



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

May 9, 2018

Ms. Jennifer Opila, Program Manager
Radiation Program
Hazardous Materials & Waste Management Division
CO Department of Public Health & Environment
HMWMD-RAD-B2
4300 Cherry Creek Drive South
Denver, CO 80246-1530

Dear Ms. Opila:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report, which documents the results of the Agreement State review held in Denver on April 9 – 12, 2018. The team's preliminary findings were discussed with you and your staff on the last day of the review. The review team's proposed recommendations are that the Colorado Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program.

The NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with the NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess Agreement States' and NRC Regional Offices' radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. The final determination of adequacy and compatibility of each Agreement State program, based on the team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review the response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. The MRB meeting is scheduled for June 26, 2018, at 1:00 pm ET. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at the NRC Headquarters in Rockville, Maryland. The NRC has video conferencing capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

J. Opila

-2-

If you have any questions regarding the enclosed report, please contact me at 301-415-5804.

Thank you for your cooperation.

Sincerely,

/RA/

Paul Michalak, Chief
Agreement State Programs Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
2018 Draft IMPEP Report

SUBJECT: COLORADO FY2018 DRAFT IMPEP REPORT

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE COLORADO AGREEMENT STATE PROGRAM

April 9 – 12, 2018

DRAFT REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Colorado Agreement State Program. The review was conducted during the period of April 9 – 12, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the States of Minnesota, Tennessee, and Texas.

Based on the results of this review, Colorado's performance was found satisfactory for all performance indicators reviewed, including the finding for the non-common performance indicator, Compatibility Requirements, improving from unsatisfactory during the previous IMPEP review to satisfactory during this review.

The team did not make any recommendations and there were no open recommendations from previous reviews for the team to consider.

Accordingly, the team recommends that the Colorado Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The team recommends that the next IMPEP review take place in approximately 4 years with a periodic meeting in approximately 2 years.

1.0 INTRODUCTION

This report presents the results of the review of the Colorado Agreement State Program radioactive materials safety program. The review was conducted during the period of April 9 – 12, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the States of Minnesota, Tennessee, and Texas. Team members are identified in Appendix A. The review was conducted in accordance with the “Agreement State Program Policy Statement,” published in the *Federal Register* on October 18, 2017, and NRC Management Directive (MD) 5.6, “Integrated Materials Performance Evaluation Program (IMPEP),” dated February 26, 2004. Preliminary results of the review, which covered the period of April 12, 2014, to April 12, 2018, were discussed with Colorado managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and applicable non-common performance indicators was sent to Colorado on November 21, 2017. Colorado provided its response to the questionnaire on March 22, 2018. A copy of the questionnaire response is available in the NRC’s Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML18082A369.

The Colorado Agreement State Program is administered by the Radiation Control Program (the Program). The Program is part of the Hazardous Materials & Waste Management Division (the Division), within the Department of Public Health and Environment (the Department). Organization charts for Colorado are available in ADAMS (Accession Number ML18082A357).

At the time of the review, the Colorado Agreement State Program regulated 316 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Colorado.

The team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicators and made a preliminary assessment of the Colorado Agreement State Program’s performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on April 11, 2014. The final report is available in ADAMS (Accession Number ML14192A009). The results of the review are as follows:

Technical Staffing and Training: Satisfactory

Status of Materials Inspection Program: Satisfactory

Technical Quality of Inspections: Satisfactory

Technical Quality of Licensing Actions: Satisfactory

Technical Quality of Incident and Allegation Activities: Satisfactory

Compatibility Requirements: Unsatisfactory

Sealed Source and Device Evaluation Program: Satisfactory

Uranium Recovery Program: Satisfactory

Overall finding: Adequate to protect public health and safety and not compatible with the NRC's program.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

The team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated Colorado's performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.

- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

The team determined that the Program has sufficient staff to carry out the responsibilities of the Agreement State Program and a good balance between licensing and inspection staffing levels. The Colorado Agreement State Program is comprised of 13 staff members, which is equivalent to 12.25 full-time equivalents (FTE) for the radioactive materials program when fully staffed. The Radiation Management Program Manager oversees both radioactive materials and machine regulation. The Radioactive Materials Unit Leader supervises the unit responsible for radioactive materials licensing and inspection. The Compliance Lead oversees inspection-related activities in the unit, while the Licensing Lead oversees the licensing activities of the unit.

