DATED: JUNE 16, 1997 SIGNED BY: HUGH J. THOMPSON, JR.

Ms. Patti Shwayder, Executive Director
Colorado Department of Public Health
 and Environment
8100 Lowry Boulevard
Denver, CO 80222-6928

Dear Ms. Shwayder:

On June 3, 1997, 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 protect public health and safety and compatible with NRC's program.

Section 5, page 26, of the enclosed final report presents the IMPEP team's recommendations. Note that there is one additional recommendation that was made by the MRB. The Colorado equivalent rule to NRC's 10 CFR 34.25, "Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources," does not contain the provision that sealed sources not fastened to, or contained in, a radiographic exposure device shall be permanently tagged. For purposes of compatibility, the MRB recommended this requirement be implemented through some form of legally binding requirement, such as a license condition, until the final regulation is promulgated. During the MRB meeting, Mr. Quillin committed to implement this recommendation. We request your evaluation and response to those recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next review will be scheduled in four years, unless program concerns develop that require an earlier evaluation.

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/

Hugh L. Thompson, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: Lee Thielen, Associate Director
Colorado Department of Public Health
and Environment
Robert Quillin, Director,
Laboratory and Radiation Services Division
Howard Roitman, Director,
Hazardous Materials and Waste Management Division

Ms. Patti Shwayder, Executive Director Colorado Department of Public Health and Environment 8100 Lowry Boulevard Denver, CO 80222-6928

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Enclosure:

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cc: Lee Thielen, Associate Director Colorado Department of Public Health and Environment

bcc: Chairman Jackson Commissioner Rogers Commissioner Dicus

Robert Quillin, Director,

Commissioner Diaz

Laboratory and Radiation Services Division Howard Roitman, Director,

Commissioner McGaffigan

Hazardous Materials and Waste Management Division

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF COLORADO AGREEMENT STATE PROGRAM March 10-14, 1997

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 periods February 18-20 and March 10-14, 1997, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of California. members are identified in Appendix A. The review was conducted in accordance with the "Interim Implementation of the Integrated Materials Performance Evaluation Program Pending Final Commission Approval of the Statement of Principles and Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs, " published in the Federal Register on October 25, 1995, and the September 12, 1995, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period April 4, 1993, to March 9, 1997, were discussed with Colorado management on March 14, 1997.

A draft of this report was issued to Colorado for factual comment on April 10, 1997. The State of Colorado responded in letter dated April 29, 1997 (attached). The State's comments were incorporated into the final report. The Management Review Board (MRB) met on June 3, 1997 to consider the proposed final report. Colorado's performance determination for the indicator, Legislation and Regulations, was deferred by the IMPEP team until NRC completed the review of Colorado's regulations, which had previously not been reviewed by NRC. The State was informed of the results of the regulation review in a letter dated May 29, 1997 to Mr. Quillin. Based on the existing NRC compatibility policy and the IMPEP evaluation criteria, the review team recommended that Colorado's performance with respect to the indicator, Legislation and Regulations, be found unsatisfactory during the MRB. However, the MRB noted that the most significant comment in the May 29, 1997 letter addressed the fact that Colorado's equivalent to NRC's 10 CFR 34.25, "Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources," does not contain the provision that sealed sources not fastened to, or contained in, a radiographic exposure device shall be permanently tagged. To maintain compatibility, the MRB recommended this requirement be implemented through some form of legally binding requirement, such as a license condition, until the final regulation is promulgated. The other four items were discussed with additional information from the State as to their status and were not considered by the MRB to create conflicts, duplications, or gaps, or other conditions that jeopardized an orderly pattern in the regulation of agreement material. State committed to implement the tagging requirement for sealed sources through a legally binding requirement and address the other four items raised in the May 29, 1997 letter. recommendation for Legislation and Regulations is satisfactory. The MRB found the Colorado radiation control program was adequate

to protect public health and safety and compatible with NRC's program.

The Colorado Department of Public Health and Environment (CDPHE) is the agency within the State of Colorado that regulates, among other public health issues, radiation hazards. Within the CDPHE, the Radioactive Materials Unit (RMU) of the Laboratory and Radiation Services (LARS) Division is responsible for the radiation control program except for uranium recovery operations, which is the responsibility of the Uranium and Special Projects Unit (USPU) of the Hazardous Materials and Waste Management Division. Colorado organization charts are included as Appendix At the time of the review, the Colorado program regulated 348 specific licenses, including commercial irradiators, manufacturers, broad academic, broad medical, radiopharmacies, radiographers, and uranium recovery operations. 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 State on November 21, 1996. Colorado provided its response to the questionnaire on February 20, 1997. A copy of that response is included as Appendix C to this 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 radiation control program licensing and inspection data base, (4) technical review of selected files, (5) field accompaniments of two 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 State'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 indicators, and Section 5 summarizes the review team's findings and recommendations.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous routine review concluded on April 9, 1993, and the results were transmitted to Dr. Patricia A. Nolan, Executive Director of Health, on May 21, 1993. The review findings resulted in recommendations in four program indicators, three of which related to the uranium recovery program. The team's review of the current status of these recommendations are as follows:

(1) The review of the State's radiation control regulations disclosed that one regulatory amendment which is a matter of compatibility had not been adopted by the State within a three-year period after adoption by the NRC. This amendment deals with a requirement for an emergency plan for certain significant licensees. Because this regulation had just become due on April 7, 1993, and given that the Radiation Control Division had already enforced this regulation by license condition, compatibility was not withheld. The recommendation that the above amendment and any others approaching the three-year period allowed after NRC adoption be promulgated as effective State radiation control regulations was identified in the report as a reminder to the State.

Current Status: The Emergency Planning Rule, Parts 30, 40, 70, became effective January 1, 1994. This recommendation is closed.

(2) In 1983, Colorado brought suits against two uranium mill operators, Cotter Corporation and Umetco Minerals Corporation. As a result of these suits, Consent Decrees were issued that put in place remedial action plans for corrective actions at the two mill sites. The NRC staff found that certain parts of the Consent Decree did not fully meet the NRC requirements for Umetco's Uravan uranium mill. Groundwater issues such as background and point-of-compliance (POC) wells at the Burbank Pit remained unresolved; the timing of remedial action, based upon a predetermined number of years or meeting agricultural standards, remained an outstanding issue; and the Ra-226 soil concentrations in the area of some of the ponds was still an issue. The staff recommended that the above issues be addressed in license conditions as they were for the Cotter uranium mill license. It was suggested that the Division inform Umetco that byproduct material areas must be cleaned up to the Colorado Radiation Control Act Part 18 radium standard if they are to be released for unrestricted use. It was also suggested that the Cotter documentation be used as an example for the preliminary licensing statement for the Uravan site.

