June 23, 2006

Mr. Howard Roitman, Director Environmental Programs Colorado Department of Public Health and Environment 4300 Cherry Creek Drive South Denver, CO 80246-1530

Dear Mr. Roitman:

On June 13, 2006, 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 the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 17, of the enclosed final report presents the IMPEP team's recommendations for the State of Colorado. Gary Baughman's letter, dated May 18, 2006, on the proposed final report contained responses to these recommendations. The proposed actions to be taken by the Radiation Control Program adequately address the IMPEP recommendations and no further response is requested at this time.

Based on the results of the current IMPEP review, the next full review of the Colorado Agreement State Program will take place in approximately four years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program and the excellence in program administration demonstrated by your staff, as reflected in the team's findings. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

#### /**RA**/

Martin J. Virgilio Deputy Executive Director for Materials, Research, State and Compliance Programs Office of the Executive Director for Operations

Enclosure: As stated

cc: Gary W. Baughman, Director Hazardous Materials and Waste Management Division

> Joseph Vranka, Manager Radiation Control Program Hazardous Materials and Waste Management Division

Steve Tarlton, State Liaison Officer

Richard Ratliff, Texas Organization of Agreement States Liaison to the MRB

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

March 13 - 17, 2006

### **FINAL REPORT**

U.S. Nuclear Regulatory Commission

#### 1.0 INTRODUCTION

This report presents the results of the review of the Colorado Agreement State program. The review was conducted during the period of March 13 -17, 2006, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement States of California and Washington. 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 <u>Federal Register</u> on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period February 10, 2001 to March 17, 2006 were discussed with Colorado management on March 17, 2006.

A draft of this report was issued to Colorado for factual comment on April 4, 2006. The State responded by letter on May 18, 2006, from Gary Baughman, Director, Colorado Hazardous Materials and Waste Management Division (the Division). The Management Review Board (MRB) met on June 13, 2006, to consider the proposed final report. The MRB found the Colorado Agreement State Program adequate to protect public health and safety, and compatible with NRC's program.

The Colorado Agreement State program is administered by the Radiation Management Program (the Program), which consists of two units: the Radioactive Materials Unit and the X-Ray/Mammography Unit. The Program, which administers the licensing and inspection portion of the Agreement State Program, is under the supervision of a Program Manager. The Program is part of the Division, which is one of several Environmental Programs located within the Department of Public Health and Environment (the Department). Organization charts for the Department and the Division are included in the report as Appendix B. At the time of the review, the Colorado program regulated 353 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, as amended) Agreement between the NRC and the State of Colorado.

In preparation for the review, a copy of the IMPEP questionnaire addressing the common and non-common performance indicators was sent to the Program on June 7, 2005. The Program provided a response to the questionnaire on July 13, 2005. Due to a postponement in the 2005 IMPEP review, an updated questionnaire response was requested during a teleconference call held on November 29, 2005. The Program updated their response to the questionnaire on February 22, 2006. Copies of the questionnaire response and the update can be found on NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Numbers ML052030425 and ML060660021, respectively.

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's licensing and inspection database; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of four Colorado inspectors; and (6) interviews with staff and management to answer questions and clarify issues. The team evaluated the information gathered against the IMPEP performance criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Agreement State program's performance.

Section 2 below discusses the Program's actions in response to recommendations made during 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. Section 5 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the Department to all recommendations in the final report.

#### 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on February 9, 2001, three recommendations were made and transmitted to Mr. David Butcher, Director, Laboratory and Radiation Services Division, Colorado Department of Public Health and Environment on May 8, 2001. The team's review of the current status of this recommendation is as follows:

1. The review team recommends that the Program develop and document a training and qualifications program which address the training requirements in the NRC/Organization of Agreement States Training Working Group Report or IMC 1246. (Section 3.3 of the 2001 IMPEP Report)

Current Status: The Program has established and maintains qualification journals for each employee. The journals were examined by the review team and were found to be equivalent to NRC Inspection Manual Chapter (MC) 1246. This recommendation is closed.

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 of the 2001 IMPEP report)

Current Status: The Program implemented this recommendation. The team noted that the Program is reporting incidents to the NRC and the Nuclear Material Events Database (NMED) in a timely manner. The Program developed an Incident Reporting Guide, based on the NRC's reporting requirements and the Colorado regulations, to ensure timely notification to the NRC is provided. However, despite the development and availability of this chart to Program staff, the general practice is to immediately report the incident to the NRC once initial evaluations are performed and initial response is determined, regardless of the reporting requirements. This recommendation is closed.

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 of the 2001 IMPEP report)

Current Status: A review of casework files and discussion with staff verified that the written results of compliance inspections and site visits are provided to uranium recovery licensees within 45-days of the completion of the inspection. 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) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; (5) Technical Quality of Incident and Allegation Activities.

#### 3.1 <u>Technical Staffing and Training</u>

Evaluation of this performance indicator included a review of 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 Program's response to the IMPEP questionnaire relative to this indicator, interviewed Program management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The Program devotes approximately 11 full-time equivalents (FTE) to the radioactive materials program, of which nine FTE are allotted for radioactive materials licensing, inspection, compliance, sealed source and device (SS&D) evaluations and uranium recovery. The remaining two FTE include program management. Currently the Program has no vacant technical positions. No significant licensing or inspection casework backlogs were noted.

The Program Manager supervises two administrative staff and eleven technical staff members. The technical staff members are classified as Environmental Protection Specialist (EPS) I, II, III or IV. Four current technical positions are filled at the EPS II level, three positions are filled at the EPS III level and four positions are filled at the EPS IV level. During the review period, the former Program Manager retired and the Program was reorganized, which resulted in the Program moving from the Laboratory and Radiation Services Division to the Hazardous Materials and Waste Management Division. Both Divisions reside within the Department.

All technical staff are trained and qualified to independently review licenses, perform inspections and respond to incidents. Three specific staff members are trained and qualified to regulate uranium recovery licensees and three staff members are qualified to perform SS&D evaluations.

The Program utilizes a written training program for license reviewers and inspectors based on the requirements specified in NRC MC 1246. Qualification journals have been developed for each staff member. The minimum educational requirements for the technical staff is a bachelor's degree or equivalent training in physical or life sciences. As part of their initial training, each of the technical staff is sent to the 5-week Health Physics course and to other basic regulatory training offered by the NRC. The Program's training plan calls for new staff to work with more senior staff until they acquire a level of training and experience to operate independently. The training plan requires the experienced staff to review licensing casework and accompany junior-level staff in order to assure regulatory consistency and an adequate level of performance. The review team confirmed the qualifications of the each of the technical staff.

During the review period, the former Program Manager and three of the technical staff retired. Another staff member moved from the Radioactive Materials Unit to the X-Ray/Mammography Unit. Six technical staff members were hired during the review period. All six are experienced Health Physicists previously employed in the radiation field. One new staff member plans to attend several NRC core courses as soon as they are scheduled. Several of the new staff were

given credit for prior education and work experience and will not be required to attend all NRC core courses. The review team verified this during the examination of the qualifications journals for each staff member.

The State's Radiation Advisory Committee (the Committee) was created under Title 25, Article 11, Section 105(1) of the Colorado Revised Statutes. Under this Statute, the Governor appoints nine members: three of whom represent industry, three from the healing arts, and three from public or private institutions of higher education. No more than four of the members can be from any one political party. The review team discussed the Committee's structure and examined the Committee's conflict of interest policy. The Committee's policy is that individual members recuse themselves on matters of self interest in order to avoid the appearance of a conflict of interest.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Colorado's performance with respect to the indicator, Technical Staffing and Training, was satisfactory.