At the time of the review, there were no vacancies. During the review period, six staff members left the program and seven staff members were hired. Three of the staff members retired, two staff members moved from Colorado due to personal reasons, and one staffer left for a career change. The positions were vacant from less than a month to approximately 6 months. Vacancies had minimal impact on the Program's performance.

The Program has a training and qualification manual compatible with the NRC's IMC 1248. The training program is managed by the Radioactive Materials Unit Leader and the Compliance and Licensing Leads who set personal training goals for staff, as well as document and discuss progress with staff. The Radioactive Materials Unit Leader and the Compliance and Licensing Leads also determine when staff are sufficiently trained to work independently while performing licensing and inspection-related activities, including partial qualification for certain activities.

Staff understand training expectations and are qualified in an appropriate amount of time. All staff receive training and experience to become qualified to perform both inspection and licensing activities. Staff spoke highly of the Program's commitment to training, especially support to attend NRC-sponsored training, the use of on-the-job training, and peer assistance while learning new duties. Experienced staff also receive support for refresher training that is compatible with the expectations detailed in IMC 1248.

c. Evaluation

The team determined that, during the review period, Colorado met the performance indicator objectives listed in Section 3.1.a. and recommends that Colorado's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

3.2 Status of Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated Colorado's performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3 licensees are performed at the frequency prescribed in IMC 2800.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under Title 10 of the *Code of Federal Regulations* 150.20."
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports").

b. Discussion

Over the course of the review period, Colorado conducted two percent, or one inspection out of 45, of Priority 1, 2, 3, and initial inspections overdue. The only overdue inspection involved a major change to a license. At the time the initial inspection was due, the Program contacted the licensee to determine if material was being used under the new authorization. The licensee indicated it was not, so the Program postponed the initial inspection. Shortly after that communication, the Compliance Lead retired and no transfer of this communication was made to the new Lead. It was discovered at the next

routine inspection that the material for the new authorization was in use and the initial inspection was considered overdue.

Colorado's inspection frequencies are the same for similar license types in IMC 2800.

A sampling of 24 inspection reports that were looked at solely for the purpose of tracking the communications of inspection results indicated that two were communicated to the licensees beyond Colorado's goal of 30 days after the inspection exit. Neither of these communications were more than 45 days after the inspection exit.

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

Colorado inspectors are required by their individual position descriptions to perform at least 50 percent of assigned inspections before or by the inspection due date and all other inspections before the overdue date. Having this requirement tied to job performance appears to ensure the Program performs nearly all inspections within the allotted time.

c. Evaluation

The team determined that, during the review period, Colorado met the performance indicator objectives listed in Section 3.2.a., and recommends that Colorado's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing inspections, and the critical evaluation of inspection records, are used to assess the technical quality of an Agreement State's inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated Colorado's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.

- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.

- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, procedures are established and followed to provide feedback information to license reviewers.
- For Agreement States, inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the quality of inspection reports and enforcement documentation, and interviewed inspectors involved in 25 materials inspections conducted during the review period. The casework reviewed included inspections conducted by 10 of Colorado's inspectors and covered medical, industrial, commercial, academic, research, and service licenses.

Team members accompanied four Program inspectors the week of February 26, 2018, and on April 2, 2018. No performance issues were noted during the inspector accompaniments. The inspectors were well-prepared and thorough, and assessed the impact of licensed activities on health, safety, and security. The team noted that nearly all Colorado inspections are announced and many are compliance-based inspections. The inspector accompaniments are identified in Appendix B.

The team identified that Colorado's inspection results were well documented and violations were well supported. The Program follows its own documented inspection and enforcement procedures. The Compliance Lead or Radioactive Materials Unit Leader performed supervisory accompaniments for each inspector annually each year of the review period.

The team noted that Colorado has ample supplies of radiation survey instruments such as Geiger-Mueller meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors to support its inspection program. The portable instruments used during the inspector accompaniments were operational and calibrated.

c. Evaluation

The team determined that, during the review period, Colorado met the performance indicator objectives listed in Section 3.3.a., and recommends that Colorado's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the Colorado licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Colorado's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements are consistent with current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk-significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Colorado performed 1,099 radioactive materials licensing actions. The team evaluated 27 of those licensing actions. The licensing actions selected for review included 5 new applications, 11 amendments, 4 renewals, 5 terminations, and 2 decommissioning financial assurance actions. The team evaluated casework which included the following license types and actions: medical broad scope, academic broad scope, medical diagnostic and therapy, byproduct material produced using an accelerator, commercial manufacturing and distribution, industrial radiography,

research and development, nuclear pharmacy, gauges, self-shielded irradiators, well-logging, service providers, decommissioning actions, and financial assurances. The casework sample represented work from eight license reviewers.