Current Status: Revisions to Part 18 of the Colorado Radiation Control Act which became effective on December 31, 1990, had strengthened the requirements for groundwater cleanup to comply with NRC Standards set forth in 10 CFR Part 40. While the Umetco Uravan Consent Decree and Remedial Action Plan of February 23, 1987, is still in effect, the review team verified that the licensee must comply with Colorado regulations that are passed after the Consent Decree became effective. The license is in timely renewal and the State is incorporating conditions in the new license which fully comply with 10 CFR Part 40 standards. While negotiations between the State and the licensee are still underway, Umetco has agreed that all wells will be POC wells at the Burbank Pit and must meet standards for drinking

water, background concentration, or alternate concentration levels based on ALARA and agreeable to the State. The Ra-226 soil concentration is an issue that will be addressed before the license is terminated and the site released for unrestricted use. Colorado regulations and the NRC Agreement require that both the State and the NRC concur in the final termination of the license. The Cotter license is being used as a model for the Uravan mill renewal license which is scheduled to be completed in 1998. This recommendation is closed.

(3) From the review of the Uravan uranium recovery operation preliminary licensing statement for the amendment authorizing two disposal cells and the Cotter preliminary licensing statement for the license renewal, it was not clear how the State is documenting the analysis of the licensee's environmental report as required in Section 18.4. The staff recommended that the State include as part of its preliminary licensing statement documentation a statement or section that specifically addresses the requirements in Section 18.4 for an environmental assessment.

Current Status: Rather than having a separate section in the preliminary licensing statement to document the entire evaluation of the licensee's remedial action plan, the State elected to evaluate each section immediately after the presentation of that section. This provides the reviewer with documentation which points to the State's decision based on their evaluation of the presented data. The review team reviewed the June 18, 1996, Decision Analysis for the Cotter Cañon City Mill license amendment package, and found the State's evaluation and analysis to be well-documented with proposed changes and the ensuing projected environmental impacts clearly stated. This recommendation is closed.

- (4) In the uranium recovery program, the NRC staff identified two surety situations which had not been fully satisfactory:
 - (a) The Long-Term Care amount for Hecla-Durita was inadequate (\$330,728) and included a \$50,000 bond from a bankrupt utility. The NRC recommended the Long-Term Care fund be increased to the required amount of \$529,000 (i.e. \$250,000 in 1978 dollars) prior to license renewal, which was scheduled to occur by September 1993.
 - (b) Sweeney Mining and Milling Company is a licensee with essentially no assets to either perform reclamation nor provide a surety. The license for this facility was under timely renewal at the time of the review. Since the licensee had not demonstrated the financial solvency to address the existing wastes on site, there was concern that any continued operations could perpetuate the problem rather than mitigate it. The staff recommended that before authorizing a license

renewal for continued operation of this facility, the State should: (1) determine whether any potential future operations will add to the quantities of licensed material (waste) existing at this facility; (2) establish how the licensee will dispose of or reclaim any waste generated from future operations as well as from the eventual dismantlement of the processing facility; and (3) ensure that the licensee has established an acceptable financial assurance arrangement to cover the costs from any future operations.

Current Status:

- (a) Hecla-Durita license has been renewed and was last amended on August 22, 1996. License condition 30.2.2 requires an appropriate long-term care fund in future dollars at the time of the License termination, which is expected to occur after September 1998. The projected long-term care fund is approximately \$580,000 and the licensee is currently only \$200,000 short. However, the State currently holds a new bond which will cover the shortfall. This recommendation is closed.
- The current Sweeny Mining and Milling Company license is for storage and possession only. The State will not authorize the licensee to conduct future operations under any circumstances. With the owner's cooperation, the State has conducted a total financial analysis of the licensee and concluded that there is no funding available for remediation and that there never will be. The State also performed an engineering evaluation of the site and concluded that there is presently no danger to public health and safety. Based on new information gathered during the audit, the State is applying to the U.S. Department of Energy (USDOE) for an evaluation of entry into the Formally Utilized Sites Remedial Action Program (FUSRAP) program for remediation. If this fails, the State intends to approach the U.S. Environmental Protection Agency (USEPA) for assistance with the clean-up under the Comprehensive Environmental Response and Liability Act of 1980 as amended (CERCLA), or Superfund, program. The State is taking the necessary precautions to ensure cleanup of this facility. This recommendation is closed.

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 Staffing and Training, (3) Technical Quality of

Licensing Actions, (4) Technical Quality of Inspections, and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: (1) inspection frequency, (2) overdue inspections, (3) initial inspection of new licenses, and (4) timely dispatch of inspection findings to licensees. The team evaluation is based on the Colorado questionnaire responses regarding this indicator, data gathered independently from the State's licensing and inspection data tracking system, the examination of licensing and inspection casework files, and interviews with managers and staff.

The team's review of the State's inspection priorities verified that the inspection frequencies for various types or groups of licenses are the same as for similar license types listed in NRC Inspection Manual Chapter (IMC) 2800 with the following two exceptions: (1) The Colorado priority schedule lists gamma knife licensees as Priority 1 and inspects the licensees annually. IMC 2800 groups gamma knife licensees with other teletherapy facilities which have 3-year inspection frequencies. (2) The NRC priority schedule requires annual inspections of medical facilities licensed to use high dose rate (HDR) remote afterloader devices; however, the State does not differentiate between Priority 3 medical institutions, which are inspected every three years, and institutions licensed to use remote afterloader devices. Review of the files showed that two hospitals are licensed to use HDR remote afterloader devices. The review team recommends that the State revise the inspection frequency for HDR remote afterloader licenses to the 1-year frequency specified in IMC 2800.

In their response to the questionnaire, Colorado indicated that as of January 21, 1997, two licenses identified as core inspections in IMC 2800 were overdue by more than 25 percent of the NRC's frequency as a result of the State changing its inspection frequency to a higher priority. Both inspections were completed in March 1997. This number is well within the 10 percent criterion for overdue inspections of Management Directive 5.6. The team noted that both inspections had been completed by the end of the review.

In reviewing the inspection files and computer reports generated within the LARS division, the review team found that the State's data control system is successfully tracking compliance data. All inspections are placed in the system and used by the supervisor to track inspections, enforcement, correspondence, and closures. The supervisor uses the data to monitor inspections and follow-up actions and make staff assignments accordingly.

Records showed that all new licenses are entered into the data base and slated for inspection within four months after the license is issued. According to State policy, if the licensee indicates that they have not received radioactive material when contacted for the first inspection, the inspection is deferred until one year after the license is issued. If the licensee still has not received material after one year, then an inspection may or may not be done, depending on a decision by management. A notation is made in the file and the staff continue to follow up until an inspection can be scheduled. The State's policy differs from IMC 2800 which directs NRC to conduct an initial inspection after one year whether or not the licensee has received radioactive material. The review team found the State's policy for initial inspections acceptable. There were 16 new licenses issued in 1995 and 17 new licenses issued in 1996; review of the records showed that all were inspected within six months after issuance.

Review of the files showed that the State is generally successful in meeting the IMPEP goal of sending inspection findings to the licensee within 30 days after the inspection. In the team's review of 20 inspection files, the team found that the two cases in which the issuance of the inspection findings failed to meet the 30-day goal involved escalated enforcement or special circumstances justifying the delay.

