

July 26, 2010

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 23, 2010, 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 Agreement State Program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 18, of the enclosed final report contains a summary of the IMPEP review team's findings and recommendations. Mr. Gary W. Baughman's letter dated May 27, 2010, adequately discusses the State's proposed actions for resolving the review team's recommendations. 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 4 years, with a periodic meeting tentatively scheduled for April 2012. During the periodic meeting and at the next IMPEP review, NRC will evaluate the effectiveness of the State's response to the review team's recommendations, as well as the overall implementation of your Agreement State program.

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. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA by Cheryl McCrary for/

Michael F. Weber
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Enclosure:
Colorado Final IMPEP Report

cc w/encl.: Steve Tarlton, Manager
Radiation Management Program

July 26, 2010

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Colorado Department of Public Health
and Environment
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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE COLORADO AGREEMENT STATE PROGRAM

April 12-16, 2010

FINAL REPORT

Enclosure

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 April 12-16, 2010, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Florida. 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 Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of March 18, 2006, to April 16, 2010, were discussed with Colorado managers on the last day of the review.

A draft of this report was issued to Colorado for factual comment on May 4, 2010. The State responded by letter dated May 27, 2010, from Gary W. Baughman, Director, Hazardous Materials and Waste Management Division (the Division). A copy of the State's response is included as the Attachment to this report. The Management Review Board (MRB) met on June 23, 2010, 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). The Program is part of the Division, within the Department of Public Health and Environment (the Department). Organization charts for the Department and the Program are included in Appendix B.

At the time of the review, the Colorado Agreement State Program regulated 346 specific licenses authorizing byproduct, source, and certain special nuclear materials (radioactive materials). The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between NRC and the State of Colorado.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Program on December 2, 2009. The Program provided its response to the questionnaire on March 24, 2010. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML101180100.

The review team's general approach for conduct of this review consisted of: (1) examination of the Program's response to the questionnaire, (2) review of applicable Colorado statutes and regulations, (3) analysis of quantitative information from the Program's database, (4) technical review of selected regulatory actions, (5) field accompaniments of seven inspectors, and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Colorado Agreement State Program's performance.

Section 2.0 of this report covers the State's actions in response to recommendations made during previous reviews. Results of the current review of the common performance indicators

are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. The review team's recommendations are comments that relate directly to program performance by the State.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on March 17, 2006, the review team made four recommendations in regard to program performance. The status of the recommendation is as follows:

1. The review team recommends the Program conduct reciprocity inspections in accordance with the criteria outlined in NRC Inspection Manual Chapter (IMC) 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20." (Section 3.2 of the 2006 IMPEP Report)

Status: The Program performed an overall average of 25 percent of all reciprocity licensees during the review period. Following the 2006 review year, the Program has met the 20 percent goal and continues to complete a continually increasing number of reciprocity inspections in each successive year. This recommendation is closed.

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 of the 2006 IMPEP Report)

Status: The Program has implemented a process to periodically review the status of provisional licenses, as well as the status of other licensing actions. There were 13 provisional licenses issued during the review period. Only two of these provisional licenses involved byproduct, source, or special nuclear materials applicable to this review. Most of the provisional licenses were for naturally occurring radioactive material or technologically enhanced radioactive material. The two byproduct material provisional licenses were issued and terminated within 6 months of determination of a need for a provisional license. This recommendation is closed.

3. The review team recommends that the Program add a section to the 2-page reviewer checklist to facilitate the appropriate, thorough, and consistent review of license decommissioning and terminations items. (Section 3.4 of the 2006 IMPEP Report)

Status: The Program incorporated license termination and documentation requirements in its License Process Document, most recently revised in April 2009. The Compliance Lead is copied on all license termination requests to determine if a close-out inspection or survey is needed to justify the licensing action. During the casework evaluations, the review team identified some areas in the processing of license terminations that were deficient. The review team found several instances where the Program should have requested additional information from the licensee or performed confirmatory surveys prior to the termination of the license. At the time of the review, the Program had not added a section to the 2-page reviewer checklist to facilitate license termination reviews,

but was considering doing so; however, the review team believes that the Program can still meet the intent of this recommendation without modifying its 2-page reviewer checklist. This recommendation remains open, but has been modified so that the emphasis is placed on a performance-based outcome in addressing the intent of this recommendation, rather than prescribing a specific means to address this recommendation. The review team recommends that the State evaluate its license termination and decommissioning processes to ensure that reviews are appropriate, thorough, and consistent.