Licensing actions were well documented. Each completed licensing action was reviewed by the Licensing Lead in its entirety. In the last step, the Radioactive Materials Unit Leader administratively reviewed and signed the license. The team noted that the incorporation of a licensing action peer review process has led to consistently high quality products.

The team evaluated the pre-licensing guidance and the pre-licensing site visit aspect of the new license application process. The Program conducted pre-licensing site visits for all unknown entities in accordance with the checklist. The Program only issued a license once the applicant had, as a minimum, adequate facilities and equipment, as well as a qualified Radiation Safety Officer(s) and user(s). In addition, a new applicant with licensed radioactive material quantity equal to or exceeding Category 2 has to implement increased security measures in accordance with Colorado's requirement prior to the issuance of the new license. Moreover, any licensee at a new location that will possess Category 2 quantities of radioactive material and above also has to implement increased security measures before the location will be authorized to possess the Category 2 quantities and above in the license.

With regard to the licensing record management, the Program has used the NRC's Web-Based Licensing (WBL) to maintain the licensee's data and licenses, as well as to track licensing actions. All other documentation related to each licensing action are electronically stored in the Colorado Department of Public Health and Environment Record Management database under a unique control number assigned to each licensing action.

All generally-licensed devices in Colorado are controlled by the Program. The Program requires all generally-licensed devices to be registered and the licensees must update their inventory and self-certification annually. In addition, the Program requires holders of any generally-licensed device with a quantity exceeding 1/10 of Category 3 radioactive material to have a specific license.

c. Evaluation

The team determined that, during the review period, Colorado met the performance indicator objectives listed in Section 3.4.a., and recommends that Colorado's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and followup actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Colorado's performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety, or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED).
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 67 incidents were reported to the NMED database by Colorado. The team selected 18 events to evaluate. The casework reviewed included: three radiography events involving the inability to retract the source; three radiography events involving source disconnects (all different licensees); one failed attempted break-in of a radiography truck; four medical events; one unplanned contamination event involving technetium-99m; two damaged portable gauge events; one leaking electron capture device foil; one self-shielded irradiator exposure drawer failure; a failure of a room mounted radiation exposure detector; and one event involving contamination from water treatment.

The team found that inspectors properly evaluated each event, interviewed involved individuals, and thoroughly documented their findings. Enforcement actions were taken where appropriate.

When an event is reported to the Program, staff and management collectively evaluates the information received to determine its health and safety significance and then decides on the appropriate response. That response can range anywhere from responding immediately to reviewing the event during the next inspection. For each incident that was determined to have potential health and safety significance, the Program responded immediately. The team also found that the Program responded to events in accordance with their established procedure.

The team evaluated the Program's reporting of events to the NRC's Headquarters Operations Officer (HOO). The team noted that in each case reviewed where HOO notification was required, the Program reported all events within the required timeframe. Additionally, an evaluation was made to determine if the Program had failed to report any events to the HOO where reporting was required, but none were found.

During the review period, 12 allegations were received directly by Colorado with 2 additional allegations referred by the NRC. The team evaluated 10 of the allegations and found that the Program took prompt and appropriate action in response to the concerns raised. All of the allegations reviewed were appropriately closed, concerned individuals were notified of the actions taken, and allegeders' identities were protected whenever possible.

c. Evaluation

The team determined that, during the review period, Colorado met the performance indicator objectives listed in Section 3.5.a., and recommends that Colorado's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements; (2) Sealed Source and Device (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste Disposal (LLRW) Program; and (4) Uranium Recovery (UR) Program. All four non-common performance indicators applied to this review.

4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license,

inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than three years after the effective date of the NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by an Agreement State within 6 months following NRC designation.

a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated Colorado's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC Web site at the following address: <https://scp.nrc.gov/regtoolbox.html>.

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.
- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program, have been adopted and implemented within six months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Impact of sunset requirements, if any, on the State's regulations.

b. Discussion

Colorado became an Agreement State on February 1, 1968. The Department is authorized as the State's radiation control agency under the Colorado Revised Statutes Title 25, Article 11, known as the Radiation Control Act.

