May 8, 2001

Mr. David Butcher, Director
Laboratory and Radiation Services Division
Colorado Department of Public Health and Environment
8100 Lowry Blvd.
Denver, CO 80230-6928

Dear Mr. Butcher:

On April 24, 2001, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Colorado Agreement State Program. The MRB found the Colorado program adequate to assure public health and safety and compatible with the Nuclear Regulatory Commission's program.

Section 5.0, page 18, of the enclosed final report presents the IMPEP team's recommendations. We request your evaluation and response to these recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be in approximately four years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Carl J. Paperiello
Deputy Executive Director
for Materials, Research
and State Programs

Enclosure:
As stated

cc: Warren E. Jacobi, Manager
Radiation Services Program
Laboratory and Radiation Services Division

Roland Fletcher, Maryland
Agreement State Liaison to
the Management Review Board

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bcc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF COLORADO AGREEMENT STATE PROGRAM

February 5 - 9, 2001

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Colorado radiation control program. The review was conducted during the period of February 5 - 9, 2001, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of New York. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 5, 1999, NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period March 10, 1997 to February 5, 2001 were discussed with Colorado management on February 9, 2001.

A draft of this report was issued to Colorado for factual comment on March 9, 2001. The State responded in a letter dated March 30, 2001. The Management Review Board (MRB) met on April 24, 2001, to consider the proposed final report. The MRB found the Colorado program was adequate to protect public health and safety and compatible with NRC's program.

The Colorado Agreement State program is administered by the Department of Public Health and Environment (the Department), and is located within the Laboratory and Radiation Services Division (the Division). The Division manages two programs: the Radiation Services Program (the Program) and the State Laboratories. The Program is under the supervision of a Program Manager. An organization chart for the Department is included as Appendix B. At the time of the review, the Colorado program regulated 332 specific licenses authorizing Agreement materials. The review focused on the 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.

In preparation for the review, a questionnaire addressing the common and non-common indicators was sent to the Program on October 17, 2000. The Program provided a response to the questionnaire on January 10, 2001. During the review, discussions with the Program staff resulted in the responses being further developed. A copy of the final response is included in Appendix G to the proposed final report.

The review team's general approach for conduct of this review consisted of: (1) examination of Colorado's response to the questionnaire; (2) review of applicable Colorado statutes and regulations; (3) analysis of quantitative information from the Program licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of five Colorado inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and non-common indicator and made a preliminary assessment of the radiation control program's performance.

Section 2 below discusses the Program's actions in response to recommendations made following the previous review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's

findings and recommendations. Recommendations made by the review team are comments that relate directly to performance by the Program. A response is requested from the Program to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous routine review, which concluded on March 14, 1997, 18 recommendations were made and the results transmitted to Ms. Patti Shwayder, Executive Director, on June 16, 1997. The team's review of the current status of these recommendations is as follows:

1. The review team recommends that the Program revise the inspection frequency for HDR remote afterloader licenses to the 1-year frequency specified in NRC Inspection Manual Chapter (IMC) 2800.

   Current Status: The Program implemented this recommendation, and inspections of the two HDR licensees' were performed at the scheduled frequency. This recommendation is closed.

2. The review team recommends that the Program adhere to the percentage of reciprocity licensees to be inspected each year specified in Appendix II of the IMC 1220.

   Current Status: The Program followed, but did not adhere strictly to Appendix II of IMC 1220. This recommendation is closed, but the inspection of reciprocity licensees is further evaluated in Section 3.1 under the indicator "Status of Materials Inspection Program."

3. In order to maintain the staffing level necessary to keep abreast of the needs of the regulatory program, the review team recommends that the Program fill the existing vacancy in the radioactive materials unit.

   Current Status: All currently authorized staff positions are filled. This recommendation is closed.

4. The review team recommends that the Program consider modeling their primary and supplementary inspection and field note forms after those found in IMC 2800, Attachment 87100, including reference to the regulation or license condition for the item under inspection.

   Current Status: The Program has implemented the use of a new inspection form; however, the form does not include reference to regulations. The Program chooses to cite the applicable regulation or license condition after the inspection results have been reviewed with management. This recommendation is closed.

5. Because inspector accompaniments and the related performance evaluations provide management with valuable insight into the quality of the inspection program, the review team recommends that the Radioactive Materials Unit supervisor or senior inspector perform annual accompaniments of each inspector and document the results.

Current Status: The Program Manager and the senior inspector accompanied inspectors annually and documented the results on a form which is based on the NRC form. This recommendation is closed.

