02  
Priority: 2  
Inspectors: DS (lead) and LV

Accompaniment No.: 3

Licensee: Jamestown Regional Medical Center  
Inspection Type: Routine, Unannounced  
Inspection Date: 03/21/13

License No.: 33-05026-01  
Priority: 3  
Inspectors: DS (lead) and LV

Accompaniment No.: 4

Licensee: American Sugar Crystal Co – Hillsboro  
Inspection Type: Routine, Unannounced  
Inspection Date: 03/22/13

License No.: 33-05208-01  
Priority: 5  
Inspectors: LV (lead) and DS

## APPENDIX E

### LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

|  |  |
|--|--|
| File No.: 1<br>Licensee: Desert NDT, LLC<br>Type of Action: Amendment<br>Date Issued: 02/26/13                       | License No.: 33-51220-01<br>Amendment No.: 2<br>License Reviewer: LV     |
| File No.: 2<br>Licensee: Northern Technologies<br>Type of Action: Amendment<br>Date Issued: 03/28/13                 | License No.: 33-32112-01<br>Amendment No.: 7 & 8<br>License Reviewer: LV |
| File No.: 3<br>Licensee: Coca Cola Enterprises<br>Type of Action: New<br>Date Issued: 04/08/10                       | License No.: 33-48406-01<br>Amendment No.: N/A<br>License Reviewer: DS   |
| File No.: 4<br>Licensee: Calfrac Well Services<br>Type of Action: Amendment<br>Date Issued: 04/12/12                 | License No.: 33-48406-01<br>Amendment No.: 2<br>License Reviewer: DS     |
| File No.: 5<br>Licensee: T & K Inspection<br>Type of Action: Termination<br>Date Issued: 01/16/13                    | License No.: 33-22313-01<br>Amendment No.: 21<br>License Reviewer: DH    |
| File No.: 6<br>Licensee: Sanford Medical Center<br>Type of Action: Amendment<br>Date Issued: 05/18/12                | License No.: 33-10227-02<br>Amendment No.: 56<br>License Reviewer: DS    |
| File No.: 7<br>Licensee: Tesoro Refining and Marketing Company<br>Type of Action: Amendment<br>Date Issued: 09/07/12 | License No.: 33-06568-03<br>Amendment No.: 17<br>License Reviewer: DS    |
| File No.: 8<br>Licensee: Bismarck Cancer Center<br>Type of Action: Amendment<br>Date Issued: 04/12/13                | License No.: 33-41919-01<br>Amendment No.: 14<br>License Reviewer: DS    |

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License Casework Reviews

E. 2

File No.: 9

Licensee: St. Alexius Medical Center

Type of Action: Amendment

Date Issued: 06/12/12

License No.: 33-11320-01

Amendment No.: 43

License Reviewer: DS

File No.: 10

Licensee: Estvold Oilfield Services, Inc.

Type of Action: New

Date Issued: 08/27/12

License No.: 33-51120-01

Amendment No.: N/A

License Reviewer: LV

File No.: 11

Licensee: Tops Well Services

Type of Action: New

Date Issued: 12/12/12

License No.: 33-51417-01

Amendment No.: N/A

License Reviewer: LV

APPENDIX F

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Midwest Industrial X-Ray, Inc.

Date of Incident: 05/16/12

Investigation Date: 05/18/12

License No.: 33-14907-01

NMED No.: 120312

Type of Incident: Equipment failure

Type of Investigation: Office review initially with followup during next inspection performed on 03/14/13

File No.: 2

Licensee: Braun Intertec

Date of Incident: 12/10/12

Investigation Date: 12/12/12

License No.: 33-48303-01

NMED No.: 120729

Type of Incident: Procedure failure

Type of Investigation: Office review initially with followup during next inspection performed on 02/14/13

ATTACHMENT

June 24, 2013 Letter from Terry O'Clair  
North Dakota's Response to the Draft Report  
ADAMS Accession No.: ML13178A248