As noted in Section 2.0, Colorado was found unsatisfactory for this indicator during the 2014 IMPEP review, largely due to a number of modifications to Colorado statutes prior to that review which were not compatible with NRC requirements. These modifications were initiated by parties outside the Department and were made by the State Legislature without concurrence by Colorado's Radiation Control Program. To resolve the issue,

Colorado management obtained permission from the Governor's Office to conduct a stakeholder process in the summer of 2014 to address incompatible sections of the Radiation Control Act. Following this process, the Department submitted the legislation changes to NRC for review, and, as noted in the July 15, 2016, letter from NRC to Colorado, the NRC indicated that it had no further comments on Colorado's legislation. The revised legislation is compatible with NRC requirements.

All Colorado state agencies are required to plan for future regulatory changes at least 1 year in advance through establishment of a regulatory agenda which is issued in November of each year. Whether a rulemaking activity will take place in the second or possibly third year following NRC issuance is dependent upon the date of the NRC rule change. Most rulemaking efforts are completed in approximately 12-14 months. On average, the State can promulgate regulations in 6 to 12 months, depending on the resolution of comments received during the various comment periods. Comments are requested from a Radiation Advisory Committee (the Committee), the NRC, and the affected community.

Under the Colorado Administrative Procedure Act (APA), all regulations in the state expire on May 15 of each year unless that expiration is postponed by the legislature (C.R.S. §24-4-103(8)(c)(I)). Each year, the legislature initiates a bill postponing nearly all regulatory expirations, including those of the Program. Those regulations required for compliance with Federal requirements are typically renewed annually, although this is at the discretion and purview of the legislature. Historically, the Colorado Rules and Regulations Pertaining to Radiation Control have been approved each year, especially since such regulations are necessary for Colorado to maintain its authority under the agreement with the NRC which is the state's policy (C.R.S. §25-11-102).

At the time of the prior IMPEP review in 2014, Colorado had a backlog of regulatory changes, some of which were dependent upon changes to statute. Some of this backlog continued into the current review period, with some regulatory changes requiring coordination of regulatory and statutory efforts. During the review period, Colorado submitted 10 proposed regulation amendments, 25 final regulation amendments, 11 revised final regulation amendments, and the previously mentioned legislation to the NRC for a compatibility review. Portions of two of the amendments were overdue for State adoption at the time of submission, from 4 months to nearly 2 years delayed. The primary reason for the delay was due to the focus of resources on addressing prior NRC regulatory comments and to initiate changes to the enabling legislation associated with NRC comments. At the time of this review, no amendments were overdue.

c. Evaluation

The team determined that, during the review period, Colorado met the performance indicator objectives listed in Section 4.1.a., and recommends that Colorado's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

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

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides information on conducting SS&D reviews and establishes useful guidance for teams. Under this guidance, three sub elements: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and Evaluation of Defects and Incidents Regarding SS&D's, are evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated Colorado's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Qualification criteria for new technical staff are established and are being followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

Technical Quality of the Product Evaluation Program

- SS&D evaluations are adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3.

Evaluation of Defects and Incidents

- SS&D incidents are reviewed to identify possible manufacturing defects and the root causes of these incidents.

- Incidents are evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to NRC, Agreement States, and others, as appropriate, occur in a timely manner.

b. Discussion

Technical Staffing and Training

Colorado has six staff qualified to perform SS&D reviews with one in training and no vacancies at the time of the review. During the review period two qualified SS&D reviewers left the program and two staff members were hired. The positions were vacant for less than a month. Colorado has a training program for SS&D reviewers equivalent to the NRC training requirements listed in IMC 1248, Appendix D.

Technical Quality of the Product Evaluation

Colorado currently has two SS&D registrants. The Program completed no SS&D actions during the review period. The team evaluated an SS&D action that was pending during the onsite review. This pending action is an amendment. The pending review is technical sound; proper checklists are being used and meet the criteria of NUREG 1556 Volume 3 Revision 1.

When Colorado completes all SS&D casework, any changes to the updated SS&D registration are tied to the applicant's radioactive materials license.

Due to the lack of review actions, Program management noted that Colorado may use alternate technical assistance for review of complex SS&D actions should it receive one.

Evaluation of Defects and Incidents Regarding SS&Ds

The team received no incidents involving SS&D registered products during the review period. Incident procedures are in place should an SS&D-related incident occur.

c. Evaluation

The team determined that, during the review period, Colorado has met the performance indicator objectives listed in Section 4.2.a., and recommends that Colorado's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

4.3 LLRW Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by states Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although the Colorado Agreement State Program has authority to regulate a LLRW disposal facility, the NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW program. There are no plans for a commercial LLRW disposal facility in Colorado. Accordingly, the team did not review this indicator.