6. The review team recommends that the Program acquire proper calibration equipment for the shielded area in the new facility in order to better perform calibrations and lower staff exposure to radiation.

   Current Status: Shortly after the 1997 review, the Program completed the move of its offices to the new facility. The Program chose to contract for calibration service in place of performing in-house calibrations. This recommendation is closed.

7. The review team recommends that the Program review the March 1995 "Handbook on Nuclear Material Event Reporting in the Agreement States: Draft for Comment," and take the steps necessary to report past and future incidents according to the procedures therein.

   Current Status: The Program followed the requirements specified in the current Handbook for entering events into the NMED. However, the Program did not report events to the NRC Headquarters Operations Center. This recommendation is closed, but events reporting is evaluated further in Section 3.5 under the indicator "Response to Incidents and Allegations."

8. The review team recommends that the form RCD 56 be revised to include an analysis as to why the event occurred and differentiate between diagnostic and therapeutic misadministrations.

   Current Status: The Program modified the regulations pertaining to the definition of misadministrations and created a new form, LARS-100, applicable only to therapeutic misadministration. This recommendation is closed.

9. The review team recommends the Program consider beginning the regulation promulgation process as soon as possible after an NRC rule change has been identified as a compatibility item.

   Current Status: The Program addressed this recommendation as part of its response to recommendation 14. This recommendation is closed.

10. The review team recommends that the Program consider developing a system to track the progress of each regulation, tracking the due and completed dates of all reviews, comments, and actions taken, from the time it is identified as a compatibility rule throughout the promulgation process until it becomes effective.

    Current Status: The Program established a database program to track the regulations as they are being promulgated. The tracking system is operated by the Program Manager. This recommendation is closed.

11. The MRB recommends that the Program implement the requirement to tag sealed sources contained in NRC's 10 CFR Part 34.25, "Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources," through some form of legally binding requirement, such as a license condition, until the final regulation is promulgated.

    Current Status: After the 1997 IMPEP review, NRC adopted a revision of 10 CFR Part 34 effective June 27, 1997. Colorado adopted regulations, effective March 30, 1998, that were compatible with former section 34.25. Subsequently, Colorado adopted regulations, effective March 24, 2000, compatible with the revised Part 34 that became effective for NRC licensees on June 27, 1998. This recommendation is closed.

12. Because of the importance of maintaining sound regulatory oversight of the extensive uranium recovery and decommissioning activities in Colorado, the review team recommends that the Program fill the vacancy in the Uranium and Special Projects Unit.

    Current Status: The vacant position and two other positions in the Uranium and Special Projects Unit were eliminated during two reorganizations. The reorganizations are discussed further in Section 4.4. The number of uranium recovery licensees dropped by one, slightly reducing the workload. The Program also used two environmental protection specialists and one engineer from other programs on a part-time basis to meet the regulatory needs. This recommendation is closed.

13. The review team recommends that the Uranium and Special Projects Unit supervisor consider personally performing one or two inspector accompaniments each year on a rotating basis, and, after appropriate training, delegating the balance of the annual accompaniments to his lead inspectors.

    Current Status: The supervisor (now the uranium lead) conducted inspector accompaniments each year during the review period. This recommendation is closed.

The 1997 review team also offered five suggestions for the Program to consider. The team found that the Program considered and adopted all five suggestions.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licenses, and timely dispatch of inspection findings to licensees. The review team's evaluation is based on the Program's questionnaire responses,

data gathered independently from the Program's licensing and inspection data tracking system, the examination of completed licensing and inspection casework, and interviews with management and staff.

The team found that Colorado inspection priorities required inspections as frequent as, or more frequent than, IMC 2800 for similar license types. For example, the inspection of Portable Moisture/Density Gauges was Priority 4 on the State schedule and Priority 5 in IMC 2800.

At the time of the review, no licenses were overdue for inspection. Inspections were conducted at the required frequency or greater for all 24 license files reviewed. The Program has the capability to adjust the inspection frequency based on the compliance history of the licensee, but has not done so.

Colorado policy required initial inspections of new licenses within six months after the license was issued or materials were received. All of the initial inspections reviewed in a random sampling were performed within six months of license issuance or receipt of materials. New licenses were hand delivered to the licensees. The inspectors used the opportunity to discuss the requirements of the license and the regulations with the licensee. Program management felt that this initial face-to-face meeting with the licensees was a very valuable tool for achieving future compliance with license conditions. The visit allowed the Program to make sure that the safety program was in place and permitted open discussion with the licensee about the compliance requirements.