#### 3.2 <u>Status of Materials Inspection Program</u>

The team focused on five factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licenses, timely dispatch of inspection findings to licensees, and the performance of reciprocity inspections. The review team's evaluation is based on the Program's response to the questionnaire relative to this indicator, data gathered independently from the Program's licensing and inspection data tracking systems, the examination of completed inspection casework, and interviews with staff.

The review team's evaluation of the Program's inspection priorities revealed that inspection frequencies for each type of license were the same or more frequent than similar license types listed in NRC MC 2800. For example, the inspection of Portable Moisture/Density Gauges is Priority 4 on the State schedule and is Priority 5 in NRC MC 2800.

The Program conducted approximately 511 routine and initial inspections during the review period. In response to the questionnaire, the Program indicated that two inspections were overdue by more than 25 percent of the NRC frequency. These inspections were completed prior to the on-site review. No other inspections were overdue at the time of the review. The review team determined that of the 141 routine Priority 1, 2, and 3 inspections sampled, only four were conducted overdue. Initial inspections were scheduled and generally conducted within six months of license issuance. At the time of the review, there were no overdue initial inspections. The review team identified only two initial inspections of the 49 sampled that were not performed within 12 months of license issuance. Through discussions with Program management and staff, the review team noted that the Program announces many of their inspections. Program management stated that the policy was to conduct inspections unannounced, but that they permitted announced inspections for purposes of efficiency or for special circumstances. The review team discussed the value of unannounced inspections for higher risk licensees with the Program. Program management agreed and indicated that when all of their staff are fully qualified they should be able to conduct more unannounced inspections.

The Program currently utilizes multiple databases to manage the inspection program. Program management stated that they were aware of the difficulty that multiple databases posed on the management of the Program. They plan to select a new data management system that will operate more efficiently within the Program, and offer a wider variety of report options.

The timeliness of the issuance of inspection findings was evaluated by the team's review of inspection casework. The Program normally utilizes Form 59, similar to NRC's Form 591, to provide inspection findings to the licensee at the end of the inspection, except when the number or severity of the violations warrants a compliance letter. Compliance letters are reviewed and signed by Program management. Of the 20 materials inspection files reviewed, all inspection reports were issued within 30 days of the inspection date. In 16 of the 20 files, the inspection findings were provided to the licensee at the end of the inspection, via the Program's Form 59.

To evaluate the reciprocity inspection program, the review team evaluated the Program's reciprocity database and response to the IMPEP questionnaire. The review team could not include the data from the 2001 time frame because the list of reciprocity licensees for that period had been archived and was not available at the time of the review. For the period 2002 - 2005, the Program conducted 10 inspections of the 72 candidate reciprocity licensees (13 percent) who worked in the State during this period. The review team determined that the Program did not meet NRC's criteria of inspecting 20 percent of candidate licensees, as prescribed in NRC MC 1220, operating under reciprocity for the period 2002 - 2005. The review team recommends the Program conduct reciprocity inspections in accordance with the criteria outlined in NRC MC 1220.

The review team determined that with respect to Commission Staff Requirements Memorandum (SRM) for COMSECY-05-0028, on increased controls, the Program has started to plan for the initial set of inspections of these licensees in accordance with the increased control requirements.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Colorado's performance with respect to the indicator, Status of Materials Inspection Program, was satisfactory.

#### 3.3 <u>Technical Quality of Inspections</u>

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 20 radioactive materials inspections conducted during the review period. The casework included work performed by seven of the Program's materials inspectors, and covered a variety of license types including: academic broad scope; medical (broad scope, private practice, and institutional); high dose-rate remote afterloader (HDR); gamma stereotactic radiosurgery; nuclear pharmacy; industrial radiography; well logging; portable gauge; self-shielded irradiator; manufacturing and distribution; and research and development. Appendix C lists the inspection casework reviewed for completeness and adequacy with case-specific comments, as well as the results of the inspection accompaniments.

Based on the casework reviewed, the review team noted that the routine inspections covered all aspects of the licensees' radiation programs. The Program uses detailed checklists specifically designed for each license type. The review team found that inspection reports were generally very thorough, complete, consistent, and of high quality, with sufficient documentation to ensure

that a licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to the licensee, and unresolved safety issues. The review team noted that independent and/or confirmatory measurements were generally conducted and documented in the inspection reports. Exit interviews were held with appropriate licensee personnel. Team inspections were frequently performed for larger, complex licensees and for training purposes.

The inspection findings were appropriate and prompt regulatory actions were taken, as necessary. Inspection findings can be issued using the Program's Form 59 or by using a compliance letter. Inspection findings are normally issued to licensees on the day of the inspection using the Form 59, similar to NRC's Form 591. The inspector may use the form to identify violations, items of concern and recommendations. An item of concern is not a violation, but has health and safety significance that could lead to noncompliance if left uncorrected. A recommendation is a suggestion of a good practice with no health and safety implication or regulatory requirement. The inspector can also direct the licensee to prepare a written response describing their corrective actions to address the violations and date of full compliance, as well as actions taken to address items of concern and recommendations. A compliance letter, signed by Program management, is used to issue inspection findings based on the severity and number of violations, or repeat violations. In addition, the Program has the ability to impose administrative penalties when it is deemed that the licensee has had a significant breakdown in operations that affects overall health and safety. All inspection findings are clearly stated and documented in the report, and reviewed by the inspection team leader. Escalated enforcement actions are reviewed and sent from the Program manager.

All the materials inspectors, except the senior inspector, were accompanied at least annually by the inspection team leader. The review team discussed the accompaniment process with the inspection team leader. The inspection team leader formally documents the accompaniments for each gualified inspector. The Program has been impacted with training several new staff within the review period. Consequently, the senior materials inspector was tasked to keep the Program's inspection program timely while the inspection team leader was training and evaluating new staff. Now that most of the Program's staff are trained, the inspection team leader intends to accompany all the qualified inspectors. The review team believes the Program's performance is acceptable in this area.

The Program has adequate numbers and types of radiation survey instruments to support the inspection program. The review included a check of survey instruments and equipment monitoring, including calibration frequency and repairs. The Program possesses and maintains a wide variety of instrumentation, including GM meters, scintillation detectors, ion chambers, micro-R meters and neutron meters. The review team noted that the Program also possesses several specialized instruments, such as a portable gamma spectrometer and a gas proportional floor monitor system. Instrument calibrations are typically performed by Ludium Instruments on an annual basis. The specialized instruments require calibration by other facilities or the manufacturer. The Program has access to the Division's radiochemistry laboratory that is equipped to conduct whole body counting, wipe tests, isotopic determination, alpha spectroscopy, liquid scintillation counting, gamma spectroscopy, and is certified for radionuclide analysis for drinking water.

Four Program inspectors were accompanied during inspections by a gualified IMPEP reviewer during the week of June 27, 2005, and by a review team member during the week of February 27, 2006. Inspection accompaniments included: medical institution/manual brachytherapy, nuclear pharmacy, industrial radiography field site, and a uranium mill. These

regulations. The inspectors were trained, prepared, and thorough in their audits of the licensees' radiation safety programs. Overall, each inspector utilized good health physics practices. Interviews with licensee personnel were performed in an effective manner, and the inspections were adequate to assess radiological health and safety at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Colorado's performance with respect to the indicator, Technical Quality of Inspections, was satisfactory.

