

March 22, 2012

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

Bradley W. Jones, Assistant General Counsel
for Reactor and Materials Rulemaking
Office of the General Counsel

Mark A. Satorius, Director
Office of Federal and State Materials
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Anne Boland, Director
Division of Nuclear Materials Safety
Region III

FROM: Michelle R. Beardsley, Health Physicist */RA K. Meyer for/*
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: JULY 9, 2012 SPECIAL MRB MEETING

A Special Management Review Board (MRB) meeting, to discuss the results of the periodic meetings held with the North Dakota and Colorado Agreement State Programs, has been scheduled for **Monday, July 9, 2012 from 2:00 p.m. to 4:00 p.m. ET, in One White Flint North, Room 17-B4**. The summaries for each of the meetings are enclosed (Enclosures 1 and 2).

In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for this meeting is enclosed (Enclosure 3).

If you have any questions or need additional information, please feel free to contact me at (610) 337-6942 or Michelle.Beardsley@nrc.gov.

Enclosures:
As stated

cc w/ encl.: Robert Gallagher, MA
Organization of Agreement States
Liaison to the MRB

MRB Members

Distribution: DCD (SP01)

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NORTH DAKOTA PERIODIC MEETING SUMMARY
Date of Meeting: March 8, 2012

NRC Attendees	North Dakota Attendees
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 financial 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 alлегers 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.

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR THE
COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

DATE OF MEETING: APRIL 17, 2012

NRC Attendees	Colorado Attendees
Randy Erickson, RSAO	Christopher Urbina, MD (Entrance Only)
Vivian Campbell, R-IV	Martha Rudolph, Director (Entrance Only)
Duncan White, FSME	Gary Baughman, P.E., Director
Stephen Poy, FSME	Steve Tarlton, Program Manager
	Jennifer Opila, HP, Unit Leader
	Ed Stroud, HP, Inspection Lead
	James Grice, HP, Licensing Lead
	James Jarvis, HP, Special Projects

DISCUSSION:

The Colorado Agreement State Program is administered by the Radiation Management Program (the Program). The Program is part of the Division, within the Department of Public Health and Environment (the Department).

The previous IMPEP review (ML1017903490) was conducted the week of April 12-16, 2010. At the conclusion of the review the team found Colorado's performance to be satisfactory for seven of the eight performance indicators reviewed and satisfactory, but needs improvement, for the performance indicator, Sealed Source and Device Evaluation Program. The review team made four recommendations regarding program performance by the State and kept open one recommendation from the previous review. Accordingly, the review team recommended and the MRB agreed that the Colorado Program is adequate to protect public health and safety and compatible with NRC's program. Additionally, the MRB agreed with the team's recommendation that the next full IMPEP review should take place in four years.

The current status of the recommendations identified during the 2010 Colorado final IMPEP report are summarized below.

- The review team recommends that the State develop and implement a policy and procedure for the handling, marking, transmitting, and storing of documents containing sensitive information. (Section 3.3) (Recommendation also applies to Sections 3.4 and 3.5)

Current Status: The Program reported that they have developed a policy and implemented procedures specific to the handling, marking, transmitting and storing of documents containing sensitive information. They have also trained the staff on the new policy and procedures. This was completed and implemented on October 1, 2010.

- The review team recommends that the State evaluate its license termination and decommissioning processes to ensure that reviews are appropriate, thorough, and consistent. (Section 3.4 of the 2006 IMPEP Review) (Modified in 2010)

Current Status: The Program reported that they are finalizing procedures related to license termination and decommissioning. Once the procedures are finalized, they plan to provide staff training. The Program expects to have specific procedures for these two program areas in place by June 1, 2012.

- The review team recommends that the State develop and implement guidance that outlines the roles and responsibilities for staff and the expectations regarding record retention to ensure that the Program's files are complete and comprehensive. (Section 3.4) (Recommendation also applies to Sections 3.5 and 4.4.2)

Current Status: The Program reported that they are developing a specific policy related to records retention which guidance on the types and manner in which records will now be maintained; including the use of the Division's new electronic records system. When the guidance is completed, they plan to provide training to staff. The Program expects to have specific procedures in place by June 1, 2012.

- The review team recommends that the State review its implementation of the pre-licensing guidance to ensure that all of the essential elements of the guidance are consistently met. (Section 3.4)

Current Status: The Program reported that they reviewed the revised NRC pre-licensing guidance and used it to make changes to their documentation where needed, and then re-implemented the guidance on September 15, 2010. The Program currently uses a pre-licensing checklist similar to NRC's checklist and now visits all unknown entities. The Program also provided training to the staff.

