



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
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ARLINGTON, TEXAS 76011-4511

April 6, 2012

Terry L. O'Clair, Director
Division of Air Quality
North Dakota Dept of Health
918 East Divide Avenue
Bismarck, ND 58501-1947

SUBJECT: SUMMARY OF PERIODIC MEETING WITH NORTH DAKOTA DEPARTMENT OF HEALTH HELD ON MARCH 8, 2012

Dear Mr. O'Clair,

A periodic meeting was held with Mr. Dan Harman and you on March 8, 2012, at your offices at the Department of Health, Division of Air Quality in Bismarck, North Dakota. The purpose of this meeting was to review and discuss the status of the North Dakota Agreement State Program. The NRC was represented by Dr. Janine Katanic from the Office of Federal and State Materials and Environmental Management Programs (FSME) and me from Region IV.

We have completed and enclosed a general meeting summary. If you or your staff determines that our conclusions do not accurately summarize the meeting discussion, or if there are any additional remarks or questions regarding the meeting, please contact me at 817-200-1116 or by e-mail at Rachel.Browder@nrc.gov to discuss your concerns. There will be a Special MRB for this Periodic Meeting, which will be coordinated with you.

Sincerely,

/RA/

Rachel S. Browder, *CHP*
Regional State Agreements Officer

Enclosure:
North Dakota Periodic Meeting Summary

Terry L. O'Clair

- 2 -

cc w/enclosure:

Dan Harman, Supervisor
Radiation Control Program
North Dakota Dept of Health
Division of Air Quality
918 East Divide Avenue
Bismarck, ND 58501-1947

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NORTH DAKOTA PERIODIC MEETING SUMMARY

Date of Meeting: March 8, 2012

Attendees

NRC	NORTH DAKOTA
Rachel Browder, RSAO	Terry L. O'Clair, Director Division of Air Quality
Janine Katanic, Ph.D., FSME	Dan Harman, Supervisor Radiation and Indoor Air Program
	Dave Stradinger, Technical Staff Radiation Control Program
	Lewis Vigen, Technical Staff Radiation Control Program

DISCUSSION:

The North Dakota Agreement State Program is administered by the Department of Health, Division of Air Quality (Division), Radiation Control Program. The Radiation Control Program regulates approximately 90 specific licenses authorizing byproduct, source, and certain special nuclear materials (radioactive materials). The number of specific licenses has increased from 76 licenses at the time of the IMPEP review in April 2011. The increase is due primarily to the increased number of radiography and well logging licenses in support of activities from the Bakken oil and gas formation in the state. The increase in the number of industrial licenses has also increased the number of inspections performed by the Radiation Control Program.

The last IMPEP review was conducted April 4-8, 2011. The review team recommended and the Management Review Board (MRB) agreed that a period of Heightened Oversight be initiated for North Dakota Agreement State Program. There were eleven recommendations which addressed training and staff retention, the inspection program, licensing program, and development of policies and procedures for incidents and allegations. The IMPEP review team further recommended, and the MRB agreed, that a Periodic Meeting be held within one year to assess the State's progress in addressing the open recommendations, and that a follow-up IMPEP review take place in approximately two years, which would be April 2013. The purpose of this Periodic Meeting is to fulfill that requirement in order to evaluate the overall implementation of the Agreement State Program.

Performance Improvement Plan

The Radiation Control Program developed a Performance Improvement Plan (PIP) (ML112341233) to address each recommendation identified during the IMPEP review. The PIP was approved by letter dated October 3, 2011 (ML112720330). Following is a status of the actions to address each recommendation. These actions should be reviewed during the next IMPEP in order to close the respective recommendation.

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 and 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. (*Technical Staffing and Training*)

Status: The Radiation Control Program is developing written policies and procedures to capture all of the necessary processes for program implementation. The overarching management document will outline the policies and the procedures will implement the program. These documents will serve as a knowledge management tool. Additional staff from other units have been identified to attend NRC training courses as a means to develop depth in staffing to support the Radiation Control Program. The Department has provided annual performance bonuses to assist with staff retention. In addition, the Department indicated that the staff may participate in the Department's mentorship program to further develop and enhance leadership and management training skills, which is an avenue to retain employees.

2. The review team recommends that the State take measures to ensure that initial inspections are performed at the interval prescribed in IMC 2800. (*Status of Materials Inspection Program*)

Status: The Radiation Control Program has developed checklists and policies to perform initial inspections at a target date of nine months after the license is issued to ensure that the twelve month initial inspection requirement is met. The nine month target is tracked in their inspection database. The Radiation Control Program reported that since the IMPEP, no initial inspections have exceeded the interval prescribed in IMC 2800.