The State's system for tracking and inspecting licensees working under reciprocity was reviewed. The State does not charge a fee for reciprocity work by an out-of-state licensee but limits each permit to 180 days. They require that each reciprocity holder have a copy of the Colorado State Regulations at all times while working in the State. If a Notice of Violation is issued, a copy is forwarded to the licensing State or NRC. All reciprocity licensees are entered into the inspection tracking system, and a file is maintained for each entry notice.

In their response to the questionnaire, Colorado reported that reciprocity was granted to 52 licensees in the 4-year reporting period. Although 16 of the licensees fell into the categories of NRC core licenses requiring inspection frequency of three years or less, only four inspections of the higher priority reciprocity licenses were performed during the review period. The State policy is to inspect as many industrial radiography licensees as possible under reciprocity. Due to location within the State, LARS was not always able to perform these inspections. The State was unaware that IMC 1220 frequency for reciprocity inspection applied to Agreement States. The review team recommends that the State adhere to the percentage of reciprocity licensees to be inspected each year as specified in Appendix II of the NRC IMC 1220.

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

3.2 <u>Technical Staffing and Training</u>

In reviewing this indicator, the review team considered the radioactive materials program staffing level, staff training,

technical qualifications of the staff, and staff turnover. 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 backlogs in licensing or compliance actions. Technical staffing and training for the sealed source and device evaluation program and uranium recovery program are addressed in Section 4 of this report.

At the time of the review, CDPHE's radioactive materials program was staffed by the LARS Director, the RMU Supervisor, and six other environmental protection specialists. The review team found that the current staffing level is adequate to administer the regulatory program, as evidenced by the lack of backlogs in program functions.

The LARS Director, in a recent reorganization, became head of the state laboratory, and the LARS Division is in the process of moving their offices from their present location to the laboratory facilities located at the former Lowry Air Force Base. At the time of the review, the Director's office had moved to the new facilities, but the RMU staff had not. The entire Division expects to complete the move by the summer, 1997.

The licensing and inspection functions of the program are segregated; however, staff members are cross-trained, and the Director has the flexibility to assign staff as necessary to achieve the necessary balance between licensing and inspection. Licensing duties are performed by the senior reviewer and two staff members; compliance duties are performed by the head of compliance and two other inspectors; all RMU staff perform duties in incident and emergency response. Because of the need for specialized training, Sealed Source and Device (SS&D) evaluations are assigned to two trained individuals.

LARS staff turnover during the review period was minimal with one retirement, one staff transfer from USPU to RMU and one staff termination. The position of the staff member who retired will be eliminated. As a result of the staff termination, one vacancy has existed in the licensing section since December 1996.

Management's goal is to fill this vacant position by July 1, 1997. In order to maintain the staffing level necessary to keep abreast of the needs of the regulatory program, the review team recommends the State fill the existing vacancy in the radioactive materials unit.

From supervisor interviews and review of the job descriptions, the review team determined that successful candidates for technical positions are required to have a Bachelor's degree in science or math or direct experience on a year-for-year basis. From review of the technical qualifications of the current staff, the team concluded that the State has been able to recruit qualified individuals. There are three certified health physicists within CDPHE.

According to the information provided in the questionnaire, all newly hired technical staff are required to attend NRC training courses which are equivalent to courses outlined in IMC 1246, as well as the five-week health physics course. However, because the NRC no longer pays for training courses for Agreement States, the State plans to do as much training internally as possible. For courses that cannot be done internally, the State will check with other Agreement States to find alternative courses and will only send staff to NRC courses if no alternative is feasible. records show that one individual has not taken the Applied Health Physics (five-week) and SS&D registry courses; one individual has not taken the Safety Aspects of Well Logging course; and one individual has not taken the Safety Aspects of Industrial Radiography course. Management explained to the team that individuals will be scheduled for courses they are lacking as soon as the NRC courses, or alternative equivalent courses become available.

The heads of licensing and inspection explained their in-house and on-the-job training processes during interviews with the review team. Briefly, a newly hired inspector is trained by accompanying the head of the inspection section, an experienced inspector, or the RMU supervisor. The supervisor continues accompaniments, where the newly hired inspectors gradually assumes the inspection duties, until it is decided the inspector is proficient and can perform the inspections independently. The new inspector is closely monitored as he or she conducts increasingly complex inspections. A newly hired license reviewer accompanies an inspector for a brief period in order to become familiar with the types of material they are licensing. The senior license reviewer then assigns the newly hired reviewer to assist with licensing actions of different types and increasing complexity before allowing the reviewer to perform independent licensing actions. The inspection reports and licensing actions of new staff are closely reviewed by senior staff and the RMU supervisor.

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

3.3 <u>Technical Quality of Licensing Actions</u>

The review team examined casework and interviewed the reviewers for 21 specific licenses. Licensing actions were reviewed 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. Casework was reviewed 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, prelicensing visits, peer or supervisory review as indicated, and proper signature authorities. Licenses were reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality. were checked for retention of necessary documents and supporting data.

The RMU licensing program is well managed and completes licensing actions in a timely manner. There are currently 348 specific licenses in effect. At the time of the review, there were only three licensing actions pending for over six months. Two of these licensing actions involved decommissioning pending termination, and one licensing action was delayed awaiting information by the applicant on financial assurance arrangements. CDPHE's policy requires each licensee to review its license at 5-year intervals and submit a complete program for review by the staff as part of the license renewal. Licenses are amended as requested by the licensee or administrative amendments may be initiated by the State as needed. NRC regulatory guides and standard review plans were readily available for staff use, if needed.

Licensing casework selected provided a representative sample of licensing actions completed in the review period and included work by all reviewers. The cross-section licensing casework sampling included two of Colorado's major licenses and included the following types: well logging (with tracer studies and neutron logging), medical broad scope (with HDR afterloader and pacemaker), academic broad scope, nuclear pharmacy, research and development, irradiator (sealed), medical institution, gas chromatograph, manufacturing and distribution, nuclear medicine, teletherapy, and portable gauges. Licensing actions included 1 new license, 9 five-year interval renewals, 7 amendments, and 4 terminations. A list of these licenses with case-specific comments can be found in Appendix D.

The review team found that, overall, the licensing actions were generally thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. License tie-down conditions were stated clearly. In most cases, licensing actions were supported by information contained in the license files. The licensee's compliance history was taken into account when reviewing renewal applications. The Division's practice is to not issue any license if there are unresolved compliance

issues. Licensing reviewers appropriately used new licensing guides; however, accompanying check sheets were not used. During the license file reviews, the team found omissions in documentation that might have been prevented by the effective use of checklists. The review team suggests that the State institute the use of checklists for licensing actions and maintain these forms in the licensing file.

Peer and supervisory review of licensing actions were clearly documented in the licensing files on a tracking sheet, "licensing cover sheet." Peer review is normally conducted of all licensing actions by the reviewers prior to issuance. All licensing actions are signed by the RMU supervisor, who also reviews complex licensing actions before they are issued.

The procedures for terminating licenses were adequately documented. All of the termination files reviewed were documented with information on disposition of materials, including verification of material transfers, and closeout survey.