4. The review team recommends that the Program transfer six sealed source and device (SS&D) certificates to inactive status, because their original manufacturers are no longer in business. (Section 4.2.2 of the 2006 IMPEP Report)

Status: The review team verified that the Program transferred the six SS&D certificates to inactive status after the 2006 review. The review team noted that the Program's review process was inconsistent from the guidance specified in NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance About Material Licenses – Applications for Sealed Source and Device Evaluation and Registration." The review team discussed with Program managers the importance of documenting and following the NUREG guidance for all SS&D evaluations to help ensure nationwide consistency of SS&D certificates. Section 4.2.2 of this report documents some of the consistency issues that the review team identified during its casework evaluations, including the Program's practices for inactivating SS&D certifications. The review team opened a new recommendation in Section 4.2.2 to address issues identified during its casework evaluations. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Program's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Program's questionnaire response relative to this indicator, interviewed Program managers and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The review team evaluated the Program's staffing and training as three individual components: the radioactive materials program, the sealed source and device evaluation program, and the uranium recovery program. This section of the report focuses on the radioactive materials program. Staffing and training for the sealed source and device evaluation program and uranium recovery program are discussed in Section 4.2.1 and Section 4.4.1, respectively. The Program Manager oversees all of the components that comprise the Colorado Agreement State Program. The Program expends approximately 13 full-time equivalents (FTE), when fully

staffed, to administer the Agreement State program, an increase of 2 FTE since the previous IMPEP review in 2006.

The Radioactive Materials Unit (the Unit), within the Program, is responsible for radioactive materials licensing, inspection, and emergency response activities. When fully staffed, the Unit is composed of the Unit Leader, eight technical staff, and one program assistant. The technical staff members, classified as Environmental Protection Specialists, perform licensing and inspection activities, as well as respond to incidents and allegations. To provide additional management oversight of the Unit, one technical staff member has been appointed as the Compliance Lead and another has been appointed as the Licensing Lead.

At the time of the review, there was one technical vacancy in the Unit. The vacancy resulted through a series of internal promotions that began at the Program Manager position and ended when a technical staff member was appointed as the Licensing Lead. The technical position has been vacant since January 2010. At the time of the review, the Program was evaluating its options for filling the vacancy, including consideration of the potential for an increase in workload in the uranium recovery program. Despite the vacancy, the review team determined that the Unit was adequately staffed based on current workload. Filling the vacancy would provide depth in the Unit and offset any unforeseen turnover. The Program was aware of an impending retirement and was factoring that into the staffing evaluation.

During the review period, five individuals left the Program, including the former Program Manager, and five individuals were hired into the Program. Three of the five departures were due to staff retirements. The Program was able to manage the turnover during the review period by recruiting and retaining highly qualified and capable staff. The Unit has benefited from hiring individuals with operational health physics or nuclear medicine experience when filling vacancies. The Program requires new hires to have a Bachelor's degree or equivalent experience in a physical or biological science or engineering.

The Unit has an established training and qualification program consistent with NRC Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area" and the NRC and Organization of Agreement States (OAS) Training Working Group Recommendations for Agreement State Training Programs; however, the training and qualification program is not formally documented in a procedure. Qualification is achieved through a combination of education and experience, formal classroom training, and on-the-job training. As evidenced in later sections of the report, the review team did not identify any performance issues that could be attributed to the Unit's lack of a formalized training and qualification procedure.

The Unit maintains training and accompaniment records for each staff member to demonstrate qualification in each of the Unit's program codes or license types. Staff typically starts by achieving qualification to inspect and license fixed and portable gauges and progress through increasingly complex license types based on experience and Unit needs. In reviewing staff's qualifications, the review team determined that the Unit has an adequate number of qualified inspectors and license reviewers for all active license types in Colorado. The review team concluded that the Unit's staffing and training is adequate to carry out its regulatory duties.

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 Status of Materials Inspection Program

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

The review team's evaluation of the Program's inspection priorities verified that inspection frequencies for all types of Colorado material licenses are at least the same frequency as those listed in NRC's IMC 2800, "Materials Inspection Program." A few categories of licenses are assigned inspection priority codes that prescribe a more frequent inspection schedule than those prescribed in IMC 2800.

The Program conducted a total of 340 inspections of Priority 1, 2, and 3 licensees during the review period. The review team determined that 14 of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. The review team did not identify any inspections that were overdue at the time of the review. The review team also evaluated the Program's timeliness for conducting initial inspections. The review team noted that the Program conducted 61 initial inspections during the review period, of which 4 were conducted greater than 12 months after license issuance as prescribed by IMC 2800. The overdue initial inspections ranged from 31 days late to 174 days late. The review team verified that there were no overdue initial inspections at the time of the review. Overall, the review team calculated that the Section performed 4.5 percent of all Priority 1, 2, and 3 and initial inspections overdue during the review period.