During the inspection casework review, the team evaluated the timeliness of the Program in providing inspection findings to the licensees. Program procedure required providing inspection findings to the licensees within 30 days after the inspection. Of the 24 files reviewed, only three inspection reports were issued late (from 11 to 33 days). In 19 of the 24 files, the inspection findings were provided to the licensee at the end of the inspection, via the Program's Form 59.

The inspectors followed a written procedure to determine when to use the Form 59. The Form 59 included a summary of the violations and required a signed compliance commitment by the licensee. For inspections with significant findings, the procedure required a Notice of Violation (NOV) be provided to the licensee by letter. The review team believes that the procedure is acceptable. In the 24 files reviewed, the Program followed the procedure.

To evaluate the reciprocity inspection program, the review team evaluated a summary printout of reciprocity inspections, and the State’s response to the IMPEP questionnaire. Overall during the period since the last review, the inspections of reciprocity core licenses exceeded IMC 1220 requirements. However, in 1998 and 1999, no Priority 3 licenses under reciprocity were inspected. IMC 1220 required two such inspections in 1998, and one inspection in 1999. The review team discussed reciprocity inspections with the program staff, and learned that the program chose not to conduct the Priority 3 inspections in 1998 and 1999, based on the apportionment of resources to program needs. For the year 2000, all inspections required under IMC 1220 were completed. The team concluded that the missed inspections do not indicate a programmatic deficiency.

Based on the IMPEP evaluation criteria, the review team recommends that Colorado's performance with respect to the indicator, Status of the Materials Inspection Program, be found satisfactory.

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 24 radioactive materials license inspections conducted during the review period. The casework included five of the Program's materials license inspectors, and covered inspections of various types including radiography, medical, academic, portable gauge, nuclear pharmacy, and gamma knife. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on the casework, the review team noted that routine inspections covered all aspects of the licensees' radiation programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed when appropriate and for training purposes.

The inspection procedures utilized by the Program were consistent with the inspection guidance outlined in NRC's IMC 2800. Inspection reports are in a format that covers all inspection areas for each inspection type.

The Program has an adequate number and types of survey meters to support the current inspection program. Survey meters are calibrated at least annually by a contractor. Appropriate calibrated survey instruments such as GM meters, scintillation detectors, ion chambers, micro-R meters and neutron meters were observed. The Program also has access to a laboratory for counting wipes and other samples.

During the review period, the compliance lead performed inspector accompaniments with each of the staff at least annually. These accompaniments are listed in the Program's response to the IMPEP Questionnaire.

Five inspectors were accompanied by an IMPEP team member during the week of January 30, 2001. The accompaniments included inspections of a nuclear pharmacy, an industrial radiographic facility (including a temporary job site) and an operating uranium mill facility. The facilities inspected are identified in Appendix C, with comments on the accompaniments.

During the accompaniments, each inspector demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance based inspections. The inspectors were trained, well prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. Each inspector conducted effective interviews with appropriate licensee personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. Their inspections were adequate to assess radiological health and safety at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends that Colorado's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Program's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed Program management and staff, and considered any possible workload backlogs. Technical staffing and training for the sealed source and device evaluation program and the uranium recovery program are addressed in Sections 4.2 and 4.4 of this report.

At the time of the review, the Program had a total of ten technical staff positions and one manager. The Program Manager reports to the Division Director. The technical staff positions are classified as environmental protection specialists. Two senior staff members are to be designated leaders. One senior staff member has been designated as a unit leader for compliance. Another will be designated as a unit leader for licensing.

Six staff members departed during the IMPEP review period, and three of the six positions were eliminated. The Program filled the other three vacancies expediently. The last vacancy was filled in January 2001, and the Program was fully staffed at the time of the review. Five members of the Program staff will become eligible for retirement over the next five years.

Although licensing and inspection functions are separate, all of the technical staff members are trained to perform license reviews and inspections, as well as emergency response. The review team determined that the Program has a well balanced staff, and a sufficient number of trained personnel to carry out its regulatory duties.

All environmental protection specialists in the Program are required to have bachelor's degrees in health physics or equivalent training in the physical and/or life sciences. New hires are assigned basic responsibilities in the program until sufficient training and experience can be obtained. New staff are allowed to work with the senior staff and under the guidance of the Program Manager until appropriate training and experience is received. The Program Manager determines when the individual is proficient and can perform the assigned tasks independently.

