



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
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May 16, 2012

Steve Tarlton, Program Manager
Radiation Control Program
Hazardous Material & Waste
Management Division
Colorado Department of Public
Health & Environment
HMWMD-RAD-B2
4300 Cherry Creek Drive South
Denver, Colorado 80246-1530

Dear Mr. Tarlton:

A periodic meeting with you, your staff, and your management was held on April 17, 2012. The purpose of this meeting was to review and discuss the status of the Colorado Agreement State Program. The NRC was represented by Duncan White and Stephen Poy from the Office of Federal and State Materials and Environmental Management Programs (FSME), Vivian Campbell from the Division of Nuclear Materials Safety (DNMS) in NRC Region IV, and me. I have completed and enclosed a general meeting summary, including any specific actions resulting from the discussions.

If you feel that our conclusions do not accurately summarize the meeting discussion, or have any additional remarks about the meeting in general, please contact me at 817-200-1143 or e-mail Randy.Erickson@nrc.gov to discuss your concerns.

Sincerely,

/RA/

Randy Erickson
Regional State Agreements Officer

Enclosure:
Periodic Meeting Summary for Colorado

Colorado Department of Public
Health and Environment

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cc w/enclosure:

Gary W. Baughman, P.E., Director
Hazardous Material & Waste

Management Division

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Publicly Available	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Non Sensitive		
RIV: RSAO	FSME:	FSME:	DD:DNMS	
RRErickson;dlf	DWhite	SPoy	VHCampbell	
<i>/RA/</i>	E - RRErickson	E - RRErickson	<i>/RA/</i>	
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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.

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- 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 development 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

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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.

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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.

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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.

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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 allegers.

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, Vogel)
- 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.