- The review team recommends that the State establish a means to ensure that SS&D evaluations are appropriately documented and conducted with thoroughness; consistency with the current version of NUREG-1556, Volume 3; and adherence to existing guidance in product evaluations. (Section 4.2.2)

Current Status: The Program reported they have developed a formal tracking system for SS&D reviews and also use current NRC guidance. Reviews are complete and documentation is now fully accessible. The Program has removed SS&D sheets from license files and placed them into their own files to better track activities. Inactive sheets also have been inactivated. The Program expects to have this completed by June 1, 2012.

Other topics covered at the meeting included.

Program Strengths: The Colorado Program is a busy program with a highly motivated staff that is responsible for the licensing and inspection of 351 specific materials licensees. Management support to the Program is outstanding and access to senior management is unencumbered. The Program noted that the dedication of their staff to making the program successful is a huge strength for them.

While the Program has experienced several staff losses in recent years mainly due to retirements, they have been very successful in filling positions with talented individuals bolstering the Program's already broad knowledge base. Approximately 60 percent of

the staff has been with the Program less than five years. Staff members work well together providing a high level of customer service to their licensees, and Program management has worked diligently to ensure that a proper balance is achieved within the Program.

Program Weaknesses: While the Program has experienced success in filling positions in the materials program, they have not had as much success in filling a position in their uranium recovery program. With the departure of a long time staff member, the Program has struggled to find the right person to backfill his position. The uranium recovery program takes up a lot of the Program's resources so filling this position is something they are anxious to complete.

Feedback on NRC's Program:

The Program discussed several issues affecting the Program including the following:

- The Program feels that guidance affecting the uranium recovery program is old and outdated. The Program would like to see updated guidance since uranium recovery is such a large part of their Program's activities.
- The Program expressed their appreciation for the support they receive in the form of training from NRC. They further stated that they are having difficulty into certain training courses such as the Brachytherapy course. The Program requested that NRC expand the number of seats available for Agreement State staff.
- The Program asked if NRC could broadcast some of the training courses as Webinar courses. This would allow additional staff to receive the training without the cost of travel.
- The Program expressed their appreciation for the support they have received from NRC staff on the Web Based Licensing (WBL) / Licensing Tracking System (LTS).
- The Program stated that they receive a lot of information from NRC, with quite a bit of it requesting information from the States. With all they have to do, sometimes a 30 day limit doesn't give them adequate time to respond. The Program believes it would be better if NRC could allow them additional time to respond to requests for information.
- The Program stated that a lot of the information received from NRC is not related to Program activities. Often these documents involve information related to reactor activities. The Program asked if documents such as Regulatory Issues Summary documents, FSME letters and Information Notices could be conspicuously marked, or the email messages they're attached to be marked as Reactor or Materials related to allow them to quickly sort through them.

Staffing and training:

The Colorado Program is a busy program which is divided into several program areas. Approximately 60 percent of the staff have been with the program less than five years and

most are still working towards full qualification in each program area. At the time of the meeting, the Program reported they were fully staffed with 13 staff in the materials program, but had one vacancy in the uranium program they were working towards filling. The status of Agreement State staff members who fail NRC core training courses was discussed. Program managers indicated it is their policy to provide other forms of training whenever this might occur.

Program reorganizations:

The Program has not been subject to reorganization since the 2010 IMPEP review.

Changes in Program budget/funding:

The Program has not experienced any problems with budgeting or funding. The Program is fee funded with the last increase occurring in 2009. The Program is no longer subject to furloughs and a requirement for staff to contribute an additional 2.5 percent of their salaries to their retirement will come to an end in 2013. Currently, the Program appears to be well positioned financially.

Materials Inspection Program:

The Program reported that they currently have no overdue inspections although the Program reported that most inspections are performed after the due date but before becoming overdue (within the + 25% window). Initial inspections are typically performed within 12 months of issuance. They continue to inspect reciprocity licensees and have not had difficulty performing inspections on at least 20 percent of candidate reciprocity licensees. The Program performs Increased Controls inspections concurrent with health and safety inspections. Supervisory accompaniments are being conducted by the Inspection Program lead and accompaniments of this individual are now performed by the Unit Leader.