RMU reviewers use copies of NRC's licensing guides. The State's license conditions were consistent with those of the NRC in most cases. No potentially significant health and safety issue were identified. However, during the licensing file reviews some discrepancies were noted. The review team suggests the State make the following changes in their licensing procedures:

- (a) Devices which no longer are acceptable under Colorado's regulation equivalent to 10 CFR 34.20, "Performance Requirements for Radiography Equipment" should be removed from industrial radiography licenses.
- (b) The State should implement the license conditions that it has developed addressing the use of HDRs and amend the State's two licenses authorized for HDR usage accordingly.
- (c) Procedures should be developed to ensure that a clear explanation and description of non-routine usage of materials is included.
- (d) Procedures should be developed to ensure consistency between well logging license documents requesting the use of the same material, for the same use, and same quantities. Colorado stated in its response to the draft report, dated April 29, 1997, that RMU did consistently use appropriate license conditions for well logging licenses. The review team disagrees with the State.

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

3.4 <u>Technical Quality of Inspections</u>

The team reviewed the inspection reports, enforcement documentation, and inspection field notes, and interviewed inspectors for 20 materials inspections conducted during the review period. The casework included all three of the State's material inspectors and focused on the higher priority licenses of various types including academic and medical broad scope, radiography, institutional medical, HDR, teletherapy, research, nuclear pharmacy, pool irradiator, R&D, manufacture and distribution, and well logging. Appendix E lists the inspection cases reviewed in depth with case-specific comments. Prior to the review, a team member performed accompaniments of two state inspectors on two separate inspections of licensed facilities.

The inspection procedures and techniques utilized by Colorado were reviewed and determined to be generally consistent with the inspection guidance provided in IMC 2800. According to the State's policy, all inspections are to be unannounced except for initial inspections, inspections of licensees in remote geographical locations, or as necessary to observe specific operations or meet with specific licensee management or personnel. However, in the review of the inspection files, the team noted that 17 of the 20 inspections were announced in advance. Although some cases involved circumstances that would require advance notice of the inspection, it appeared that at least eight of the inspections could have been unannounced. The review team suggests the State place more emphasis on adhering to their policy of conducting unannounced inspections.

The State's inspection report forms were reviewed and found to have little narrative to describe the scope of the inspection. The team also reviewed a preliminary draft of a new form currently being tested by the LARS total quality management (TQM) team. Although several improvements were included on the revised form, the team noted that the form has no reference to the applicable regulation or license condition. Although in one of the inspections reviewed by the team, the inspector used the IMC 2800 attachment 87100 for teletherapy inspections, RMU does not make a practice of supplementing their general inspection form with forms designed for specific license categories. During interviews with the staff, the team learned that the TOM team plans to develop these supplements later, and the team encouraged them to do so. The review team recommends that the State 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.

The reports were reviewed to determine if the reports adequately documented the scope of the licensed program, licensee organization, personnel protection, posting and labeling, control of materials, equipment, use of materials, transfer, and disposal. The reports were also checked to determine if the reports adequately documented operations observed, interview of workers,

independent measurements, status of previous noncompliance items, substantiation of all items of noncompliance, and the substance of discussions during exit interviews with management. Overall the quality of the reports is satisfactory although some details were lacking in the routine reports.

Colorado uses their form RCD 59, Notice of Compliance Inspection Results, as their primary method for communicating the results of the inspection to the licensee. This form is generally completed in the field by the inspector and handed to the licensee during the exit interview. The form, which must be signed and dated by the licensee, contains information meeting the posting requirements and requires the licensee to agree to correct the violations within 30 days or submit to the State in writing their plans for corrective actions. The team found that the form, which would be appropriate for minor violations, is being used almost exclusively by the inspectors to identify items of non-compliance regardless of the severity of the violation. Also, the review team found this form difficult to read and understand, in most cases due to the inspector's handwriting. The review team suggests that the State restrict the use of the short form, RCD 59, to cases where minor violations are identified during the inspection, and that the State issue a formal enforcement letter for more serious or multiple items of non-compliance.

The inspection files reviewed were complete and included a supervisor sign-off of the entire package. The State has an elaborate system for billing the licensee for their inspection services; therefore, the package must be complete before transfer to accounting for billing. The licensee's response is reviewed by the supervisor and if all items are adequately addressed a close-file letter is signed by the Division Director. All inspections reviewed showed appropriate regulatory action was taken by the program.

The files were found to be well organized, orderly, and easily accessed for information. The files were also found to be complete with all license and enforcement documents and correspondence. The enforcement letters and correspondence were determined to be written in appropriate regulatory language. Inspection reports are filed in the same folder as the licensing actions; therefore, if the licensing staff need to look at a licensee's compliance history everything is in one place.

Although Colorado has the authority to levy civil penalties, CDPHE relies primarily on the use of follow-up inspections for escalated enforcement whenever the number and severity of violations merit it. The charge imposed by the State for follow-up inspections, in effect, levies additional penalties on the licensee. Fourteen follow-up inspections were conducted during the review period. Information furnished to the review team showed that the State issued orders to revoke two licenses during the review period and turned jurisdiction of one bankrupt licensee to the USEPA. At the time of the review, the State was in the process of conducting follow-up inspections against two recalcitrant licensees.

A member of the review team conducted accompaniments of two Colorado inspectors prior to the team review. On February 19, 1997, one inspector was accompanied during an inspection of a pharmaceutical research and manufacturing facility in Boulder. The second inspector was accompanied on February 20, 1997, during an inspection of the Colorado Department of Agriculture, a gas chromatograph licensee. Both inspectors prepared well and performed thorough inspections of the licensees' radiation safety programs. The inspectors demonstrated appropriate inspection techniques including observations, interviews, review of records, and knowledge of regulations. The technical performance of the inspectors was satisfactory, and their inspections were adequate to access the radiological health and safety of the licensee. The accompaniments are identified in Appendix E.

In their response to the questionnaire, LARS listed the inspectors accompanied by senior management during the review period and stated that, although not specifically documented, the inspection supervisor makes frequent inspector accompaniments. During interviews with LARS staff, the team found that, although inspector performance evaluations had not been documented during the accompaniments, the RMU senior inspector in charge of compliance had accompanied each inspector at least once during the previous year. 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 RMU supervisor or senior inspector perform annual accompaniments of each inspector and document the results.

The program has an adequate supply of survey meters to support the staff during routine inspections and emergencies. There is one neutron-rem ball-meter; six GM pancake probes, six air proportional alpha meters; one portable multi-channel analyzer and two Victoreen 450 ion chambers. There is also an ample supply of emergency response protective clothing and equipment, including respirators for each inspector. The program has a respiratory protection program for each employee that includes an annual physical and mask fitting.

The team found that instruments are calibrated annually, some each quarter, so that instruments are always available that have been calibrated within the current quarter.

In calibrating the instruments, LARS uses an in-house Cs-137, 30 mCi, source that is National Institute of Standards and Technology (NIST) traceable. They do not have a calibration range, beam collimator, or attenuators to use for calibrations. Staff generally calibrate in an open area during off hours. Although this technique satisfies the minimum requirements, it is difficult to reproduce geometry and accuracy, and it does not meet ALARA requirements. The review team recommends the State acquire proper calibration equipment for the shielded area in the new facility in order to better perform calibrations and lower staff exposure to radiation.