4.4 Uranium Recovery (UR) Program

The objective is to determine if Colorado's UR Program is adequate to protect public health and safety. Five sub-elements are used to make this determination: (1) Technical Staffing and Training; (2) Status of UR Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

a. Scope

The team used the guidance in State Agreements procedure SA-110, "Reviewing the Non-Common Performance Indicator: Uranium Recovery Program," and evaluated Colorado's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- Qualified and trained technical staff is available to license, regulate, control, inspect, and assess the operation and performance of the UR program.
- Qualification criteria for new UR technical staff are established and are being followed or that qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing the UR licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing UR licensing and inspection activities are adequately qualified and trained to perform their duties.
- UR license reviewers and inspectors are trained and qualified in a reasonable period of time.

Status of UR Inspection Program

- The UR facility is inspected at prescribed frequencies.
- Statistical data on the status of the inspection program are maintained and can be retrieved.
- Deviations from inspection schedules are coordinated between UR technical staff and management.
- There is a plan to reschedule any missed or deferred inspections or a basis has been established for not rescheduling any missed inspections.
- Inspection findings are communicated to licensees in a timely manner.

Technical Quality of Inspections

- Inspections of UR licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each UR inspector to assess performance and assure consistent application of inspection policies.
- For Agreement States, inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

Technical Quality of Licensing Actions

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Applicable UR guidance documents are available to reviewers and are followed (e.g., pre-licensing guidance, regulatory guides, etc.).
- Essential elements of license applications have been submitted and meet current NRC or Agreement State regulatory guidance (e.g., financial assurance, increased controls, etc.)
- UR license reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Licensing practices for risk significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).

- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

Technical Quality of Incident and Allegation Activities

- UR Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the NMED.
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

Technical Staffing and Training

The team determined that the Program's qualifications and staffing levels for the uranium recovery program were adequate. At the time of the review, there were no vacancies; one qualified technical staff member performed most of the project management, inspections, and licensing actions for Colorado's uranium recovery program. Colorado had two qualified uranium recovery staff over the course of the review period. One of the staff members retired from the program in 2015. That FTE is no longer dedicated to the uranium recovery program.

The uranium recovery program has a training program equivalent to the NRC training requirements listed in IMC 1248, Appendix E. The uranium recovery program staff has training in health physics, geology/geophysics, and inspection procedures. The staff also receive annual facility safety refresher training and attend NRC-sponsored training and webinars. The uranium recovery program technical staff member demonstrated thorough understanding of State regulations and the NRC guidance related to uranium recovery.

The uranium recovery program also has access to individuals from within the Program, staff in the Hazardous Materials and Waste Management Division, and the Department, for technical support. The uranium recovery program has contracts with consulting firms to assist as needed, as well.

Status of UR Disposal Inspection Program

The uranium recovery program staff performed seven inspections during the review period. The team determined that the program completed the inspections in accordance with the frequency in the NRC's IMC 2800.

Inspection findings for the UR program were communicated by formal correspondence to the licensee within 30 days following the inspection. Two instances of late reports issued to licensees were noted, sent from 39 to 54 days after the completion of the inspection. The delay was attributed to extra staff time taken to review the inspection report and inspection results letter.

The Program updated the Inspection Procedure for Uranium Recovery Facilities in Closure (revised December 6, 2017) that are licensed under the License Category of 14.A for decommissioning under the State of Colorado Rules and Regulations Pertaining to Radiation Control. Under the updated procedure, these facilities are to be inspected every three years. The facilities are also Uranium Mill Tailings Radiation Control Act (UMTRCA) Title II sites. The inspector created an "Inspection Procedure for Uranium Recovery Facilities in Closure" to establish the routine compliance inspection program for conventional uranium mills in closure to be consistent with NRC guidance 1620 Appendix D "Guidance to the U.S. Nuclear Regulatory Commission Staff for Reviewing Long-Term Surveillance Plans."

The team identified that one uranium site inspection (Sweeney Mining & Milling Corporation) was, at the time of the review, overdue by nearly 3 years (35 months). This was due to the fact that inspection results from the 2015 inspection had not been presented to the licensee in a manner consistent with the Radiation Control Act. During the onsite review, Program staff noted that a routine inspection is planned in the spring of 2018. In addition, the Program was implementing a plan to ensure that, in the future, no licensee will have an overdue inspection based on an inability to communicate inspection results to a licensee.