The inspection reports and licensing actions of new staff are closely reviewed by senior staff and the Program Manager. The Program has established a tracking system for all staff training. The staff receives training in health physics, inspection procedures, licensing procedures, diagnostic and therapeutic nuclear medicine, industrial radiography, well logging, transportation as well as several emergency response courses. The Program has used on-the-job training to supplement the course work so that individuals may broaden their work areas. The team confirmed the qualifications of the staff hired since the l997 IMPEP review and verified their performance through the review of licensing and compliance casework.

The Program has limited funding (reduced 15% this fiscal year) for out-of-State travel, which limits the staff participation in out-of-State training courses. The review team is concerned that reduced

training can degrade the technical quality of the Program, and may become a significant issue due to the anticipated loss of senior staff over the next five years. The Program does not have a documented training plan. Such a plan should specify minimum training requirements, and supervisory sign off on completion of that training. The review team recommends that the Program develop and document a training and qualification program which address the training requirements in the NRC/Organization of Agreement States Training Working Group Report or IMC 1246.

Based on the IMPEP evaluation criteria, the review team recommends that Colorado's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 19 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated for timeliness; adherence to good health physics practices; reference to appropriate regulations; documentation of safety evaluation reports, product certifications or other supporting documents; consideration of enforcement history on renewals; pre-licensing visits, peer or supervisory review as indicated; and proper signature authority. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions that were completed during the review period. The sampling included the following types: well logging, industrial radiography, medical (institution, private practice, and broad scope), nuclear pharmacy, academic (broad scope and irradiator), research and development, analytical, portable gauge and provisional possession. Types of licensing actions selected for evaluation included one new license, ten amendments to existing licenses, three license renewals, and five license terminations. A list of the licenses evaluated with case-specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, of high quality and properly addressed health and safety issues. The staff followed appropriate licensing guides during the review process to ensure that licensees submit information necessary to support their request. Complicated deficiencies were addressed in letters containing appropriate regulatory language. Telephone conversations addressed and documented simple deficiencies on the action tracking sheet. The use of license templates by the staff resulted in notable consistency between reviewers.

A second individual reviewed each licensing action, then the Program Manager reviewed the license before it was issued. The peer and supervisory reviews contributed to the notable consistency between reviewers and the high quality of licensing documents. All licenses evaluated were signed by the Program Manager, or by designated staff in his absence. The Division Director signed all correspondence evaluated.

The team noted that the Program had started a new practice of not specifically identifying authorized users on medical institution licenses. This was part of an effort to streamline the processing of licensing actions. The Program required the medical institution's radiation safety committee to review and approve all authorized users in accordance with the training and experience requirements specified in Colorado Regulations. The Program's inspectors reviewed the committee's approval at the next scheduled inspection. The team did not observe any performance issues from this practice. However, because this practice has been in place only one year, there is not enough data to determine the effectiveness. The review team discussed the practice with the Program staff, and the staff agreed to share information on their experience with NRC.

The team also noted, however, that Colorado Regulation RH 7.2 defines the term "authorized user." An authorized user is a practitioner of the healing arts identified on a license that authorizes the medical use of radioactive material. The review team discussed this issue with the Program staff. The Program Manager will consider seeking legal advice to determine if the new practice is in conflict with the regulations.

The team examined the Program's handling of financial assurance. The State keeps original financial assurance instruments in the Colorado Treasury Department. The Program maintains copies of the documents in the license files. The Program reviewed financial assurance instruments annually. The team concluded that the Program handles financial assurance appropriately.

The team found that actions terminating licenses were well documented, and included the appropriate material survey records. The evaluation revealed that most license terminations were for licensees possessing only sealed sources. All files reviewed contained documentation of proper disposal or transfer.

Colorado renewed licenses every five years. Licenses under timely renewal were amended separately from the renewal as necessary to assure public health and safety during the renewal process.

The team discussed the subject of potentially contaminated sites formerly licensed by AEC/NRC located in Colorado with the Program Manager. The Program requested in a letter dated February 5, 2001, that Region IV transfer the files for these licenses. A total of 11 files were transferred February 9, 2001. Although the Program had not reviewed any of the files, the Program intended to apply for funding from the Grant Program for Funding Assistance for formerly License Sites in Colorado.

Based on the IMPEP evaluation criteria, the review team recommends that Colorado's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the Program's actions in responding to incidents, the review team examined the Program's response to the questionnaire relative to this indicator, evaluated

selected incidents reported for Colorado in the Nuclear Material Events Database (NMED) against those contained in the Colorado files, and evaluated the casework and supporting documentation for 14 material incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The team also reviewed the Program's response to seven allegations involving radioactive materials including one allegation referred to the Program by the NRC during the review period.