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. (*Status of Materials Inspection Program*)

Status: The Radiation Control Program has drafted and issued a procedure that specifies findings should be communicated to licensees within 30 days of the date of the inspection. The target date for inspection report issuance is tracked by the Radiation Control Program in an electronic assignment tracker system.

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 be 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 that were dispatched to licensees. (*Technical Quality of Inspections*)

Status: The Radiation Control Program has drafted and implemented procedures to ensure that the identified findings are captured in the letter issued to the licensee. The Radiation Control Program is continuing to review and address comments associated with Appendix C from the last IMPEP report. To assist the Radiation Control Program in addressing the Appendix C comments, Dr. Katanic provided further clarification to the Branch Manager regarding the comments that lacked specific detail.

5. The review team recommends that the State obtain additional training (formal and on-the-job, as appropriate) for the Branch 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 operation and use of radiation survey and measurement instrumentation. (*Technical Quality of Inspections*)

Status: Regarding item (1), the Radiation Control Program has continued to work with the State of Minnesota to obtain training on cyclotron inspections. The continued training consisted of the Radiation Control Program observing cyclotron inspections in the State of Minnesota and an inspector from the State of Minnesota performing an accompaniment of the inspector performing the cyclotron inspection in North Dakota jurisdiction. Regarding item (2), the staff from NRC's TTC, along with contracted personnel from ORISE, provided specific instrumentation training to the technical staff members in the State of North Dakota during the week of October 25-27, 2011. In addition, to further enhance the technical staff inspection skills, the Radiation Control Program is coordinating with the Region IV office to observe NRC inspections, and then will coordinate NRC accompaniments of the Radiation Control Program inspectors, in order to obtain NRC's evaluation and feedback.

6. The review team recommends that the State: (1) take measures to ensure that the Branch'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. (*Technical Quality of Licensing Actions*)

Status: The Radiation Control Program has developed written policies and procedures to address licensing action processes. The policies and procedures address new license applications, renewals, routine amendment requests, and reciprocity requests. In addition, appropriate licensing action checklists have been developed and are being used to ensure actions are completed in accordance with the appropriate NUREG-1556 guidance. The Radiation Control Program has reviewed the casework identified in Appendix D and have taken measures as appropriate to address the licensing deficiencies that were identified in the comments. In addition, the Radiation Control Program has requested additional information from the license holders of the broad scope and cyclotron licenses, in order for the Program to review and evaluate the respective licensee's program.

7. The review team recommends that the State provide additional training to the Branch 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. (*Technical Quality of Licensing Actions*)

Status: The Radiation Control Program has received specific training for more complicated types of licensing actions by the Region IV staff during the week of March 5, 2012. Region IV staff has also provided informal training to Radiation Control Program staff based on their inquiries to specific types of licensing actions. In addition, the Radiation Control Program has developed checklists for each type of licensing action supported by the NUREG-1556 series.

8. The review team recommends that the Branch 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. (*Technical Quality of Licensing Actions*)

Status: The Radiation Control Program has developed checklists to provide a basis of confidence that radioactive materials will be used as intended. The Radiation Control Program reported that they have been utilizing the checklists during the pre-licensing process, including performing and documenting pre-licensing visits where necessary. The checklists will be incorporated into the policies and procedures for performing licensing actions.

9. Regarding financial assurance, the review team recommends that the State: (1) develop a procedure or policy to assess finance assurance requirements as part of significant licensing actions and during licensing renewals; (2) review all North Dakota licenses to determine whether licensees require financial assurance, and either request financial assurance for licenses that are authorized to possess the applicable quantities or revise the license conditions to ensure clear quantity limits that will not require provision of financial assurance; and (3) take measures to ensure that any financial assurance instruments received by the Branch are maintained and stored in accordance with State requirements. (*Technical Quality of Licensing Actions*)

Status: The Radiation Control Program instituted use of a procedure and spreadsheet to determine whether applicants or existing licenses required financial assurance. The Radiation Control Program indicated that the licenses had been reviewed for financial assurance and the necessary instruments had been obtained, as required. The instruments were stored in accordance with the Program's policy. The Radiation Control Program intends to perform an annual audit of the financial assurance program to ensure that the requirements are being met. In addition, the Radiation Control Program has reviewed and modified open-ended possession limits as appropriate for applicable licenses.