#### 3.4 <u>Technical Quality of Licensing Actions</u>

The review team examined completed licensing casework and interviewed the staff and discussed licensing actions related to 22 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, service provider, portable gauge, fixed gauge and provisional possession. Types of licensing actions selected for evaluation included one new license, eighteen amendments to existing licenses, three license renewals, and three 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 and complete, but in some cases lacked sufficient documentation and/or follow up to ensure health and safety as well as security issues, were appropriately addressed. Staff discussions and review of licensing files demonstrated the consistent use of a two-page reviewer check list (action tracking sheet) for licensing actions performed. Staff stated that in most cases, peer discussion (staff experience) as opposed to specific licensing guides, was the primary mode used during the review process. Complicated deficiencies were addressed in letters and/or emails containing appropriate regulatory language. Telephone conversations addressed and documented simple deficiencies on the action-tracking sheet. The Program does not maintain a separate list of standard license conditions. When new licenses are issued, it is the practice to retrieve electronic versions of similar licenses previously issued, as a means of a template for the new license to be issued. With regard to the license review process, a second individual reviewed each licensing action, then the Technical Lead reviewed the license before it was issued. The peer and supervisory reviews contributed to the notable consistency between reviewers. All licenses evaluated were signed by the Technical Lead, or by designated staff in his absence.

During the last IMPEP, 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. In October 2005, Part 7 (Use of Radionuclides in the Healing Arts) of the State's regulations was revised to facilitate compatibility with 10 CFR Part 35. The State resumed the practice of specifically listing authorized users on medical institution's licenses. Licensees were informed prior to the regulatory change and were advised to send a list of authorized users along with training and qualifications. The State has approximately 92 medical facilities of which 72 were in need of license amendments to add authorized users. The review team examined two applicable amendments for completeness and accuracy.

The review team noted documentation shortfalls in the provisional licensing process. Issuance of a provisional license mandates that a facility do the following: provide a written plan for identification, characterization, and disposal of radioactive material within 30 days from the issuance of a provisional license; store radioactive material in a manner that will preclude access and use by unauthorized personnel. Additionally, provisional licenses are only valid for 180 days. The review team noted that in 2004 and 2005 there were multiple instances pertaining to approximately four facilities where provisional licenses should have been issued but were not. The review team recommends that the Program develop and implement a process for issuance of provisional licenses in a timely manner as well as timely termination of these licenses.

The review team did not examine specific financial assurance documents but had in-depth discussions regarding the process used to calculate financial assurance. The Program has developed a financial surety spread sheet, "Crystal Ball," that is primarily used with laboratories. The Program factors in isotopes used, facility square footage, percentile factoring, and other pertinent parameters. The review team concluded that the Program handles financial assurance appropriately.

The review team found that actions terminating licenses had some documentation shortfalls. It was noted that in the three termination actions reviewed, two cases should have included more thorough documentation. These reviews are addressed in Appendix D of this report. The review team recommends that the Program add a section to the two-page reviewer checklist to facilitate the appropriate, thorough and consistent review of license decommissioning and terminations items.

The review team examined the licenses that the Program had determined met the criteria for the increased controls, as per COMSECY-05-0028. The review team determined that the Program had, in part, correctly identified the Colorado licensees that require increased controls based on this criteria. Each licensee was issued a license amendment requiring increased controls in accordance with the timelines established by the Commission in the SRM for COMSECY-05-028. The Program had identified 16 additional licensees, medical licensees authorized to use HDR afterloaders for brachytherapy, that were unlikely to posses quantity of concern (QOC) values except under abnormal conditions and during a source exchange. In the October to November, 2005, timeframe an e-mail was sent to licensee medical physicists recommending that they reduce the authorized quantities used in HDR afterloaders. Copies of this correspondence were not in the applicable license files and the Program could not locate a copy of this e-mail in any other location. All HDR licensees submitted an amendment request to reduce their possession limits to less than the QOC values. The review team performed an in-

depth review of 3 of the 16 licenses that had been amended to reduce the possession limit to less than QOC values. Although the reduction in possession limits was appropriately performed, the review team observed a license condition that authorized the possession limit (Colorado Regulation RH 7.42) for brachytherapy that exceeds the QOC value for an additional specific radionuclide. At the time of the review, the Program had not documented the process used to determine which licensees meet the increased control criteria. Prior to the end of the review, Program staff provided the review team with documentation of the process used to determine which licensees meet the increased controls criteria. The review team discussed with Program management the value of evaluating the remaining 13 licenses and amending all 16 licenses in a timely manner to reflect possession limits below the QOC values.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Colorado's performance with respect to the indicator, Technical Quality of Licensing Actions, was satisfactory.

#### 3.5 <u>Technical Quality of Incident and Allegation Activities</u>

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 15 materials 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 ten allegations involving radioactive materials, including three allegations 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's Headquarters Operations Center with the Program Manager and selected staff. The Program had 96 materials incidents during the review period, of which 63 incidents were reportable under the NRC criteria. Fifteen incidents were selected for review. The incidents included: lost/stolen materials, equipment failures/disconnects, contamination/spills, damaged devices and packages, and misadministrations.

The review team found that incident files were very well documented and that the Program's response 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. Corrective actions are appropriately followed up during the course of the incident's investigation and prior to closure. Any pending actions are followed up during the next routine inspection and inspection frequencies are increased, if necessary.

As part of the Program's incident response process and once a notification is received, the Program Management, the inspection team leader, and other staff, as appropriate, perform preliminary evaluations of the events to determine the appropriate response. As soon as the event is evaluated and appropriate response determined, a preliminary notification is faxed to the NRC. Periodic updates are provided to the NRC and NMED contractor as the incident's investigation progresses and more information is available. This process continues until the incident is closed.

The review team noted that a written procedure for handling incidents was not present. Instead, there is a practice for handling incidents and consistency among the Program's staff on what this process is was noted. The inspection team leader 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, and the reporting of incidents to the NMED system. The review team discussed the importance of documenting the Program's incident response procedures to meet the IMPEP criteria in MD 5.6 Handbook, particularly in view of anticipated staff turnover due to retirements. The inspection team leader committed to document the procedure and make it available to Program staff.

The review team noted that the Program sent copies of all event reports, except one, to the NRC and NMED contractor. All significant events were reported to the NRC's Headquarters Operations Center in accordance with STP Procedure SA-300, "Reporting Material Events." The review team noted that Program staff were timely in their reporting incidents to the NRC and NMED. Based on the NRC's reporting requirements and the Colorado regulations, the Program developed an Incident Reporting Guide to ensure timely notification to the NRC is provided. However, despite the development and availability of this chart to Program staff, the general practice is to immediately report the incident to the NRC once initial evaluations are performed and initial response is determined, regardless of the reporting requirements. The NRC noted that the event that was not reported was initially determined by the Program to be non-reportable. However, the review team re-evaluated the incident and determined that it is reportable and recommended the Program to report it to NMED as soon as possible.

The review team followed up on five incidents still open in NMED. The review team confirmed that the Program had already closed two of these events but it was not reflected in the NMED database. The Program will follow up with the NMED contractor to close these events. The review team found that, of the remaining three open items, the Program is taking steps to close two of them. The Program is still working on the remaining event, involving uranium ore samples (yellow cake) found at a non-licensee's house. The Program retrieved the material from the individual's house and stored it in the State's radiochemical laboratory. The Program is negotiating with a uranium mill licensee to have them accept the material as an alternative to disposal. The Program will arrange for the material's disposal if the uranium mill licensee decides that it will not accept the material.

The evaluation of the ten allegation cases (three referred by NRC) indicated that the Program took prompt and appropriate action in response to the allegers' concerns. Through review of the casework and interviews with staff, the review team determined that the Program provided feedback to the allegers either verbally or in writing. Any alleger requesting anonymity is informed that every effort will be made to protect his/her identity, but it cannot be guaranteed. The Program prepares an internal memorandum documenting the actions taken and the final resolution. There were no performance issues identified from a review of the allegation files.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Colorado's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, was satisfactory.