The review team discussed incident and allegation procedures, file documentation, the Program's event and allegation tracking system, NMED, and notification of incidents to the NRC Operations Center with the Program Manager and selected staff.

The team found that responsibility for initial response and follow up actions to materials events and allegations rests solely with the Program. The Program Manager, the compliance lead, and others as appropriate, evaluate events to determine the appropriate response. They evaluate all complex incidents and events, and those with potential for affecting public safety.

The Program had 78 materials incidents during the review period, of which 34 incidents were reportable under the NRC criteria. Fourteen incidents were selected for review. The incidents included: stolen and lost gauges; equipment failure; contamination; damaged devices; a leaking source; and misadministrations. The review team found that the Program's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated and the level of effort was commensurate with the health and safety significance. The Program dispatched inspectors for on-site investigations when appropriate, and took suitable enforcement action. Actions were coordinated with the license reviewers and other agencies, and appropriately followed up.

The team found that the Program had a practice but did not have written procedures for handling incidents. The compliance lead explained the principal elements of the Program's practice. These included the actions to be taken upon the notification of an event, the tracking system, event evaluation and investigation, documentation, coordination with other agencies, and the reporting of incidents to the NMED system. The team noted inconsistencies in the implementation of the practice, however, and believes that the casework comment items could have been avoided if written incident response procedures were in place.

The team discussed the comments with the Program staff. The team also discussed the numbering system used by the tracking system and the similarity between incident numbers and misadministrations that could cause reporting discrepancies. The team concluded that Program should have written procedures to meet the IMPEP criteria in MD 5.6 Handbook, particularly in view of anticipated staff turnover due to retirements.

The review team recognized that the Program self identified the lack of written procedures, and that the Program Manager directed the staff to develop them. The procedures are expected to be completed and implemented by the end of the fiscal year, June 30, 2001. The team discussed the Program's planned development and implementation of written Incident Response Procedures.

The team noted that the Program had two individuals trained on submitting event reports to NMED. Both individuals had copies of the Handbook of Office of State and Tribal Programs

(STP) Procedure SA-300, "Reporting Material Events." The Program sent copies of all event reports except one to the NMED contractor. However, the team noted that only one of 10 significant events was reported to the NRC's Emergency Operations Center. The other nine significant events were first reported to NRC in the written reports to NMED. The team discussed this issue with the Program Manager and the staff members responsible for NMED data entry. The review team recommends that the Program report all significant events to the NRC Emergency Operations Center in accordance with STP Procedure SA-300, "Reporting Material Events."

During the review period, NRC referred one allegation to the Program, and the Program received six allegations directly. All allegations were reviewed. The casework indicated that the Program took prompt and appropriate action in response to the concerns raised and made every effort to protect the alleger's identity. All of the allegations reviewed were appropriately closed with written letters to the alleger as appropriate. The team noted that allegations were treated and documented internally in the same manner as events. There were no performance issues identified from the review of the allegation files and documentation.

Based on the IMPEP evaluation criteria, the review team recommends that Colorado's performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

The State of Colorado has posted its laws on an Internet website. The team had the opportunity to review the statutes applicable to radiation control, along with the responses to the questionnaire. Colorado Revised Statutes (CRS) Title 25, Article 11 (the Radiation Control Act), authorizes the Governor to enter into agreements with the Federal Government in matters relating to radiation safety, and designates the Department as the radiation control agency for the State of Colorado. This act gives the Department specific powers and duties among which are authorities to promulgate regulations, issue licenses, perform inspections, collect fees, and issue civil penalties. The review team noted that no legislation affecting the radiation control program was passed since this indicator was found satisfactory during the previous review.

4.1.2 Program Elements Required for Compatibility

The Colorado Rules and Regulations Pertaining to Radiation Control apply to all ionizing radiation, whether emitted from radionuclides or devices. Colorado requires a license for

possession, and use, of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the procedures used in the Program's regulatory process and found that the public and other interested parties are offered an opportunity to comment on proposed rules. The NRC is provided with drafts for comment. The Program obtains departmental approval and publishes a rulemaking notice of intent and public hearing. The Program develops the new rules and consults the Radiation Advisory Committee in a meeting that is open to the public. The rule is revised as needed based on the comments, and is then sent to the Board of Health for adoption. The State has a Rules Review Commission that reviews and approves new rules and the General Assembly is provided a time period in which to veto the rule. During the review period, none of the Program's proposed rules were rejected. Typically, rule promulgation requires 4 to 14 months. The Program's Rules and Regulations are exempt from the State "sunset" law.