Licensing Program:

The Program reported that the licensing program is very active, having issued more actions recently than they have over the last five years. They average about 10-15 terminations each year and currently have 351 specific licenses. The Program also has an active General License Program (GL) with approximately 1600 registered devices. They do not perform inspections of GL devices currently, but have that as a goal for the future. The Program also reported they now use licensing templates to make the process more consistent. Licensing meetings are conducted with staff every two months that provide the opportunity for sharing information.

The Program reported they have developed and implemented a formal procedure on how they address pre-licensing guidance requirements including pre-licensing visits. Because the 2010 IMPEP review team noted inconsistencies in the way pre-licensing actions were implemented, the Program revised their pre-licensing guidance and re-implemented it on September 15, 2010. The Program now uses a pre-licensing checklist similar to NRC's checklist and now visits all unknown entities. The Program also provided training to the staff on this procedure.

Sealed Source and Device Evaluation Program (SS&D):

The Program reported that the SS&D Program is a small part of their activities with only five or less amendments being processed since the 2010 IMPEP review. The Program had previously explored returning this part of their Program to NRC, but has since committed to maintain it. In response to that decision, they have begun to formalize and refresh the Program with the development of new policies and procedures, development of a formal tracking system for SS&D reviews and the use current NRC guidance. They have found they now have more standardization in their reviews and better retention of documentation. The Program has removed SS&D sheets from license files and placed them into their own files to better track activities. The Program expects to complete implementation of the SS&D Program and to complete the inactivation of all inactive sheets by June 2012.

Uranium Recovery Program:

At the time of the periodic review, Colorado's uranium recovery program had regulatory oversight of four licenses that are in the process of decommissioning. Three of the 4 sites in closure have been remediated and are in the process of NRC concurrence for license termination and/or appropriate transfer to the U.S. Department of Energy's long-term care program. The status of each of the site undergoing decommissioning was discussed and FSME staff provided a status for those currently with the Commission. The Program issued a license to a new conventional mill site, but the operator has not received all their permits from other groups within the Department. The license is being challenged in state court with the Department awaiting a decision from the court. The Program also mentioned that that they anticipate an application for an in-situ recovery facility in the future.

Regulations and Legislative changes:

The Program reported that three legislative packages were finalized following the 2010 IMPEP review that affected the Program. These included

- Legislation affecting groundwater contamination at uranium recovery sites.
- Legislation affecting public comment periods associated with financial assurance.
- Legislation affecting the Program's enforcement process increasing penalties.

The following are regulations that still need to be addressed by the Program.

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendments (71 FR 15005), that is due for Agreement State implementation by March 27, 2009.
- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendments (72 FR 45147, 72 FR 54207), that was due for Agreement State implementation by October 29, 2010.
- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864), that was due for Agreement State implementation by November 30, 2010.

- “Medical Use of Byproduct Material – Authorized User Clarification,” 10 CFR Part 35 amendment (74 FR 33901), that is due for Agreement State implementation by September 28, 2012.
- “Decommissioning Planning,” 10 CFR Parts 20, 30, 40, and 70 amendments (76 FR 35512), that is due for Agreement State implementation by December 17, 2015.
- “Licenses, Certifications, and Approvals for Materials Licensees,” 10 CFR Parts 30, 36, 39, 40, 70, and 150 amendments (76 FR 56591), that is due for Agreement State implementation by November 14, 2014.

NRC and Program staff also discussed the State’s progress in addressing the NRC letters dated October 13 and 24, 2011 regarding their legislation, uranium recovery regulations and three NRC amendments. The Program discussed their approach to addressing the comments raised in the letters and have started work on a majority of them. Although clearly committed to addressing the legislative comments in the October 24, 2011 letter, the Program described the process challenges to expediently addressing the legislative comments.

Event reporting, including follow-up and closure information in NMED.

Since the 2010 IMPEP review, the Program had reported eight events to NMED, with 3 remaining open. The Program will close the open events when they are able to obtain the necessary information.

Response to incidents and allegations.

The Program continues to be sensitive to notifications of incidents and allegations. Incidents are quickly reviewed for their affect on public health and safety. Incidents are evaluated for safety significance and staff is dispatched to perform onsite investigations whenever possible.

One item noted during the 2006 IMPEP review and again during the 2010 IMPEP review was that the Program did not have formal procedures for the handling of incidents and allegations. Following the 2010 IMPEP review, the Program provided staff training for handling incidents and allegations.

Status of allegations and concerns referred by the NRC for action.