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 Branch response; (2) licensee event reports are reviewed by the Branch for completeness and appropriate corrective actions; and (3) the Branch's evaluation of licensee events, whether based on a review of licensee reports, on-site reviews, or inspection follow-up, is properly documented to facilitate future follow-up. (*Technical Quality of Incident and Allegation Activities*)

Status: The Radiation Control Program has developed a checklist to ensure that pertinent incident information is obtained for various types of materials incidents. The Radiation Control Program is developing policies and procedures to process, track and close the incident, as well as develop criteria to determine when to inspect, perform on-site reviews, and ensure that licensee corrective actions are documented and implemented appropriately. There have been no reported incidents since the IMPEP so the Radiation Control Program has not had the opportunity to utilize this new process.

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 Branch response; (2) the Branch's evaluation of allegations and any actions taken in response to allegations is properly documented to facilitate future follow-up; and (3) processes are in place to provide a response to allegeders as appropriate. (*Technical Quality of Incident and Allegation Activities*)

Status: The Radiation Control Program has developed a checklist to ensure that pertinent information for the allegation is obtained. The Radiation Control Program is developing policies and procedures to address how to process, track and close allegations. In addition, the Program indicated that they are developing criteria to determine when to inspect, perform on-site reviews, and ensure the allegation is properly documented. The Radiation Control Program expressed that they provide the results of the investigation into the allegation to the concerned individual at the conclusion of the investigation, either by email or formal correspondence.

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. Over the past year since the last IMPEP review, there has been stability in the staffing of the Radiation Control Program positions. 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 Director indicated that the staff are very competent and have gained significant confidence in implementing the program requirements. The Director indicated that as the staff gain more experience and confidence then it will greatly enhance the program. The Director indicated that another strength of the program is that the budget is well funded overall in state programs and therefore does not impact program resources.

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 Director indicated that minimum staffing levels could potentially be a weakness, in the event the program experiences any 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 limited medical inspections.

Feedback on NRC's Program

The Radiation Control 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 of 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.

Staffing and Training

The Radiation Control Program experienced a number of turnovers during the last IMPEP review period. However, during the past two years, there has been stability in staff supporting the program, which includes one supervisor and two staff members. One of the technical staff members is qualified to perform all program type inspections, and the second staff member is qualified to perform fixed and portable gauge inspections. The second staff member is working towards completing his inspection qualification journal for all program types. The Radiation Control Program follows the guidance in IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area" by generating qualification journals to support the qualification of each technical staff member.

Both technical staff members work independently as well as collaboratively to ensure that licensing actions address all health and safety issues and reflect the licensing guidance in NUREG-1556 series. The licensing actions are reviewed by the Supervisor and signed by the Division Director.

As part of the cross-training initiative, the Radiation Control Program is training two additional staff members from other units to support the Radiation Control Program, by sending them to the NRC-sponsored core training courses. This effort should lessen any future impacts as a result of turnovers or retirements.

The Radiation Control Program indicated that they have been able to obtain the training classes necessary to support the inspection and licensing qualification program.

Program Reorganizations

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

Changes in Program Budget/Funding

North Dakota state programs, including the Radiation Control Program, have 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 Radiation Control 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). The year 2013 will be the third year in the six-year program. Even with the increase in fees, the North Dakota fee structure is approximately 20-40 percent of the NRC fee structure.

Materials Inspection Program

The number of licenses in the Radiation Control Program has increased by approximately 20 percent over the last year, to approximately 90 specific licenses total. The majority of new licenses issued are radiography and well logging to support the oil and gas industry in the state. The inspection interval for a radiography license with temporary jobsite authorization is every year and the interval is three years for well logging license. At the time of this periodic meeting, the Radiation Control Program reported that there were no overdue inspections. The security inspections were being performed in conjunction with the health and safety inspections. The Radiation Control Program schedules the initial inspection for new licenses within nine months to ensure the inspection is completed within the first year. The Radiation Control Program follows IMC 2800 for the inspection priority codes assigned to the respective program code. Reciprocity activities are tracked in a database to ensure inspections of licensed activities are performed when possible to meet the inspection criteria in IMC 2800. The Radiation Control Program has faced challenges in performing routine and reciprocity inspections of licensed activities involving the oil and gas industry due to lodging shortages in the geographic area and the extensive driving distances involved to reach the work locations.

Materials Licensing Program

As already indicated, there was an increase in the number of new licenses issued during this review period. The Radiation Control Program indicated that they were performing pre-licensing visits in accordance with the risk significant radioactive material (RSRM) guidance and performing the pre-licensing security inspections as required by IMC 2800. The Radiation Control Program indicated that their expectation was to complete licensing actions within 30-days, once the technical staff had received the completed application or amendment request and all supporting documentation. The Radiation Control Program indicated that they do not have a backlog of licensing actions. Since the last IMPEP review, the Radiation Control Program has reviewed all licenses for financial assurance and ensured that the required instruments were submitted. The financial assurance instruments were controlled in accordance with the Division's policy.