At the time of the review the LARS radiochemistry and counting laboratory had just moved to new facilities at the former Lowry Air Force Base. The laboratory serves all of the State agencies requiring radiochemistry, including RMU and USPU. In addition, they can perform all bioassay work and possess a total body counter. They can measure radiation in any form. A review team member toured the facility on February 18, 1997, and noted that the laboratory had acquired a good inventory of state-of-the-art analytical equipment. The laboratory participates in the EPA and NIST standards checking, and consistently performs well. The turn-around time, which the review team confirmed with the inspectors, ranged from immediate in emergencies to a few days for routine samples.

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.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents and allegations, the review team examined the State's response to the questionnaire relative to this indicator, reviewed the incidents reported for Colorado in the "Nuclear Material Events Database" (NMED) against those contained in the Colorado files, and reviewed the casework and supporting documentation, as appropriate, for 12 incidents. In addition, the review team interviewed the RMU supervisor and head of licensing. The State recorded no allegations during the review period.

The review team examined Colorado's incident and misadministration logs for the period January 1, 1994, through December 31, 1996, and found that 47 incidents and 23 misadministrations were recorded during the 3-year period. The State treats allegations as incidents and they are not tracked separately. The 12 incidents selected for review included four misadministrations, two overexposures, one leaking source, two lost sources, one reported loss of control, one contamination event, and one radiography camera found at a non-licensed facility. A list of the incident response casework with comments is included as Appendix F.

Prior to the IMPEP review, the review team was asked by OSP to evaluate Colorado's lack of reporting of event information to NRC during the six-month trial program between the NRC and the Agreement States to assess the effectiveness of voluntary Agreement State reporting of such information to the NRC. Review of the records showed that during the 6-month trial period which began in April 1995, two incidents occurred in Colorado which met the NMED reporting criteria identified in "Handbook on Nuclear Material Event Reporting in the Agreement States," Draft Report, March 1995. One is listed correctly on the NMED log (NMED 951041), and the review team could not determine why Colorado was listed as one of the States that did not report during the trial period. The team verified that the second incident was reported

to the Region IV State Agreements Officer on August 3, 1995 but not entered into NMED.

According to the State's response to the questionnaire, one incident occurred during the review period which involved failure of equipment or an approved operating system, and they notified the NRC appropriately. NMED contained three reportable incidents for this period. Four of the incidents included in the file reviews were reportable under NMED reporting criteria. Of these, two were reported correctly, one was inadvertently not reported, and as stated previously, one was reported to the NRC Region. The review team recommends that the State 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.

In discussions with the RMU, the review team noted the list of contributing factors considered for misadministration did not include an analysis as to why the event occurred. The State's event reporting form RCD 56, "Diagnostic Misadministration Report" is used by the staff for both diagnostic and therapeutic misadministration. 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.

The State's incident response program and written emergency plan are available to all staff on the local area network (LAN). During the incident file reviews, the plan's effectiveness was demonstrated by RMU's response actions. For the most part, the response actions were appropriate and timely. The level of effort was typically commensurate with the hazard to the public. Responsibility for initial response and follow up actions to radioactive materials incidents and allegations rests with RMU. Incident response procedures require that the RMU supervisor determines who responds to an incident and or allegation. The team verified that all incidents examined in the casework reviews were cross-referenced to the license file.

For those incidents in which on-site investigations are required, the team confirmed that the investigators are evaluating the licensee's compliance with regulations or license conditions and citing violations. For those incidents in which an on-site inspection is not necessary, the investigation is closed by a memo to file or by an acknowledgment letter to the licensee or individual reporting the incident or allegation. Letters regarding incident investigations were written in appropriate regulatory language.

Management review and involvement in incident and allegation response consists of a closeout technical review by the inspector, a closeout review by the RMU supervisor and a closeout review by the Director of the LARS Division.

Allegations are handled by the State as incidents. To protect the individual reporting an incident or making an allegation, a written procedure entitled "Preserving The Confidentiality Of State Information Versus Your Role As A Public Servant" provides guidance protecting the identity of individuals adequately and providing public access to State and licensee records as permitted within the constraints of laws for protection of personal, private and proprietary information.

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 Regulations, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery.

4.1 Legislation and Regulations

4.1.1 <u>Legislative and Legal Authority</u>

Along with their response to the questionnaire, the State provided the review team with copies of legislation that affects the radiation control program. 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 of Public Health and Environment 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.

In addition, CRS 13-25-126.5, 13-90-107 and 25-1-114.5 - Concerning Environmental Self-Evaluation, declares that if users of radioactive material identify, correct, and notify the State of potentially detrimental environmental issues, they may be relieved of civil and/or criminal penalties if the corrective actions meet with State approval.

4.1.2 <u>Status and Compatibility of Regulations</u>

The review team compared the State's regulations against the latest Chronology of Amendments and found that, with the exceptions identified below, the State has promulgated all necessary amendments which were due for adoption by the Agreement States through 1997. In addition, the State had adopted the "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649, 60 FR 25983) that will become effective March 1, 1998, and the "Compatibility with the

International Atomic Energy Agency, " 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996.

The status of the regulations which had become due but were not effective at the time of the review is as follows:

- "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 amendments (58 FR 7715) that became effective July 1, 1993, and which was due on July 1, 1996. This was adopted in November 1996, and will become effective July 1, 1997. Colorado has only one licensee affected by this amendment, and the review team verified that the licensee must comply with this regulation through the use of license conditions.
- "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 amendments (58 FR 39628) that became effective on October 25, 1993, and which was due on October 25, 1996. This rule was adopted on February 19, 1997, and will become effective on July 1, 1997.
- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70 amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994, and which became due on January 28, 1997. This rule was also adopted on February 19, 1997, and will become effective on July 1, 1997.
- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendments (56 FR 34104) that became effective January 27, 1992. The State has deferred adoption of this amendment pending the final Commission approval of the Statement of Principles of Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs.

The State was reminded of the following regulations which will become due in the next review period:

- "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32 and 35 amendments (59 FR 61767, 59 FR 65243, 60 FR 322) that became effective on January 1, 1995, and which will become due on January 1, 1998.
- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments (60 FR 7900) that became effective on March 13, 1995, and which will become due on March 13, 1998. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose to continue to require annual medical examinations).

- "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendments (60 FR 28323) that became effective on June 30, 1995, and which will become due on June 30, 1998.
- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995, and which will become due on August 14, 1998.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995, and which will become due on November 24, 1998.
- "Medical Administration of Radiation and Radioactive Materials" 10 CFR Parts 20 and 35 (60 FR 48623) that become effective on October 20, 1995, and which will become due on October 20, 1998.
- Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20 and 30 (61 FR 24669) that became effective on May 16, 1996, and which will become due on May 16, 1999.

In reviewing the promulgation procedures and policies, the review team noted that, "A Notice of Rulemaking and Proposed Reguations" is published in The Colorado Register. After an initial informational hearing by the Board of Health a formal hearing is scheduled by the Board of Health and is noticed in the "Calendar of Hearings" of The Colorado Register. Once the rule is adopted, it is noticed in "Changes in the Code of Colorado Regulations" in The Colorado Register. In addition, the Division uses the Radioactive Materials newsletter to notice licensees. The State must respond to the comments and present them to the Board of Health before the regulation can be adopted.