The team evaluated Colorado's responses to the questionnaire, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy. The team identified six regulation changes that will be needed in the future. Colorado has rulemaking in progress for the following three:

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change" 10 CFR Parts 20, 35, 36 amendments (63 FR 39477 and 63 FR 45393) that became effective October 26, 1998;

- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment" 10 CFR Part 20 amendment (63 FR 50127) that became effective November 20, 1998;

- "Radiological Criteria for License Termination of Uranium Recovery Facilities" 10 CFR Part 40 amendment (64 FR 17506) that became effective June 11, 1999.

Colorado will need to address the following three regulations in upcoming rulemaking or by adopting alternate legally binding requirements:

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524) that became effective February 2, 2000;

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000;

- "New Dosimetry Technology" 10 CFR Parts 34, 36, 39 amendments (65 FR 63749) that became effective January 8, 2001.

It is noted that MD 5.9, Handbook, Part V, (A)(1)(a) provides that the above regulations should be adopted by the State as expeditiously as possible, but not later than three years after the effective date of the NRC rule.

Based on the IMPEP evaluation criteria, the review team recommends that Colorado's performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory.

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

In assessing the State's Sealed Source & Device (SS&D) evaluation program, the review team examined information provided by the State in response to the IMPEP questionnaire on this indicator. A review of selected new and amended SS&D evaluations and supporting documents covering the review period was conducted. The team interviewed the staff involved in SS&D evaluations.

4.2.1 Technical Quality of the Product Evaluation Program

The review team examined one new, one amended, two inactivated, and one transferred SS&D registry certificates and their supporting documentation. The certificates reviewed covered the period since the last program review in 1997 and represented the work of three reviewers. The SS&D certificates issued by the State and evaluated by the review team are listed with case-specific comments in Appendix G.

The review of the SS&D casework confirmed that Colorado uses NUREG-1556, Volume 3, to guide product evaluations and the preparation of registry sheets. The casework files contained appropriate correspondence, photographs, engineering drawings, radiation profiles, and results of tests conducted by the applicant. All pertinent ANSI Standards and Regulatory Guides are available and used. The device sheets were forwarded to NRC when completed, and were observed by the team to be posted on the STP website.

Based upon the review of the registration files, guidance documents and procedures, and the SS&D sheets issued, the review team found that the technical quality of the Colorado product evaluation program is adequate for the current device reviews.

4.2.2 Technical Staffing and Training

The Program’s senior evaluator at the time of the last IMPEP review left the Program during the IMPEP review period. The individual that was the junior evaluator is now the Program’s senior reviewer. A new individual was trained to conduct SS&D reviews, and the current Program Manager is qualified to conduct reviews.

The new evaluator has a bachelor degree in Health Physics, plus an associate degree in engineering. He also has experience in the use and maintenance of sources and devices. He demonstrated understanding of prototype testing, test set-ups and results, engineering drawings, how devices and safety features work, the appropriate regulations, conditions of use, external dose rates, source activities, nuclide chemical form, engineering materials and materials properties.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The review team determined, based on the responses by Colorado to the questionnaire, and based on the response to queries to NMED, that there were no incidents or defects regarding SS&Ds evaluated by the Program.

Based on the IMPEP evaluation criteria, the review team recommends that Colorado's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low-Level Radioactive Waste (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 Colorado has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW 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, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Colorado. Accordingly, the review team did not review this indicator.

4.4 Uranium Recovery Program

In conducting this review, five sub-indicators were used to evaluate the Program's performance regarding the uranium recovery program. These sub-indicators include: (1) Status of Uranium Recovery Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations. The results of the uranium recovery program review will be discussed under each of these sub-indicators.

The uranium recovery program was transferred from the Radiation Control Division to the Hazardous Materials and Waste Management Division in December 1996. Both the personnel and the regulatory responsibilities transferred. The program was subsequently transferred to the Laboratory and Radiation Services Division, Radiation Services Program, effective December 1, 1999.

During the review period, the program regulated seven licensees under Part 18, "Milling of Uranium, Thorium and Related Radioactive Materials" of the Colorado Department of Public Health and Environment's "Rules and Regulations Pertaining to Radiation Control." The program also regulated eight sites under Part 3, "Licensing of Radioactive Material."

4.4.1 Status of the Uranium Recovery Inspection Program

The review team focused on several factors in evaluating the uranium recovery program's performance for this sub-indicator, including inspection frequency, overdue inspections, timely issuance of inspection reports and findings to licensees, inspection follow up, and retrievability of uranium recovery inspection materials. The review team's evaluation is based on an evaluation of the responses to the questionnaire, the uranium recovery inspection schedule, inspection files, and interviews with inspection staff and management.