Technical Quality of UR Inspections

The team evaluated seven inspection files which included a variety of uranium recovery inspection activities in different stages of license operations, and determined that the inspection reports were thorough, complete, consistent, and had sufficient documentation to ensure that licensee performance with respect to health, safety and security was acceptable. The inspection results were well-founded, supported by regulations, and were appropriately documented. There was no enforcement action for the period of review.

The Program's inspectors followed the radioactive materials unit inspection manual (revised June 2016) for conducting inspections. The Program has inspection procedures specific to the uranium recovery program. The inspector used checklists to document inspections. Inspection reports were well documented and provided suitable depth of coverage, addressed license conditions and the regulations, and demonstrated

that the inspector followed corrective actions for items of concerns that were identified. Some of the inspection files contained photographs supporting both the facility structures and items of concerns. The Program's records indicated that supervisor accompaniments of the inspector were performed annually during the review period.

Technical Quality of UR Licensing Actions

The Program completed seven licensing actions during the review period. The team examined the files and associated documentation related to the licensing of conventional uranium recovery mill facilities which included six amendments, and one renewal.

The uranium recovery program manages the following uranium recovery sites:

1. Piñon Ridge Mill,
2. Cotter Corporation Cañon City Mill,
3. Umetco Uravan Mill, and
4. Hecla Durita Mill.

The uranium recovery program manages the following contaminated sites:

1. Cotter Corporation Schwartzwalder Mine,
2. Sweeney Mill, and
3. Colorado School of Mines Research Institute Table Mountain Research Center

There were no operational facilities in the State at the time of the review except for Cotter Corporation Schwartzwalder Mine which is a water treatment facility. The Umetco Uravan Mill and the Hecla Durita Mill are in closure status.

The licensing actions completed during the review period consisted of: decommissioning plans, modification of the restricted area, designation of radiation safety officer, license transfer, annual financial assurance updates, and compliance monitoring. The team interviewed staff members about the status of each regulated site. Management and staff were familiar with the technical details and conditions existing at each site.

The team concluded that the licensing actions were complete, consistent, and of acceptable quality. Program staff use a review procedure and checklist for licensing reviews. All response letters for each incoming request or report contained secondary technical or management review and approval.

The team evaluated the decision analysis reports for all the licensing actions which included public comments. The team also evaluated the license for the Cotter Corporation request to change the restricted area specified in the license and release the requested areas to be unrestricted. The Cotter Corporation decision analysis document contained a thorough evaluation of the application, as well as an adequate basis for the staff's licensing decision.

Technical Quality of Incident and Allegation Activities

The uranium recovery program did not respond to any incidents and received no allegations during the review period.

c. Evaluation

The team determined that, during the review period, the uranium recovery program met the performance indicator objectives listed in Section 4.4.a., and recommends that Colorado's performance with respect to the indicator, Uranium Recover Program, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Colorado's performance was found satisfactory for all performance indicators reviewed. The team did not make any recommendations regarding program performance and there were no recommendations from the 2014 IMPEP review to be addressed.

Accordingly, the team recommends that the Colorado Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the team recommends that the next full IMPEP review take place in approximately 4 years, with a periodic meeting in approximately 2 years.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspection Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Areas of Responsibility
Lance Rakovan, NMSS	Team Leader Technical Staffing and Training Compatibility Requirements
Randy Erickson, Region IV	Technical Quality of Incident and Allegation Activities
Sherrie Flaherty, MN	Status of Materials Inspection Program Technical Quality of Materials Inspections
Frank Tran, Region III	Technical Quality of Licensing Actions
Ron Parsons, TN	Sealed Source & Device Evaluation Program
Gehan Flanders, TX	Uranium Recovery Program
Orysia Masnyk-Bailey, Region I	Inspector Accompaniments
Lizette Roldan-Otero, Ph.D., NMSS	Inspector Accompaniments

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: CO 854-02
License Type: Diagnostic Nuclear Medicine	Priority: 5
Inspection Date: 02/26/2018	Inspector: DB

Accompaniment No.: 2	License No.: CO 997-01
License Type: Industrial Radiography	Priority: 1
Inspection Date: 02/27/2018	Inspector: MD

Accompaniment No.: 3	License No.: CO 1139-01
License Type: Portable Gauge	Priority: 5
Inspection Date: 02/28/2018	Inspector: TT

Accompaniment No.: 4	License No.: CO 038-02
License Type: High Dose Remote Afterloader	Priority: 2
Inspection Date: 02/29/2018	Inspector: RL

Accompaniment No.: 5	License No.: CO 997-01
License Type: Industrial Radiography (TJS)	Priority: 1
Inspection Date: 04/03/18	Inspector: MD