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

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

Program. Colorado's Low-Level Radioactive Waste program did not address Agreement materials during the review period; therefore, only three of the four non-common performance indicators were applicable to this review.

#### 4.1 <u>Compatibility Requirements</u>

#### 4.1.1 Legislation

The Department is authorized as the State's radiation control agency under the Colorado Revised Statutes (CRS) Title 25, Article 11 (the Radiation Control Act). The Act authorizes the Governor to enter into agreements with the Federal Government in matters relating to radiation safety. The Act also 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 two new legislative actions occurred that affect the radiation control program since this indicator was found satisfactory during the 2001 IMPEP review. Part 2, Section 25-11-201 of the Act, was amended early in the review period to include a definition for "classified material." The definition includes radioactive material that is: (1) Type 2 byproduct material, as defined in 42 USC Section 2014(e)(2); (2) Naturally occurring or technologically enhanced naturally occurring radioactive material; (3) Non-11e.(2) material; or, (4) Ore. Section 25-11-203 of the Act was also amended to request licensees with classified material for which "an application for storage, processing, or disposal has already been submitted to the department to provide to a library in the community in which the facility is located the material acceptance report prepared, consistent with and containing the information required by the interim guidance on disposal of non-AEA 1954, Section 11e.(2) byproduct material in tailings impoundments, RIS 2000-23, and interim position and guidance on the use of uranium mill feed material other than natural ores , RIS 2000-23, as such guidance documents are amended from time to time, which report has also been provided to the Department."

The review team noted that these amendments at this time affect only one licensee. The NRC has requested Colorado to analyze these legislative changes to determine if they constitute an alternative standard under the last paragraph of Section 2740. of the Atomic Energy Act. This evaluation and any subsequent action will be addressed outside of the IMPEP process.

#### 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 radioactive materials, such as radium, and accelerator-produced radionuclides.

The review team examined the procedures used in the Program's regulatory process. The Program drafts all proposed rules and obtains departmental approval to submit the proposed rules to the Radiation Advisory Committee (the Committee) and the affected community for preliminary review and comments. During this time the NRC is also provided with a draft for comment. Once the preliminary comments from the Committee and the affected community are received, the State's Board of Health (the Board), the State's regulation promulgations body, is contacted to request a public hearing to formally present and discuss the proposed rules. Once the Board establishes the hearing date, a public notice is issued to request public comments. The comment period lasts 60 days, at the end of which, the hearing is held. The Program and

the Committee will meet, if necessary, before the hearing to address any changes considered necessary as a result of comments received during the comment period. Once the Board approves the new rule it goes into effect two months after the hearing. Typically, rule promulgation requires four to six months. The Program's rules and regulations are exempt from the State "sunset" law.

The review team evaluated the Program's response to the questionnaire, reviewed the status of regulations required to be adopted by the State under the NRC's adequacy and compatibility policy and verified the adoption of regulations with information contained on the State Regulation Status (SRS) sheet by the NRC's Office of State and Tribal Programs.

The review team found that the Program has adopted, and sent in for NRC's review, all of the regulations that were due for Agreement State adoption during this review period.

The following regulation will become due in the future and is included here to assist the State in including it in future rulemakings or by adopting alternate generic legally binding requirements:

• "Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71amendment (69 FR 3697) that became effective October 1, 2004.

The team noted that the Program has already drafted a package to address this regulation and plans to submit it to the promulgation process within the next several months.

The review team followed up on a minor change in 6 CCR 1007.1, Part 18, previously identified by NRC staff. Due to the enactment of the Energy Policy Act of 2005 (EPAct), which may affect Part 18 as well as other Parts of the Colorado regulations, the Program will address any changes to the State's regulations required by the new provisions in the EPAct after the NRC final regulations to address the EPAct are promulgated. Addressing all changes will take place after February 2007.

The review team requested information on how the State is implementing their equivalent 10 CFR 34.41(a), also known as the two person rule. The Program implements the rule in the same way the NRC does, with a modification that allows the first radiographer to perform radiographic operations safely, while the second radiographer is nearby engaged in other job-related activities, as long as the first radiographer has complete view of the surrounding job area, such as in open fields, to prevent unauthorized entry into the working area. The team did not attribute any events or incidents in Colorado as a result of implementing this rule in this manner.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Colorado's performance with respect to the indicator, Compatibility Requirements, was satisfactory.

#### 4.2 <u>Sealed Source and Device (SS&D) Evaluation Program</u>

In conducting this review, three sub-indicators were used to evaluate the Program's performance regarding the SS&D Evaluation Program. These sub-indicators include: (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation Program; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Program's SS&D evaluation activities, the review team examined information provided by the Program 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 review team noted the staff's use of guidance documents and procedures, interviewed the staff and the supervisor involved in SS&D evaluations, and verified the use of regulations, license conditions, and inspections to enforce commitments made in the applications.

#### 4.2.1 <u>Technical Staffing and Training</u>

Since the last review, four staff members have conducted SS&D evaluations. Presently, there are three staff members in the Program qualified to conduct SS&D evaluations. One of the qualified staff members that performed a review has transferred to another Unit in the Program. Since the last review, one new staff member has been qualified by the Program to perform SS&D evaluations. The new evaluator has a Bachelor's degree in nuclear medicine and a Master's degree in health physics.

Colorado has a documented training and staff qualification program that all reviewers have completed. The staff is sufficiently qualified to perform safety evaluations on the basis of the training courses taken, work experience, and attendance of the NRC's SS&D workshop.

#### 4.2.2 <u>Technical Quality of the Product Evaluation Program</u>

The review team evaluated all five SS&D product evaluations that the Program completed during the review period. Two of the cases were amendments and three were new evaluations. A list of the SS&D casework examined along with specific comments are found in Appendix F.

The Program's SS&D reviewers stated that they used the guidance in NRC's NUREG-1556, Volume 3 - Applications for Sealed Source and Device Evaluation and Registration. The team's review of the casework and interviews with the staff confirmed that the Program followed the NRC SS&D guidance with a few exceptions as noted in Appendix F. Appropriate standards, Regulatory Guides, and NRC's SS&D workshop references were available and used when performing SS&D reviews.

The registration files contained all correspondence, engineering drawings, radiation profiles, and results of tests conducted by the applicant. The files were well organized in a consistent manner. The review team found the evaluations were of high quality with health and safety issues properly addressed.

The review team noted that three reviewer checklists were not in the case files. The review team did not identify any missed safety issues in the casework reviewed. The review team discussed with the Program the benefits of using and including the file reviewer checklists when evaluating new sealed source or device cases and technical amendment requests to ensure

consistency among reviews. The Program committed to utilizing reviewer checklists and including the checklists in the file for future reviews.

The review team noted from the IMPEP questionnaire that there are six licensees that have terminated licenses, but have active SS&D certificates. The guidance in Section 13.4 of NUREG-1556, Vol. 3, directs the regulatory authority to transfer a registration certificate to inactive status if it is known that the registration certificate holder is out of business. The review team recommends that the Program transfer six sealed source and device certificates to inactive status, because their original manufacturers are no longer in business.

The team reviewed a unique case involving a Colorado SS&D certificate holder. The registration certificate for Boulder Scientific Model 200 had been evaluated for a lower activity level than was being used during source replacement. The user was appropriately licensed to handle the source. The Program reviewed the information and properly handled the situation. The State is currently reviewing an amendment request to reflect the higher activity level.

#### 4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED and the Program's response to the questionnaire, the review team reviewed incidents or failures regarding SS&D registered products during the review period. The team conducted two reviews: events within the boundaries of Colorado and events nationwide involving the products of Colorado licensees.