Since the last review, only 1 of the 9 regulations required for compatibility became effective within the 3-year time frame. By policy, regulations in Colorado become effective on the January 1st or July 1st following their adoption, thus increasing the lead time necessary for the State to begin the promulgation process in order to meet the due date. The review team recommends the State consider beginning the regulation promulgation process as soon as possible after the rule has been identified as a compatibility item.

A compatibility review for CDPHE regulations promulgated during this review period had not been conducted by NRC. The review team could not determine from the records whether the State was consistently following the Division policy of sending drafts of proposed and final regulations to the NRC for review and comment. Only one applicable cover letter transmitting a CDPHE regulation to NRC for review was found in the correspondence files. The State indicated all other regulations were transmitted to NRC Region IV by informal buckslip. Region IV has neither a record of

receipt nor the regulations. The review team recommends the State 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. As part of the tracking system, the team suggests that a file be maintained with the cover letters of all regulations sent to the NRC for comment, the NRC response, and an explanation of whether the comments were incorporated into the final regulations.

The team notes that NRC staff is currently reviewing all Agreement State equivalent regulations to Part 20, Standards for Protection Against Radiation. These reviews are being conducted outside the IMPEP process and the States will be notified of the results.

The review team recommended in the draft report that Colorado's performance determination for this indicator, Legislation and Regulations, be deferred until the State can send those regulations previously not reviewed by the NRC to the Office of State Programs for review. The State was informed of the results of the regulation review in a letter dated May 29, 1997 to Mr. Based on the existing NRC compatibility policy and the IMPEP evaluation criteria, the review team recommended during the MRB that Colorado's performance with respect to the indicator, Legislation and Regulations, be found unsatisfactory. However, the MRB noted that the most significant comment in the May 29, 1997 letter addressed the fact that Colorado's equivalent to NRC's 10 CFR 34.25, "Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources," does not contain the provision that sealed sources not fastened to, or contained in, a radiographic exposure device shall be permanently tagged. To main compatibility, the MRB recommended this requirement be implemented through some form of legally binding requirement, such as a license condition, until the final regulation is promulgated. The other four items were discussed with additional information from the State as to their status and were not considered by the MRB to create conflicts, duplications, or gaps, or other conditions that jeopardized an orderly pattern in the regulation of agreement material. The State committed to implement the tagging requirement for sealed sources through a legally binding requirement and to address the other four items raised in the May 29, 1997 letter. The MRB final recommendation for Legislation and Regulations is satisfactory.

4.2 <u>Sealed Source and Device Evaluation Program</u>

In assessing the 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 new and amended SS&D evaluations and supporting documents covering the review period was conducted. The team observed the staff's use of guidance documents and procedures, and interviewed the staff involved in SS&D evaluations.

4.2.1 Technical Quality of the Product Evaluation Program

The review team examined three new, one inactivated, and two amended SS&D registry certificates and their supporting documentation. The certificates reviewed covered all of the SS&D sheets issued by the State since the last program review in April 1993 and represented cases completed by the two Colorado SS&D reviewers. The SS&D certificates issued by the State and evaluated by the review team are listed with case-specific comments in Appendix G. In addition, the team examined the 32 registry certificates that had been inactivated by the State during the review period; however, the files of these certificates were not reviewed.

In September 1995, two members of the Colorado staff attended the NRC sponsored "Sealed Source and Device Workshop." A review of the files confirms that Colorado utilized the information obtained during the SS&D Workshop and followed the recommended guidance. The registration file contained all correspondence, photographs, engineering drawings, radiation profiles, and results of tests conducted by the applicant. In addition, a checklist received at the workshop is being used to assure all relevant materials have been submitted and are reviewed, and was contained in the registration file. The notebook and reference material received at the SS&D workshop are being routinely used in reviews. All pertinent ANSI Standards and Regulatory Guides are available and used. In addition, the formats for device sheets are consistent with those of the NRC.

Moreover, subsequent to the workshop, the Division reexamined its register sheets and inactivated 32 register sheets based upon license terminations. Copies of these sheets had been distributed to the NRC and the team was able to confirm that they were a part of the national SS&D registry.

Based upon the review of the registration files, staff interviews, SS&D sheets issued, the guidance documents and procedures, and the technical training received by the device reviewers during the NRC sponsored SS&D workshop, the review team found that the technical quality of the Colorado product evaluation program is adequate for the current device reviews.

4.2.2 <u>Technical Staffing and Training</u>

Colorado has two persons that have the experience and training needed to perform SS&D reviews. Both employees attended the NRC sponsored SS&D Workshop for training on device reviews and registrations. The State also plans to train an additional backup person for SS&D reviews, and the review team encourages the State to follow through on this plan.

The lead reviewer for SS&D reviews has a M.S. in Chemistry and has been with the Division for 27 years. He is an experienced health physicist who has served several years as supervisor of the licensing materials section and is responsible for evaluating all

major or complex license applications. The person responsible for peer audits of SS&D reviews has a B.S. in Radiation Protection and has been with the Division a little over a year. Based upon the device reviews performed by Colorado and interviews with the staff, the review team believes that the Colorado's SS&D reviewers are qualified to understand and interpret appropriate prototype tests which ensure the integrity of the products under normal, and likely accidental conditions of use; understand and interpret test results; read and understand blueprints and drawings; understand how the devices work and how the safety features operate; understand and apply the appropriate regulations; understand the conditions of use; and understand external dose rates, source activities and nuclide chemical form.

Based upon the additional technical training received by the device reviewers during the SS&D workshop, the experience in performing complete device reviews since the previous review, and our interviews with the device reviewers, the review team found that the Colorado staff has adequate qualifications and training for the current device reviews.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The review team determined that there were no incidents or defects regarding SS&Ds as determined from the evaluation of the incident files and responses to the questionnaire from Colorado.

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 <u>Low-Level Radioactive Waste (LLRW) Disposal Program</u>

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. Although Colorado was designated as a host state in the Rocky Mountain Low-Level Radioactive Waste Compact, that Compact subsequently reached an agreement with the Northwest Low-level Radioactive Waste Compact where Washington is designated as host State. 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 <u>Uranium Recovery Program</u>

In the process of evaluating this performance indicator, the review team studied the State's responses to the questionnaire; reviewed information provided by the State regarding the license status, inspection history, site status, description of wastes, radiological hazard, financial assurances, and status of decommissioning activities of each uranium recovery facility licensed by the State; compared the State's regulations against pertinent 10 CFR Part 40 regulations; reviewed selected licensing and inspection files; reviewed the State's written procedures, plans, and training materials; evaluated the qualifications of the technical staff; and interviewed all staff and managers assigned to the uranium recovery program. In addition, the review team reviewed various Consent Decrees, decision analyses, and remedial action plans.

USPU is responsible for the uranium recovery program and complex decommissioning issues. Late in 1996, the unit was moved from the LARS to the Hazardous Materials and Waste Management Division. USPU staff work closely with LARS, both reporting to the CDPHE Director and sharing the same laboratory.