The team determined that the uranium inspection frequency was consistent with IMC 2801, "Uranium Mill and 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program." The Program performed site visits (limited, partial inspections) almost monthly at the Cotter Cañon City Mill, with each visit addressing different areas. The inspection frequency was adjusted on the basis of licensee performance and activities at the site. The team believes this practice to be satisfactory.

The Program identified one overdue inspection (by 14 months) of a uranium licensee, the Colorado School of Mines Research Institute. Although a Part 18 license, the facility engaged in research and development, and was in remediation at the time of the overdue inspection. The team's review of the Part 18 license files did not identify any other overdue inspections. Considering the reorganizations of the uranium recovery program and the nature of the licensee, the team concluded that the missed inspection did not indicate a programmatic deficiency.

Inspectors communicated inspection results to the licensees before they left the site. When inspectors identified substantial noncompliance, the Program sent a written NOV within 30 days of the inspection. However, one of the seven inspection reports reviewed was not completed until after 30 days. Further, the files reviewed did not indicate that the site visit memoranda had been sent to the licensees. The Program sent summary letters each 6 months for the site visits at one licensee. There was no written procedure, and the Program staff did not follow a consistent process. The review team recommends that the uranium recovery program consistently provide written results of inspections and site visits to all licensees within 45 days of the completion of the inspection.

When an inspection identified a noncompliance, the Program took appropriate follow-up actions. Inspection files were easily retrieved and accessible. Management reviewed and gave appropriate attention to the letters and inspection reports.

It was not clear from the files that all of the site visit memoranda were transmitted to the licensees. The team discussed this with the Program staff, and does not believe that this was a performance deficiency. The Program staff agreed to consider transmitting all site visit memoranda to licensees, and adding information to the inspection schedule documentation.

The review team noted that the inspection reports and site visit memoranda for Hecla Durita contained color photographs of site reclamation activities. At the exit meeting, the team discussed this as a potential good practice for use at the other uranium recovery sites. After further consideration, the team notes that a good practice was identified previously for using photographs to document licensee facilities, equipment, and operations. The photographs were used to help supervisors and future inspectors, i.e., persons within the program staff, have a visual indication of licensee operations.

The review team believes the Colorado Program photographs of decommissioning construction activities, such as riprap placement, diversion channels, erosion/gullying, etc., will be useful to interested persons outside the program staff. They will be particularly useful during license termination and long term surveillance. Based on the extended usefulness of photo documentation of decommissioning construction activities, the team identified this to be a good practice.

4.4.2 Technical Quality of Inspections

In reviewing this sub-indicator, the review team examined inspection files, inspection reports, and enforcement documentation for the licensees regulated under Part 18. The team also briefly reviewed the files of four Part 3 licensees, and had no comments. The review of records covered inspections conducted during the review period representing a range of uranium recovery inspection activities in various stages of license operations. Members of the IMPEP team also accompanied two uranium program inspectors on an inspection of the Cotter Corporation Cañon City Mill. Inspectors and management were interviewed to assess the adequacy of their preparation for the inspections, the depth and content of the actual inspections, and the appropriateness of inspection findings. The review team's findings are discussed below.

Periodic compliance inspections were team (two inspectors) inspections. The site visits were one inspector, and focused on a specific item or area of inspection. The inspection teams reviewed relevant license requirements, previous inspection reports, and other background information prior to the inspection. The inspectors did not use checklists, however, the team did not find deficiencies in the inspections caused by this.

The review determined that, during a typical inspection, inspectors observed licensee operations; interviewed workers, managers, and contractors; reviewed facility records; examined site operating plans and procedures; and made independent measurements, as appropriate. The team verified these activities during the inspection accompaniment at the Cotter Corporation Cañon City Mill.

Although the Program inspectors primarily focused on health physics and radiation safety issues, they also inspected for geotechnical, environmental monitoring, management and organizational issues, and general housekeeping practices. The review team found that the inspection reports provided appropriate depth of coverage. They addressed compliance conditions for the licensees, and demonstrated that the inspectors pursued root causes where problems or violations were identified.