The review team examined six of the nine events that occurred in Colorado that involved equipment or source failures within the period. The review team found that the State analyzed the events, reviewed the issues, and followed up on the incidents. Colorado reported all events to NRC through NMED. None of the six were related to SS&D failures.

There are ten SS&D vendors in Colorado that have active registration certificates. Five of the ten vendors were selected and events involving products from these five vendors were reviewed. None of the vendors had reportable events that were related to SS&D failures.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Colorado's performance with respect to the indicator, Sealed Source and Device Evaluation Program, was 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 such disposal authority, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, 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 full scope LLRW disposal facility in Colorado.

During the review period, Colorado issued a limited scope license for a LLRW disposal site which authorizes disposal of defuse Naturally Occurring Radioactive Materials (NORM) in the RCRA Subtitle C facility. The license was issued under 10 CFR Part 61-like standards, however, a number of exemptions were included due to the license's limited scope. Although the Rocky Mountain LLRW Compact defines certain NORM as LLRW, it does not meet the NRC's definition of LLRW and is not covered under the terms of the 274b. Agreement between the State of Colorado and the NRC. Since recent activity in this area was not related to the Colorado Agreement, the review team did not evaluate this indicator.

#### 4.4 <u>Uranium Recovery Program</u>

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) Technical Staffing and Training; (2) Status of Uranium Recovery Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities. The results of the uranium recovery program review will be discussed under each of these sub-indicators.

During the review period, the program regulated ten licensees under Part 18, "Milling of Uranium, Thorium and Related Radioactive Materials" of the Department's "Rules and Regulations Pertaining to Radiation Control" and under Part 3, "Licensing of Radioactive Material." The uranium recovery sites are: Cotter Canon City Mill, Umetco Uravan, Umetco Maybell, Hecla Durita, and Sweeney Mill. The Program also manages the following uranium decay chain contamination sites: Cotter Schwardzwalder, CSMRI Creekside, CSMRI Table Mountain, and AMAX Research and Development. The Cotter Mill was the only operational facility at the time of the review. The other facilities listed above were in storage-only or Decontamination and Decommissioning (D&D) status.

#### 4.4.1 <u>Technical Staffing and Training</u>

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 licensing personnel. For an effective uranium recovery program there must be a team of interdisciplinary expertise. The program requires expertise in health physics, hydrogeology, and engineering.

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. The Program has an effective interdisciplinary team of expertise with an appropriate training program in place.

The review found that the expertise for radon analyses and cap design in the Program was not evident at the time of the review. The review team discussed with the Program the need for expertise in this area because as the Program reviews and approves Cotter Mill's Revised Reclamation Design and Decommissioning Plan the expertise for effective radon analyses becomes more significant.

#### 4.4.2 <u>Status of Uranium Recovery Inspection Program</u>

The review team focused on several factors in evaluating the uranium recovery program's performance for this sub-indicator, including inspection frequency, overdue inspections, and

timely issuance of inspection reports and findings to licensees. The review team's evaluation is based on an evaluation of the Program's response to the questionnaire relative to this indicator, the uranium recovery inspection schedule, inspection casework files, and interviews with inspection staff and management.

The review team determined that the uranium inspection frequency was consistent with MC 2801, "Uranium Mill and 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program." The Cotter Mill is inspected on a frequency greater than required by MC 2801. Inspections are conducted three to four times a year due to repetitive compliance issues, Notices of Violation (NOVs) and escalated enforcement actions (Orders) that are ongoing. The unit also makes frequent site visits to the mill for various meetings and tours.

The remainder of the uranium recovery facilities are inspected at least annually, as they are in D&D status and mostly completed.

In addition to inspection status being timely, review of the program also found that inspection findings are communicated to licensees timely, both through exit interviews and letters.

#### 4.4.3 <u>Technical Quality of Inspections</u>

In reviewing this sub-indicator, the review team examined inspection files, inspection reports, and enforcement documentation for the licensees regulated under Part 18. 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.

Periodic compliance inspections were team (two inspectors) inspections. The site visits were typically conducted by one inspector, who focused on a specific item or area of inspection. Inspectors reviewed relevant license requirements, previous inspection reports, and other background information prior to the inspection.

Review of inspection records by the review team found that the compliance inspections for the last three years at the Cotter Mill did not have all elements on the checklist reviewed at the time of these inspections. However, those elements not reviewed at the time of compliance inspections were reviewed during the site visits over the course of the year. Even though inspectors primarily focused on health physics and radiation safety issues, they also inspected for geotechnical, environmental monitoring, management and organizational issues.

The review team found that the inspection reports provided appropriate depth of coverage. Inspectors addressed compliance conditions for the licensees, and demonstrated that the inspectors pursued root causes where problems or violations were identified. The review team discussed the Program's approach to conducting uranium recovery inspections and that it should ensure that all elements of an uranium recovery facility are inspected and documented on an annual basis.

The review team found the inspections to be satisfactory using checklists without written procedures, due to the experience of the staff. The review team discussed the benefits of having written procedures in view of the anticipated staff turnover because of pending retirements.

#### 4.4.4 <u>Technical Quality of Licensing Actions</u>

The licenses for the Cotter Mill, Umetco Uravan, and Hecla Durita were reviewed in detail. The licenses for these facilities properly address health, safety and environmental issues. These licenses are thorough and of acceptable technical quality.

The review team evaluated licensing actions related to the Cotter Mill. Through staff interviews and review of documents, the review team looked at the broad scope of Cotter's preparation of a revised D&D plan. The proposed placement of additional wells at the Point of Compliance of Cotter's active tailings impoundment was reviewed in detail.

Based upon review of license files and licensing actions, the team concluded that licensing actions were appropriate and that the license conditions were clear and well-written.

#### 4.4.5 <u>Technical Quality of Incident and Allegation Activities</u>

This sub-indicator was reviewed under the common performance indicator, Technical Quality of Incident and Allegation Activities, in Section 3.5 above.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Colorado's performance with respect to the indicator, Uranium Recovery Program, was satisfactory.

#### 5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team recommend and the MRB agreed that Colorado's performance for all performance indicators be found satisfactory. Accordingly, the review team recommended and the MRB agreed that the Colorado Agreement State Program is adequate to protect public health and safety and compatible with NRC's program. The review team recommended and the MRB agreed that the next full IMPEP review take place in approximately four years.

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

#### **RECOMMENDATIONS:**

- 1. The review team recommends the Program conduct reciprocity inspections in accordance with the criteria outlined in NRC MC 1220. (Section 3.2)
- 2. The review team recommends that the Program develop and implement a process for issuance of provisional licenses in a timely manner as well as timely termination of these licenses. (Section 3.4)
- 3. The review team recommends that the Program add a section to the two-page reviewer checklist to facilitate the appropriate, thorough and consistent review of license decommissioning and terminations items. (Section 3.4)
- 4. The review team recommends that the Program transfer six sealed source and device certificates to inactive status, because their original manufacturers are no longer in business. (Section 4.2.2)

#### LIST OF APPENDICES AND ATTACHMENT

Appendix AIMPEP Review Team MembersAppendix BColorado Organization ChartsAppendix CInspection Casework ReviewsAppendix DLicense Casework ReviewsAppendix EIncident Casework ReviewsAppendix FSealed Source and Device Casework ReviewsAttachmentMay 18, 2006 Letter from Gary Baughman<br/>Colorado's Response to Draft IMPEP Report

#### APPENDIX A

#### IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Lloyd Bolling, STP	Team Leader Technical Staffing and Training
Vivian Campbell, Region IV	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments (assisted by Robert Evans, Region IV)
Osiris Siurano, STP	Compatibility Requirements
Dennis Sollenberger, STP	Technical Quality of Incident and Allegation Activities
Nima Ashkeboussi, NMSS	Sealed Source and Device Evaluation Program
Frieda Taylor, California	Technical Quality of Licensing Actions
Dorothy Stoffel, Washington	Uranium Recovery Program