At the time of the review, Colorado had eight active licenses for facilities in various phases of uranium recovery operations: one operating uranium mill, the Cotter Corporation Cañon City Milling Facility; four sites in active reclamation or remediation, The Cotter Corporation Whitewater Ore Transfer Station Site, The Hecla Mining Company Durita Site, The Umetco Minerals Corporation Maybell Heap Leach Site and Uravan Mill Site; two inactive sites, Unocal Molycorp Louviers Metals Extraction Plant and Sweeny Mining and Milling Corporation; and one license for possession and storage, Colorado School of Mines Research Institute.

4.4.1 <u>Status of Uranium Recovery Operations Inspection</u>

USPU maintains a computerized tracking system to follow all licensing actions, inspections, enforcement, site operation or status, and financial standing of each licensee. The inspection schedule compares favorably with IMC 2801 in that all licensees, including stand-by and decommissioning sites are inspected annually. In addition, staff make frequent visits to licensed sites to keep abreast of work progress or decommissioning plans. The Cotter Cañon City Milling Facility is presently retooling to begin alkaline leaching. When full operation begins, the State plans to increase the inspection frequency to 6-month intervals. There are no in situ mining facilities in Colorado.

At the time of the review, there were no overdue inspections or backlogs in the uranium recovery program. The State conducted 31 of the 32 required annual inspections during the review period. The 1995 inspection of the Cotter Cañon City Milling Facility was missed; however, there were six site visits to the facility that, because of alternate resource demands, were not compiled into a

formal report. The team verified that the visits were conducted and documented.

The review team found that USPU is not meeting the IMPEP criteria of notifying the licensee of inspection findings within 30 days. In only one out of seven cases reviewed was the enforcement letter issued within the 30 day period. The average turn-around time was 60 days, but in one case, five months elapsed before the licensee was notified in writing of the inspection findings. The team noted that the letters in question had no items of non-compliance or only minor findings, so this issue is not considered a significant health and safety problem. The staff explained that, in addition to heavy workload demands, inspection findings in uranium recovery operations are normally complex; consequently, the reports and enforcement letters require more time for preparation. The team did observe that the letters were very comprehensive with relatively long lists of items of concern or recommendations to the licensee to implement or consider in performing decommissioning. The review team suggests that USPU place greater emphasis in timely dispatch of inspection findings to licensees.

4.4.2 <u>Technical Staffing and Training</u>

Review of this indicator included considerations of the adequacy of the uranium recovery program staffing strategy, which includes training, technical qualifications of the staff, and any staff turnover that may have occurred throughout the assessment period.

USPU is an integrated program where all staff participate in all licensing and inspection activities. USPU is organized by project site with a project manager who has lead responsibility for licensing and inspection of the site. The project managers have the flexibility to use any personnel within the unit to assist as needed in regulation of the site.

At the time of the review USPU had five environmental protection specialists, one half-time consultant (a State employee from another group), a working unit leader, and one vacancy, for a total of 6.5 FTEs. This number appears to be adequate because no backlogs exist in licensing or inspection activities; however, the vacancy only occurred in December 1996, so the effect of the vacancy has not yet become apparent. As a result of the new reorganization, USPU is in the process of developing new procedures, tracking systems, event response plans, and other supporting procedures, thus increasing the need for full staffing. 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 State fill the vacancy in the uranium recovery program.

The team found that USPU's minimum requirements for hiring include graduation from an accredited college or university in geology, hydrology, or a related scientific field, plus work experience in,

or knowledge of, radiation control, environmental protection, decommissioning, financial analysis of environmental projects, hazardous waste management, and contingency operations. Review of the qualifications of the current staff, including the newest member, shows that they far exceed the minimums. Several of the staff have advanced degrees, including a Ph.D. in Physical Chemistry. The records also showed that the program has qualified staff with backgrounds in health physics (including a Certified Health Physicist), civil engineering, geology (including a Certified Professional Geologist), hydrology, earth science, environmental science, and risk assessment. In addition, USPU works closely with the Colorado Geological Survey and currently has a contract with them to assist on several sites.

Although the program has one vacancy, the staff continuity is very good, with six individuals with nine or more years in the program. The level of staff experience ranges from one to eighteen years in uranium recovery and from four to eighteen years in decommissioning.

In reviewing the training records provided by the State in their response to the questionnaire, the team found that the State has been diligent in sending staff to the NRC courses and other training courses, workshops, and meetings. Management's commitment to training and retraining is evidenced by the fact that staff in the uranium recovery program have collectively attended more than 100 training courses or similar meetings. newest member of the staff has yet to complete the NRC core courses; however, she is a Certified Health Physicist who comes to the program with four years' experience in decommissioning activities including work at the Rocky Flats USDOE facility. staff are trained on the job by working with senior staff for a minimum of a year, after which they are evaluated by management and senior staff before they are permitted to work independently. The team found that the assigned work is commensurate with the individual's training and experience.

4.4.3 <u>Technical Quality of Licensing Actions</u>

The State completed 23 licensing actions during the review period including three renewals and one major amendment. USPU also administratively added requirements from Colorado's equivalent regulations to 10 CFR 20, Part 4, to all eight licenses. Because the review team lacked the time and technical expertise to perform in-depth reviews of uranium recovery licensing actions, the team concentrated on reviewing the evaluation process used by the State in making licensing decisions and on the status of decommissioning activities at licensed sites.

Amendment 32 of the Cotter Cañon City Milling Facility, License No. 369-01, became effective February 9, 1997. This was considered a major amendment as it authorized retooling to alkaline leaching. The review team reviewed the June 18, 1996, Decision Analysis prepared by the State for the proposed amendment and discussed the document at length with USPU staff. The team

found the document to be clearly written and complete, documenting the site geologic, topographic and hydrologic features, prior concerns and their resolution, proposed facility changes and projected impacts, regulation requirements, proposed license conditions, and maps and drawings of the facility. The public was provided opportunity for comment before the amendment was adopted.

Various decommissioning, remedial, and reclamation activities were underway at all eight sites at the time of the review, and the State provided the review team with a summary of the status of the decommissioning activities and financial assurances in place at each site. In each case the licensee had been required to submit detailed decommissioning and remedial action plans before the license or amendment was granted. When new regulations or other circumstances dictate changes or additions to the decommissioning plans, the new plans are evaluated by the State, and after approval, are incorporated into the license as license conditions. The review team verified that the State is closely inspecting the decommissioning or remedial activities during annual inspections and interim site visits. Two of the licenses are in timely It was apparent to the team that the State is ensuring renewal. the remedial and reclamation work at each site will be completed to the satisfaction of the applicable State and Federal agencies before the licensee is released from liability.

The team reviewed the State's method of evaluating decommissioning plans and found that USPU reviews use a wide range of guidance material in making the evaluations: NRC Title 10; USEPA Title 40; CDPHE Statutes and regulations; NRC documents such as Reg Guides 1.23, 8.11, 8.15, 3.5, 3.11, 4.14, 4.15, 3.11.1, 8.29, 3.51, 3.8, 8.31, 3.30, 8.22, 3.65, 3.66, NUREGS 0706 and 0859 with references therein, new draft guides, branch technical positions, and responses to technical assistance requests; numerous internal communications, reports and studies; various professional publications, and other disciplinary guidance.