Regulations and Legislative Changes

The State is up to date on the submittal of regulatory amendments currently required for compatibility, and they have a process in place to address the comments which were identified in the final rule packages for (RATS ID 2006-2) and (RATS ID 2007-3). The state did not have

any comments for (RATS ID 2001-1), which concerns generally licensed devices (GLDs). This regulation review has been held in abeyance as a result of the proposed rule on GLDs. However, as discussed during the periodic meeting and as documented in FSME letter 12-016, there was a change in compatibility of 10 CFR 31.5 and 31.6, as well as the withdrawal of the proposed rule and closure of Petition For Rulemaking: Organization of Agreement States and Florida Department of Health, Bureau of Radiation Control. The NRC will review (RATS ID 2001-1) and (RATS ID 2012-1) and self initiate changes to North Dakota's State Regulation Status (SRS) Data Sheet and close the review by letter. Therefore, the State will not be required to submit a package for (RATS ID 2012-1). The State indicated that they didn't have any plans to modify this section of the regulations.

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

Event Reporting, Including Follow-up and Closure Information in NMED

At the time of the periodic meeting, the Radiation Control Program did not have any events reported in the Nuclear Material Events Database (NMED) since the April 2011 IMPEP review. The Radiation Control Program has developed procedures to track and investigate events. The procedure follows the guidance in FSME procedure, SA-300, "Reporting Material Events."

Response to Incidents and Allegations

The Radiation Control Program continues to be responsive to notifications of incidents and allegations. The Radiation Control Program responded to several allegations received during the review period. There were not any events during the review period. The Radiation Control Program recognizes the importance of having a regulatory presence in the field to respond to events and allegations, as well as the importance and impact that the regulatory presence and availability of the technical staff in the field can provide to the licensee.

The Department performs outreach to the North Dakota Petroleum Council (NDPC). The NDPC is a trade association that provides government relations support to approximately 325 companies involved in all aspects of the oil and gas industry in the State. The Department works with the Council for solutions to minimize wastes, reduce the number of spills, or minimize the amount of NORM generated. The Division indicated that they would reach out to the NDPC to also make them aware of the different uses of radioactive materials in the oil and gas industry. The Division indicated that this is another opportunity to communicate safe uses of radioactive materials and facilitate the message that it is the licensee's primary responsibility to safely handle and secure radioactive materials, while it is the Radiation Control Program's responsibility to regulate the licensee and provide independent oversight through its inspection and assessment processes.

Status of Allegations and Concerns Referred by the NRC for Action

NRC referred three allegations to the Radiation Control Program during the review period. Two of the allegations involved licensed radioactive materials and the third allegation involved technically enhanced naturally occurring radioactive materials (TENORM), which is not regulated under the NRC regulations and is not a matter of compatibility under the 274i Agreement of the Atomic Energy Act, as amended, and is therefore not reviewed under the IMPEP process. The Radiation Control Program indicated that they investigate allegations in accordance with their procedures and policies, as required. One of the allegations is continuing to be investigated. At the conclusion of the investigation into the allegation, the Radiation Control Program indicated that they communicate the results of their investigation to the concerned individual. The communication is typically performed by either email or formal correspondence.

Emerging Technologies

The Radiation Control Program did not have any emerging technologies during the review period.

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

The Radiation Control Program is reviewing a cyclotron license which was split from an academic broad scope license. The license is complicated because the cyclotron has been operational under the academic broad scope license and the licensee is now required to develop their own policies and procedures under their specific license.

Current State Initiatives

The Radiation Control Program is cross-training two technical staff members from another unit to support the Radiation Control Program. The two technical staff members have expertise in X-ray licensing and inspections and will generate a qualification journal to support the cross-training effort by the Radiation Control Program.

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.

CONCLUSION

The North Dakota Agreement State Program remains an active program with excellent management support. The Radiation Control Program experienced a number of staff turnovers during the last IMPEP review period; however, during the past two years there appears to be a stable work force. The Radiation Control Program has continued to address the recommendations identified during the last IMPEP review through tracking the resolutions using the Performance Improvement Plan.

Schedule for the Next IMPEP Review

The period of Heightened Oversight will continue and be evaluated during the next IMPEP review. NRC staff recommends that the next IMPEP review be held, as currently scheduled, in April 2013.