#### APPENDIX B COLORADO ORGANIZATION CHARTS

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# Question A.I.1(b)

#### Hazardous Materials and Waste Management Division -February 2006



#### APPENDIX C

#### INSPECTION CASEWORK REVIEWS

## NOTE: CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY.

File No.: 1 Licensee: Denver Health Medical Center License No.: 097-04 Inspection Type: Routine, unannounced Priority: 3 Inspection Date: 1/22/02 Inspector: ES File No.: 2 Licensee: Team Industrial Services, Inc. License No.: 388-01 Inspection Type: Routine, unannounced, field Priority: 1 Inspection Date: 3/1/06 Inspectors: ES, JJ File No.: 3 Licensee: Sabia, Inc. License No.: 811-02 Inspection Type: Routine, announced, initial Priority: 5 Inspection Date: 6/16/04 Inspectors: TP, JO File No.: 4 Licensee: ProTechnics, Division of Core Laboratories LLP License No.: 545-01 Inspection Type: Routine, announced, initial Priority: 3 Inspection Date: 10/8/02 Inspector: BV File No.: 5 Licensee: Vail Valley Medical Center License No.: 807-01 Inspection Type: Routine, unannounced Priority: 3 Inspection Date: 1/5/06 Inspector: ES File No.: 6 Licensee: Intermountain Testing Company License No.: 060-01 Inspection Type: Routine, announced, office Priority: 1 Inspection Date: 7/19/05 Inspector: TB Comment: Independent surveys were not documented in the inspection file. File No.: 7 Licensee: NDE Services, Inc. License No.: 406-01 Inspection Type: Routine, announced, office Priority: 1 Inspection Date: 1/9/04 Inspectors: TB, PS File No.: 8 Licensee: High Mountain Inspection Service, Inc. License No.: 1042-01 Inspection Type: Routine, unannounced Priority: 1 Inspection Dates: 8/31/04 and 9/8/04 Inspector: ES Colorado Final Report **Inspection Casework Reviews** File No.: 9 Licensee: Cardinal Health Inspection Type: Routine, unannounced Inspection Date: 6/17/05 File No.: 10 Licensee: Ground Engineering Consultants, Inc. Inspection Type: Routine, unannounced Inspection Date: 3/1/05 File No.: 11 Licensee: Mallinckrodt, Incorporated Inspection Type: Routine, announced Inspection Date: 3/2/06 File No.: 12 Licensee: Martek Biosciences Boulder Corporation Inspection Type: Routine, announced Inspection Date: 12/17/04 File No.: 13 Licensee: University of Colorado Inspection Type: Routine, announced Inspection Date: 3/1-5/04 File No.: 14 Licensee: University of Colorado at Denver Health Sciences Center Inspection Type: Routine, announced Inspection Date: 1/5/04 File No.: 15 Licensee: University of Colorado at Denver Health Sciences Center Inspection Type: Routine, announced Inspection Dates: 4/12-16/04 File No.: 16 Licensee: University Hospital Inspection Type: Routine, announced Inspection Date: 1/11/05 File No.: 17 Licensee: University Hospital Inspection Type: Routine, announced Inspection Dates: 3/15-16/05 File No.: 18 Licensee: Swedish Medical Center Inspection Type: Routine, announced Inspection Dates: 5/31-6/1/05

License No.: 392-03 Priority: 2 Inspector: ES

License No.: 586-01 Priority: 5 Inspector: ES

License No.: 859–01 Priority: 2 Inspectors: TP, JO

License No.: 1080-01 Priority: 5 Inspector: JO

License No.: 082-08 Priority: 3 Inspectors: ES, JJ

License No.: 163-10 Priority: 5 Inspector: TB

License No.: 835-01 Priority: 2 Inspectors: ES, JJ

License No.: 828-01 Priority: 2 Inspector: JJ

License No.: 828-01 Priority: 2 Inspector: ES

License No.: 251-02 Priority: 3 Inspector: JJ Colorado Final Report Inspection Casework Reviews

File No.: 19 Licensee: Dry Creek Surgery Center Inspection Type: Routine, announced Inspection Date: 4/19/05

File No.: 20 Licensee: Southwest Health System Inspection Type: Routine, announced Inspection Date: 6/9/05

File No.: 21 Licensee: Cotter Corporation Mill Inspection Type: Routine, unannounced, partial Inspection Dates: 11/15-19/04

File No.: 22 Licensee: Cotter Corporation Mill Inspection Type: Routine, announced, partial Inspection Dates: 9/13-17/04

File No.: 23 Licensee: Cotter Corporation Mill Inspection Type: Routine, announced, partial Inspection Dates: 6/9-12/03

File No.: 24 Licensee: UMETCO Uravan Inspection Type: Routine, announced, partial Inspection Date: 3/14/06

File No.: 25 Licensee: UMETCO Maybell Inspection Type: Routine, announced, partial Inspection Date: 8/21/05

File No.: 26 Licensee: UMETCO Maybell Inspection Type: Routine, unannounced, complete Inspection Dates: 10/19-20/04

File No.: 27 Licensee: HECLA Mining Co. Inspection Type: Routine, unannounced, complete Inspection Date: 8/30/04

File No.: 28 Licensee: HECLA Mining Co. Inspection Type: Routine, unannounced, partial Inspection Date: 10/12/05 License No.: 1001-01 Priority: 3 Inspector: TB

License No.: 471-01 Priority: 3 Inspector: JJ

License No: 369-01 Priority: 1 Inspectors: JO, ES

License No: 369-01 Priority: 1 Inspector: JJ

License No: 369-01 Priority: 1 Inspector: JJ

License No: 660-02 Priority: 1 Inspector: PS

License No: 660-01 Priority: 1 Inspector: PS

License No: 660-01 Priority: 1 Inspector: PS

Licensee No: 317-02 Priority: 1 Inspector: PE

Licensee No: 317-02 Priority: 1 Inspectors: PS, EE

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#### INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1 Licensee: Columbia Medical Center of Aurora Inspection Type: Routine, announced Inspection Date: 6/28/05

Accompaniment No.: 2 Licensee: Cotter Corporation Mill Inspection Type: Routine, unannounced Inspection Dates: 6/30-7/1/05

Accompaniment No.: 3 Licensee: Mallinckrodt, Incorporated Inspection Type: Routine, announced Inspection Date: 3/2/06

Accompaniment No.: 4 Licensee: Conam Inspection, Inc. dba Quality Services Laboratories, Inc. Inspection Type: Routine, unannounced Inspection Date: 3/3/06 License No: 205-03 Priority: 3 Inspector: JJ

License No: 369-01 Priority: 1 Inspector: PE

License No: 859-01 Priority: 2 Inspectors: TP, JO

License No: 963-01 Priority: 1 Inspector: TP

#### APPENDIX D

#### LICENSE CASEWORK REVIEWS

## NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1 Licensee: SomaLogic Type of Action: Renewal Date Issued: 2/13/06

File No.: 2 Licensee: Martek Biosciences Type of Action: Amendment Date Issued: 2/1/05

File No.: 3 Licensee: University of Colorado at Boulder Type of Action: Amendments Dates Issued: 12/1/05, 2/23/06

File No.: 4 Licensee: The Alpha Group and Associates, L.L.C. Type of Action: Termination Date Issued: 3/1/06

Comment:

Disposal, transfer, or leak test records not provided to the Program; instrument calibration due dates not provided or requested (reviewed during inspection); surveys not signed; pre-decontamination levels not provided, appropriate signatures not on surveys, calibration due dates for instruments not provided.