The review team noted that the team approach used by USPU provides effective peer and supervisory review for licensing activities.

4.4.4 <u>Technical Quality of Inspections</u>

The team reviewed the inspection reports, enforcement documentation, and inspection field notes, and interviewed the inspectors for seven inspections of uranium mills or decommissioning sites conducted during the review period. All of USPU's inspectors were included in the casework which included licenses for uranium recovery operations in various stages of operation or decommissioning. Appendix E includes the list of inspection files with case-specific comments.

The State's inspection guides are a compilation of guides used by the NRC, the USEPA, the USDOE, with supplements to suit USPU's needs.

The review team found that the reports, which are written in narrative style, are among the most complete reports that team members had seen. In addition to the standard items that are routinely inspected, inspection reports list each license condition with an evaluation of the licensee's performance with respect to that condition. The reports appropriately document the scope of the inspection, show corrective actions taken in response to previous items of non-compliance, and identify and substantiate current items of non-compliance. Items of concern and recommendations are also included and are clearly differentiated from items of non-compliance. The reports document the substance of discussions with the licensee, both at entrance and exit meetings. The completed inspection report is sent to the licensee along with a cover letter summarizing the inspection results and corrective actions required from the licensee. The review team verified that the reports had been reviewed and signed off by the supervisor.

Licensee responses are reviewed first by the inspector, then by the supervisor and, in cases of serious findings, by other unit members. USPU uses a team approach to determine the appropriate enforcement or escalated enforcement action. The team found that letters to the licensees were written in appropriate regulatory language.

During this review period, no follow-up inspections were required; however, a cursory examination of past inspections showed that follow-up inspections had been used effectively in the past. There was evidence that open items are followed in detail and not closed until the problem is satisfactorily resolved.

There are no formal procedures in place to identify root causes of licensees' problems. However, root cause identification has been included in staff training courses, and the staff explained that USPU uses the team approach in which they meet and discuss the possible root cause of poor licensee performance when it occurs.

The instrumentation and laboratory facilities are currently provided by the LARS and are discussed in Section 3.4 of this report.

The complexity of uranium mill and decommissioning facilities is such that all annual inspections are team inspections. Although a supervisor is sometimes part of that team, the State could only identify three cases during the four-year review period in which the supervisor had accompanied an inspector and documented his evaluation of the individual's performance. The supervisor stated that the experience level and quality of work of his inspectors were such that his time could be more effectively used in other program functions. The review team recognizes that conducting five inspector accompaniments each year at remote uranium facilities could divert the supervisor's attention from more pressing responsibilities. The review team recommends that the USPU 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.

4.4.5 <u>Response to Incidents and Allegations</u>

No incidents or allegations occurred during the review period that involved the uranium recovery program.

Because USPU has been separated from LARS, they plan to generate incident and allegation procedures specific to the uranium recovery operations. Meanwhile the Department's incident and allegation procedures apply to the uranium mill program.

Based on the IMPEP evaluation criteria for the above five performance areas, 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 the State's performance with respect to all performance indicators to be satisfactory. Accordingly, the team recommended, and the MRB concurred, in finding the Colorado program to be adequate to protect public health and safety and compatible with NRC's program.

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

- 1. The review team recommends that the State revise the inspection frequency for HDR remote afterloader licenses to the 1-year frequency specified in IMC 2800. (Section 3.1)
- 2. The review team recommends that the State adhere to the percentage of reciprocity licensees to be inspected each year as specified in Appendix II of the NRC IMC 1220. (Section 3.1)
- 3. In order to maintain the staffing level necessary to keep abreast of the needs of the regulatory program, the review team recommends the State fill the existing vacancy in the radioactive materials unit. (Section 3.2)
- 4. The review team suggests that the State institute the use of checklists for licensing actions and maintain these forms in the licensing file. (Section 3.3)
- 5. The review team suggests that the State make the following changes in their licensing procedures:
 - (a) Devices which no longer are acceptable under Colorado's regulation equivalent to 10 CFR 34.20, "Performance

- Requirements for Radiography Equipment" should be removed from industrial radiography licenses.
- (b) The State should implement the license conditions that it has developed addressing the use of HDRs and amend the State's two licenses authorized for HDR usage accordingly.
- (c) Procedures should be developed to ensure that a clear explanation and description of non-routine usage of materials is included.
- (d) Procedures should be developed to ensure consistency between well logging license documents requesting the use of the same material, for the same use, and same quantities. (Section 3.3)
- 6. The review team suggests the State place more emphasis on adhering to their policy of conducting unannounced inspections. (Section 3.4)
- 7. The review team recommends that the State 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. (Section 3.4)
- 8. The review team suggests that the State restrict the use the short form, RCD 59, to cases where minor violations are identified during the inspection, and that the State issue a formal enforcement letter for more serious or multiple items of non-compliance. (Section 3.4)
- 9. 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 RMU supervisor or senior inspector perform annual accompaniments of each inspector and document the results. (Section 3.4)
- 10. The review team recommends the State acquire proper calibration equipment for the shielded area in the new facility in order to better perform calibrations and lower staff exposure to radiation. (Section 3.4)
- 11. The review team recommends that the State 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. (Section 3.5)
- 12. 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. (Section 3.5)

- 13. The review team recommends the State consider beginning the regulation promulgation process as soon as possible after the rule has been identified as a compatibility item. (Section 4.1.2)
- 14. The review team recommends the State 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. As part of the tracking system, the team suggests that a file be maintained with the cover letters of all regulations sent to the NRC for comment, the NRC response, and an explanation of whether the comments were incorporated into the final regulations. (Section 4.1.2)
- 15. The MRB recommends that the State 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. (Section 4.1.2)
- 16. The review team suggests that USPU place greater emphasis in timely dispatch of inspection findings to licensees. (Section 4.4.1)
- 17. 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 State fill the vacancy in the uranium recovery program. (Section 4.4.2)
- 18. The review team recommends that the USPU 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. (Section 4.4.4)

LIST OF APPENDICES AND ATTACHMENTS

Appendix A IMPEP Review Team Members

Appendix B Colorado Organization Charts

Appendix C Colorado's Questionnaire Response

Appendix D License File Reviews

Appendix E Inspection File Reviews

Appendix F Incident File Reviews

Appendix G SS&D File Reviews

Attachment 1 Colorado's Response to Review Findings

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Jack Hornor, RIV, WCFO	On-Site Team Leader Legislation and Regulations Uranium Recovery Program
Donald E. Bunn, California	Status of Materials Inspection Technical Quality of Inspections
Jacqueline D. Cook, RIV	Technical Staffing and Training Response to Incidents and Allegations
Cardelia H. Maupin, OSP	Technical Quality of Licensing Actions Sealed Source and Device Evaluations

APPENDIX B

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

ORGANIZATION CHARTS

APPENDIX C

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) QUESTIONNAIRE