The Program continues to process allegations as they are received. In addition to 13 allegations received directly by the Program since the 2010 IMPEP review, NRC also referred three allegations to the Program. Each of the allegations received by the Program have been investigated and closed. The Program continues to be sensitive to issues of identity protection regarding allegeders.

Significant events and generic implications.

The Program reported that the most significant event since the 2010 IMPEP review was a medical event at the University of Colorado Hospital. It involved an ablative dose of iodine-131, meant for a cancer patient but given to the wrong patient. The Program has completed their investigation in this medical event continues to monitor the situation and

enforcement action will be issued.

In September 2011, CDPHE issued a compliance order to one of their licensees regarding a number of violations including receipt and re-distribution of sources, receipt and analysis of sealed radioactive source leak tests and providing services not authorized on their license. The licensee was also cited for performing licensed activities at locations not authorized on their license including locations in other Agreement States and under NRC jurisdiction. CDPHE and the licensee are still negotiating a settlement to the order and the proposed monetary penalties and back fees.

Current State Initiatives.

The Program reported that current initiatives they are involved with include:

- Implementing the WBL system as their new main database.
- Specific licensing for Generally Licensed Devices that have activities greater than 1/10 IAEA Category 3. The Program has been actively doing this for the last year.
- Applying T-NORM guidance to the collection and disposal of NORM concentrates related to drinking water treatment facilities.
- The new Colorado enforcement policy allowing for larger civil penalties.

Emerging Technologies.

The Program reported that new emerging technologies the Program is actively working with include:

- The use of Cardio-Gen generators.
- The use of iodine-125 seeds for palpable lesions.
- The Perfexion Gamma Knife.
- New mining/milling technology proposed by Black Range Minerals.

Large, complicated, or unusual authorizations for use of radioactive materials.

The Program reported the following as examples of large and complicated authorizations:

- Uranium facilities including Energy Fuels Piñon Ridge, Cotter-Cañon City, and Hecla-Durita.
- Cotter-Schwardzwalder Mine – Mining and water treatment systems.
- The University of Colorado-Denver which is the Program's only medical Broad Scope license.

State's mechanisms to evaluate performance.

The Program reported the following as examples of how they evaluate program performance:

- Staff performs self audits twice yearly.
- Management meets with each staff member twice yearly

- Inspector accompaniments are performed to ensure they are performing at the expected level.

Current NRC initiatives:

The following NRC initiatives were discussed with the Program:

- NRC senior management changes (Virgilio, Satorius, McDermott)
- Region IV senior management changes (Caniano, Vegel)
- NRC's inspector qualification program
- Updates on the NUREG 1556 series revisions
- Status of the WBL/LTS roll-out
- The reduction of security levels for LTS
- NRC's response to the import of contaminated products
- Updates on the Adequacy and Compatibility statement out for public comment
- Status of the MD 5.9 revision
- Updates to the General License program
- Status of the Trans-boundary Policy Statement
- Status of the new Proposed Part 35 revision
- Status of the revision of Part 61 (LLRW revision)
- 10 CFR 20.2002 Alternate Disposal
- Updates on NRC's Safety Culture Policy Statement

Schedule for the next IMPEP review:

It is recommended that the next IMPEP review to be held on schedule in April 2014.

**Agenda for Management Review Board Meeting
July 9, 2012 2:00 p.m. – 4:00 p.m. EST, O-17-B4**

1. Announcement of Public Meeting to all attendees and request for identification of any members of the public participating in this meeting.
2. MRB Chair convenes meeting. Introduction of MRB members, NRC staff members, State representatives, and other participants.
3. Discussion of Periodic Meetings:
 - a. Colorado
(April 16, 2012) – ML12137A866 – Erickson / White / Poy
 - b. North Dakota
(March 7, 2012) – ML12097A460 – Browder / Katanic
4. Adjournment

Invitees:	Michael Weber, OEDO	Brian McDermott, FSME
	Bradley Jones, OGC	Duncan White, FSME
	Mark Satorius, FSME	Chris Einberg, FSME
	Anne Boland, Region III	Lisa Dimmick, FSME
	Bob Gallagher, MA	Michelle Beardsley, FSME
	Steve Tarlton, CO	Karen Meyer, FSME
	Jennifer Opila, CO	Janine Katanic, FSME
	Terry O'Clair, ND	Randy Erickson, RIV
	Dan Harman, ND	Rachel Browder, RIV
	Anton Vegel, RIV	Stephen Poy, FSME
	Vivian Campbell, RIV	Daniel Merzke, OEDO