File No.: 5 Licensee: Soil Testing & Engineering Type of Action: Renewal Date Issued: 12/2/04

File No.: 6 Licensee: Ground Engineering Consultants, Inc. Type of Action: Renewal Date Issued: 3/11/05

File No.: 7 Licensee: Cardinal Health Type of Action: Amendment Date Issued: 12/15/04

File No.: 8 Licensee: University of Colorado Health Sciences Center Type of Action: Amendment Date Issued: 3/7/05 License No.: 1006-01 Amendment No.: 04 License Reviewer: RT

License No.: 1080-01 Amendment No.: 1 License Reviewer: JO

License No.: 082-08 Amendment Nos.: 36,37 License Reviewer: JJ

> License No.: 1048 Amendment No.: 4 License Reviewer: JJ

License No.: 612-01 Amendment No.: 5 License Reviewer: RT

License No.: 586-01 Amendment No.: 15 License Reviewer: RT

License No.: 392-03 Amendment No.: 3 License Reviewer: RT

License No.: 835-01 Amendment No.: 23 License Reviewer: JJ Colorado Final Report License Casework Reviews

File No.: 9 Licensee: Twentymile Coal Company Type of Action: New Date Issued: 10/20/05

File No.: 10 Licensee: The Prostate Seed Center Type of Action: Amendments Dates Issued: 10/18/05, 10/24/05

File No.: 11 Licensee: Centura Health Type of Action: Amendment Date Issued: 10/24/05

File No.: 12 Licensee: Layne Christensen Company OLOG Division Type of Action: Amendment Date Issued: 1/17/06

File No.: 13 Licensee: Array Bio Pharma, Inc. Type of Action: Amendment Date Issued: 3/16/05

File No.: 14 Licensee: Heska Corporation Type of Action: Termination Date Issued: 3/18/05

Comment:

Historical site assessment (use of radioactive material to include, spills, etc.) not provided. No evidence that the Program performed a walkthrough of the facility prior to license termination. Licensee disclosure of radioactive waste after termination; radioactive waste disposed via sanitary sewage. No on-site presence by the Program and license termination not reissued.

File No.: 15 Licensee: Exempla Lutheran Medical Type of Action: Amendment Date Issued: 12/2/05

File No.: 16 Licensee: The Children's Hospital Type of Action: Amendment Date Issued: 12/1/05 License No.: 811-01 Amendment No.: 00 License Reviewer: JJ

License No.: 972-01 Amendment Nos.: 11, 12 License Reviewer: JJ

> License No.: 197-02 Amendment No.: 93 License Reviewer: JO

> License No.: 971-02 Amendment No.: 09 License Reviewer: TP

License No.: 11 Amendment No.: 05 License Reviewer: RT

License No.: 849-02 Amendment No.: 15 License Reviewer: JO

License No.: 227-02 Amendment No.: 14 License Reviewer: TP

License No.: 75-02 Amendment No.: 25 License Reviewer: JJ Colorado Final Report License Casework Reviews

File No.: 17 Licensee: Aeroflex UTMC, Microelectronics Systems, Inc. Type of Action: Amendment Date Issued: 12/01/05

File No.: 18 Licensee: Rocky Mountain Gamma Knife, LLC Type of Action: Amendment Date Issued: 12/01/05

File No.: 19 Licensee: Acuren Inspection Inc. Type of Action: Amendment Date Issued: 12/01/05

File No.: 20 Licensee: Lockheed Martin Space Systems Type of Action: Amendments Dates Issued: 12/1/05, 2/13/06

File No.: 21 Licensee: Swedish Medical Center Type of Action: Amendment Date Issued: 12/1/05

File No.: 22 Licensee: IBM Corporation Type of Action: Termination Date Issued: 7/23/03

File No.: 23 Licensee: Cotter Corporation Mill Type of Action: Amendment Date Issued: 12/14/04

File No.: 24 Licensee: Hecla Mining Co. Type of Action: Amendment Date Issued: 8/16/99

File No.: 25 Licensee: Umetco Uravan Type of Action: Amendment Date Issued: 7/14/04 Page D.3

License No.: 468-02 Amendment No.: 01 License Reviewer: JJ

License No.: 857-01 Amendment No.: 11 License Reviewer: JJ

License No.: 997-01 Amendment No.: 12 License Reviewer: JJ

License No.: 012-12 Amendment No.: 56, 57 License Reviewer: JJ

> License No.: 251-02 Amendment No.: 20 License Reviewer: JJ

> License No.: 277-02 Amendment No.: 08 License Reviewer: JJ

License No: 369-01 Amendment No: 42 License Reviewers: UR Team

License No: 317-02 Amendment No: 12 License Reviewers: UR Team

License No: 660-02 Amendment No: 10 License Reviewers: UR Team

#### APPENDIX E

#### INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1 Licensee: Syncor Pharmaceuticals Inc. Date of Incident: 4/27/01 Investigation Date: 5/30/01

File No.: 2 Licensee: CTC Geotech Date of Incident: 7/9/01 Investigation Date: 7/17/01 License No.: CO-162-05 Incident Log. No.: I-01-21 Type of Incident: Loss of Material Type of Investigation: Licensee Report

License No.: CO-552-01 Incident Log. No.: I-02-01 Type of Incident: Loss/Theft of Material Type of Investigation: On-site

File No.: 3 Licensee: Midwest Inspection Services Date of Incident: 10/14/02 Investigation Date: 10/17/02

License No.: CO-902-01 Incident Log. No.: I-03-04 Type of Incident: Radiography Source Disconnect Type of Investigation: On-site

File No.: 4 Licensee: Professional Service Industries Date of Incident: 12/16/02 Investigation Date: 12/20/02

License No.: CO-928-02 Incident Log. No.: I-03-08 Type of Incident: Loss of Material Type of Investigation: On-site

File No.: 5 Licensee: Conam Inspection and Engineering Services Date of Incident: 8/18/04 Investigation Date: 9/22/04

File No.: 6 Licensee: State Farm Mutual Automobile Insurance Company Date of Incident: 7/04 Investigation Date: 8/2/04 License No.: CO-963-01 Incident Log. No.: I-04-08 Type of Incident: Potential dose to members of the public in excess of regulatory limits Type of Investigation: Licensee report

> License No.: N/A Incident Log. No.: I-05-01 Type of Incident: Loss of Material Type of Investigation: Licensee report

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File No.: 7 Licensee: Cotter Corporation Mill Date of Incident: 8/12/04 Investigation Date: 8/12/04

License No.: CO-369-01 Incident Log. No.: I-05-03 Type of Incident: Contamination Type of Investigation: On-site

Comment:

This event is non reportable under the NRC criteria.

File No.: 8 Licensee: AG Wassenaar Date of Incident: 9/7/04 Investigation Date: 10/18/04

License No.: CO-212-01 Incident Log. No.: I-05-04 Type of Incident: Equipment damage Type of Investigation: On-site

Comment:

This incident is reportable under STP Procedure SA-300 as a significant event under 10 CFR 30.50(b)(2)(ii), but the initial notification was not made to the NRC's Headquarters Operations Center.