The review team determined that during the review period, the Program Manager did not accompany inspectors each year. The two primary inspectors are senior personnel with twenty-plus years of experience each. The uranium lead accompanied staff inspectors on both routine inspections and as accompaniments. However, it was not always clear from program records which inspections were considered to be the formal accompaniments. The review team discussed this with the staff, and they agreed to consider how to clarify the records. The review team found that the Program Manager met with the uranium inspectors after their inspections to review findings and plan follow-up strategy. The team found no signs of performance deficiency due to lack of supervisory accompaniment by the Program Manager.

There are no written inspection procedures applicable to the Part 18 licenses. The team found the inspections to be satisfactory without procedures, due to the experience of the staff. The review team discussed the benefit of procedures with the inspection staff, and the uranium recovery program will consider developing specific inspection procedures in view of the anticipated staff turnover.

4.4.3 Technical Staffing and Training

In reviewing this sub-indicator, the review team evaluated the uranium recovery program staffing level, the technical qualifications of the staff, staff training, and staff turnover. This evaluation included general examination of the qualifications of the inspectors and reviewers.

Various members of the uranium recovery program staff participated in inspections and licensing activities at the uranium recovery sites. The amount of participation varied, depending on the individual's qualifications and workload. Three individuals, who were primarily uranium recovery reviewers and inspectors, left the uranium recovery program during 1999 and 2000. However, the departures were balanced in part by utilizing materials program staff for uranium recovery activities.

Review of the uranium recovery program staff qualifications indicates that the inspectors and technical reviewers have appropriate education and experience.

4.4.4 Technical Quality of Licensing Actions

Colorado's regulations require that a preliminary decision to amend a Colorado uranium milling license be accompanied by a written analysis of the basis of decision. The decision analysis summarizes a review of the applicant's qualifications and presents notice to the public of an opportunity to comment on the amendment. The team looked at three decision analyses, for Cotter Corporation Cañon City, Umetco Maybell, and Hecla Durita.

The analyses reviewed covered all aspects of the licenses, including site/mill history, radiological and non-radiological public health impacts, impacts on surface water and groundwater, and surety. The analyses were performed to ensure that the amended/renewed license requires compliance with all applicable State requirements.

Based on this review, the team determined that the analyses are of acceptable technical quality. The analyses addressed technical evaluations in areas such as flood determinations, water surface profiles, erosion protection design, sediment analyses, and rock durability.

The team also evaluated licensing actions related to the Cotter Corporation Cañon City mill. Based on an inspection accompaniment and a review of the licensing file, the team concluded that licensing actions were appropriate and that the license conditions were clear and well-written. Requirements associated with these conditions were based on a need to meet the regulations and to protect health and safety.

4.4.5 Response to Incidents and Allegations

For this sub-indicator, the review team examined files related to uranium recovery incidents and allegations. During the review period, the Program responded to one allegation in the uranium recovery area. Based on the review of the files, the team determined that the Program personnel acted promptly and appropriately in addressing the concerns. The review team determined that the Program's process, procedures, and overall performance for uranium recovery facilities were acceptable.

Based on the IMPEP evaluation criteria, the review team recommends that Colorado's performance with respect to the indicator, Uranium Recovery Program, be found satisfactory.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found Colorado's performance to be satisfactory for all nine performance indicators reviewed. Accordingly, the review team recommended and the MRB concurred in finding the Colorado Agreement State program to be adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the next full review will be in approximately four years

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for implementation and evaluation, as appropriate, by the State.

RECOMMENDATION:

1. The review team recommends that the Program develop and document a training and qualification program which address the training requirements in the NRC/Organization of Agreement States Training Working Group Report or IMC 1246. (Section 3.3)

2. The review team recommends that the Program report all significant events to the NRC Emergency Operations Center in accordance with STP Procedure SA-300, "Reporting Material Events." (Section 3.5)

3. The review team recommends that the uranium recovery program consistently provide written results of inspections and site visits to all licensees within 45 days of the completion of the inspection. (Section 4.4.1)

GOOD PRACTICE:

Based on the extended usefulness of photo documentation of decommissioning construction activities, the review team identified this to be a good practice. (Section 4.4)

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Richard Blanton, STP	Team Leader Legislation and Program Elements Required for Compatibility Sealed Source and Device Evaluation Program
Richard Woodruff, R(II)	Inspection Accompaniments Response to Incidents & Allegations
Vivian Campbell, R(IV)	Technical Staffing and Training Technical Quality of Licensing Actions
Kenneth Hooks, NMSS	Uranium Recovery Program Uranium Inspector Accompaniment
Gary Baker, NY State Health Department	Status of Materials Inspection Program Technical Quality of Inspections

APPENDIX B

Colorado

Department of Public Health and Environment

ORGANIZATION CHART

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