File No.: 9 Licensee: Colorado State University Date of Incident: 1/26/05 Investigation Date: 1/26/05

License No.: CO-002-27 Incident Log. No.: I-05-10 Type of Incident: Shipping package damage Type of Investigation: Licensee report

File No.: 10 Licensee: Midwest Inspection Services Date of Incident: 5/11/05 Investigation Date: 5/31/05

File No.: 11 Licensee: Pro-Technics Date of Incident: 8/22/05 Investigation Date: 8/26/05

File No.: 12 Licensee: Cardinal Health 418, Inc. Date of Incident: 12/7/05 Investigation Date: 1/4/06

File No.: 13 Licensee: Kumar & Associates Date of Incident: 1/30/06 Investigation Date: 2/1/06 License No.: CO-902-01 Incident Log. No.: I-05-18 Type of Incident: Equipment malfunction Type of Investigation: Licensee report

> License No.: CO-545-01 Incident Log. No.: I-06-01 Type of Incident: Contamination Type of Investigation: On-site

License No.: CO-162-06 Incident Log. No.: I-06-08 Type of Incident: Loss of material Type of Investigation: Licensee report

> License No.: CO-778-01 Incident Log. No.: I-06-01 Type of Incident: Loss of material Type of Investigation: On-site

#### Page E.2

Colorado Final Report Incident Casework Reviews

File No.: 14 Licensee: Kaiser Permanente Date of Incident: 6/29/01 Investigation Date: 7/2/01

File No.: 15 Licensee: Exempla Saint Joseph Hospital Date of Incident: 12/13/01 Investigation Date: 12/14/01 Page E.3

License No.: CO-668-01 Incident Log. No.: —01-01 Type of Incident: Misadministration Type of Investigation: On-site

License No.: CO-038-02 Incident Log. No.: —02-01 Type of Incident: Misadministration Type of Investigation: Telephone/Licensee report

#### APPENDIX F

#### SEALED SOURCE AND DEVICE REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1 Registry No.: CO-1230-D-101-S Manufacturer: Hazen Research, Inc. Date Issued: 5/12/05

SS&D Type: (T) Neutron Generator Model No.: NEM 16 Series Type of Action: New SS&D Reviewers: ES, TP

Comment:

First page of the certificate lists "Custom Source" instead of "Custom Device."

File No.: 2 Registry No.: CO-1217-D-101-G Manufacturer: Particle Measuring Systems Date Issued: 10/14/04

SS&D Type: (N) Ion Generator Model No.: Part No. 10000072232 Type of Action: New SS&D Reviewers: JJ, TP

Comments:

- a) First page of the certificate lists "Custom Source" instead of "Custom Device."
- b) No reviewer checklist in the file.

File No.: 3 Registry No.: CO-1012-D-102-S Manufacturer: MF Physics Corp. Date Issued: 4/24/02

SS&D Type: (T) Neutron Generator Model No.: A-325 LL Neutron Generator Head Type of Action: New SS&D Reviewers: BV, ES

Comments:

- a) First page of the certificate lists "Custom Source" instead of "Custom Device."
- b) Format: The model number appears under the "Manufacturer/Distributor" heading
- c) Inconsistent issuance date and review date, issued on 4/24/02, second reviewer signed on 4/25/02.
- d) Name on the certificate "MF Physics Corporation" is out of date. Current name is "Thermo MF Physics Corporation".

File No.: 4 Registry No.: CO-1012-D-101-S Manufacturer: Thermo MF Physics Corp.

Dates Issued: 1/04/02, 7/16/03

SS&D Type: (T) Neutron Generator Model No.: A-3000 Series Neutron Generator Tubes Type of Action: Amendments SS&D Reviewers: TP, BV, ES

Comments:

- a) First page of the certificate lists "Custom Source" instead of "Custom Device."
- b) No reviewer checklist in the file.
- c) Inconsistent issuance date and review date, issued on 7/16/03, second reviewer signed on 7/23/03.

#### ATTACHMENT

May 18, 2006 Letter from Gary Baughman Colorado's Response to Draft IMPEP Report

ADAMS: ML061430467

## STATE OF COLORADO

Bill Owens, Governor Dennis E. Ellis, Executive Director

Dedicated to protecting and improving the health and environment of the people of Colorado

4300 Cherry Creek Dr. S. Denver, Colorado 80246-1530 Phone (303) 692-2000 TDD Line (303) 691-7700 Located in Glendale, Colorado Laboratory Services Division 8100 Lowry Blvd. Denver, Colorado 80230-6928 (303) 692-3090

Colorado Department of Public Health and Environment

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http://www.cdphe.state.co.us

May 18, 2006

Lloyd A. Bolling, Health Physicist Office of State and Tribal Programs U.S. Nuclear Regulatory Commission Washington, DC 20555-0001

> Draft Report on the Colorado Integrated Materials Performance Evaluation Program

Dear Mr. Bolling:

We have reviewed the U.S. Nuclear Regulatory Commission's (NRC's) draft Integrated Materials Performance Evaluation Program (IMPEP) report for Colorado based on the review conducted in Colorado on March 13-17, 2006. We find the report accurately reflects the review process conducted for the State of Colorado radioactive materials program. We have no corrections or changes to suggest at this time.

You requested that we respond to the four recommendations listed in the report. Our initial responses are provided below for your consideration:

1. The review team recommends the Program conduct reciprocity inspections in accordance with the criteria outlined in NRC MC 1220. (Section 3.2)

Response: The Inspection Team has discussed methods for more frequent tracking of reciprocity inspections at Inspection Team meetings on April 3, 2006 and May 9, 2006, and expects to develop a process description this summer as part of the Inspection Manual revision. Meanwhile, the Unit Leader and Inspection Lead are developing an assignment strategy to identify higher priority reciprocity inspection targets, which should be in place within a few weeks.

2. The review team recommends that the Program develop and implement a process for issuance of provisional licenses in a timely manner as well as timely termination of these licenses. (Section 3.4)

Response: Development of a provisional license process description was discussed and assigned to a staff member at our March 24, 2006 Licensing Team meeting. This information will be added to a broader licensing process description we expect to complete this summer.

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Mr. Lloyd Bolling May 18, 2006 Page 2 of 2

3. The review team recommends that the Program add a section to the two-page reviewer checklist to facilitate the appropriate, thorough and consistent review of license decommissioning and terminations items. (Section 3.4)

Response: Decommissioning and license termination requirements and documentation were discussed at our March 24, 2006 Licensing Team meeting. We determined that the license reviews and the license process documentation will include more specific information on these issues. In addition, we have already initiated a process as part of license review docketing to copy termination requests upon receipt to the Inspection Lead for consideration of a closeout inspection or survey concurrent with the licensing activity. We will consider the recommendation to add information to our reviewer checklist to ensure the additional information is included.

4. The review team recommends that the Program transfer six sealed source and device certificates to inactive status, because their original manufacturers are no longer in business. (Section 4.2.2)

Response: This recommendation was discussed at our March 24, 2006 Licensing Team meeting and agreement was reached to incorporate this into the licensing process documentation by this summer. Specific file reviews have not been assigned, but will be implemented in the near future.

We will provide updates to our progress on these recommendations at the annual program review meetings or as appropriate.

I would like you to know that Colorado staff involved in the IMPEP review were extremely complimentary of the NRC and Agreement State staff conducting the review. Most of our staff found the experience challenging, but surprisingly enjoyable and a good learning experience. They noted that your reviewers were knowledgeable, extremely thorough, pleasant to work with, and genuinely interested in our program and in identifying potential improvements. As a result of this interaction, we have already implemented many of the ideas identified during the review which we believe add value to our program.

We appreciate the effort you have put into this process. We will be contacting you soon to determine the logistics for either sending a representative to the Management Review Board meeting and/or setting up participation through videoconferencing capabilities. Should you have any questions or additional comments, please contact me at 303-692-3338 or Joe Vranka at 303-692-3402.

Sincerely,

Ciary U. Baughima

Gary W. Baughman, Director Hazardous Materials and Waste Management Division

CC: Joseph Vranka Steve Tarlton