The review team evaluated the Program's timeliness of issuance of inspection findings. The Program has a goal of communicating inspection findings to licensees within 30 days of the end of the inspection. The majority of inspection findings are communicated to the licensee using Colorado Form RCD-59, "Compliance Inspection Report," a form similar to NRC's Form 591, "Safety Inspection Report and Compliance Inspection." A completed form is typically issued on-site upon the completion of an inspection. The review team determined that, if a Colorado Form RCD-59 was not issued at the conclusion of the on-site inspection, a "Notice of Violation" was issued from the office within 30 days of the inspection. Of the 33 inspection files reviewed by the review team, the Program only issued 2 inspection findings beyond the 30-day goal.

The Program considers all companies that request to work in Colorado under reciprocity each calendar year to be candidates for inspection, which is more conservative than NRC's guidance for identifying candidate reciprocity licensees in IMC 1220. The review team determined that the Program received requests for reciprocity from approximately 64 candidate reciprocity licensees, as defined in IMC 1220, over the review period. The review team found that; while the Program did not fully meet the 20 percent goal in 2006, completing inspections of 16 percent of candidate reciprocity licensees; they did exceed the 20 percent goal in each successive year

of the review period. Overall, the Program performed an average of 25 percent of all candidate reciprocity inspections over the entire review period.

The review team determined that the Program adequately planned for the initial set of Increased Controls inspections. The Program initially identified 34 licensees that were subject to the Increased Controls and performed all of the first-year inspections in a timely manner, with all inspections being performed within the first 2 years. Subsequent inspections of Increased Controls licensees are now performed in conjunction with health and safety inspections and continue to evaluate the ongoing aspects of the licensee's increased security measures.

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 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 33 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by three former and nine current inspectors and covered a wide variety of inspection types. These included medical, academic, and research and development broadscope licensees; industrial radiography; well logging; self-shielded irradiator; service provider; gamma knife; positron emission tomography (PET); veterinarian nuclear medicine; medical; nuclear pharmacy; portable gauges; and reciprocity licensees. The review also included initial and followup Increased Controls inspections. Appendix C lists the inspection casework files reviewed, with case-specific comments.

Based on the evaluation of casework, the review team determined that inspections covered all aspects of the licensees' radiation safety and security programs. The review team noted that inspection reports were generally thorough, complete, consistent, and of high quality with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable. The review team noted that inspectors were conducting confirmatory reviews of source inventories in the National Source Tracking System for affected licensees. Inspection documentation supported violations, recommendations made to licensees, unresolved safety issues, and discussions held with licensees during exit interviews.

While on site, the review team evaluated the Program's handling and storing of sensitive documents. The review team determined that in most cases, license and inspection files holding documents containing sensitive information were stored in color-coded folders in a locked radiation control file room with controlled electronic access. The review team noted that information in non-sensitive, manila folders were offered the same level of access protection. The review team noted that, although the sensitive documents were in color-coded folders, sensitive documents were not appropriately marked on each page containing sensitive information. The review team interviewed the file room staff and found that, while documents contained in the red folders were not marked as sensitive, the staff was trained to know that anything contained in the red folders was protected and not subject to release under Freedom of Information Act-equivalent State law. Additionally, when an open records request comes in, the file room staff does not release information without getting Program staff approval.

During casework evaluations, the review team identified sensitive, security-related information and personally identifiable information (i.e., alleged identities) that was not appropriately marked intermingled with non-sensitive information in unsecured file cabinets within in a large cubicle style general work area that is accessible to individuals who do not have a need for access to that information. The review team noted that outgoing correspondence that contained sensitive information was not appropriately marked as containing sensitive information. The review team discussed the importance of these markings to signify that the licensees need to appropriately protect the documents. The review team did not discover any evidence of an inadvertent release or unauthorized disclosure on the part of the Program or any licensees; however, the review team believes that the Program would benefit from formalizing its policies on sensitive information. The review team recommends that the State develop and implement a policy and procedure for the handling, marking, transmitting, and storing of documents containing sensitive information.

The Compliance Lead has been delegated the responsibility to conduct annual supervisory accompaniments of the Program's inspectors. The review team noted that the Compliance Lead conducted annual supervisory accompaniments for all inspectors during the review period; however, the Compliance Lead, who regularly performs inspections, was not accompanied during the review period. This same issue was noted and discussed with Program managers during the 2006 IMPEP review. In 2006, Program managers stated that accompaniments of the Compliance Lead had not been performed due to staff turnover at the Unit Leader position. There was turnover at the Unit Leader position again during this review period; therefore, the Program had not taken any action to address this issue. The current Unit Leader committed to ensuring that the Compliance Lead is accompanied annually in the future.

The review team verified that the Program maintains an adequate supply of appropriately calibrated survey instruments to support the inspection program, as well as to respond to radioactive materials incidents and emergency conditions. Instruments used to support the materials inspection program are sent to the manufacturer for calibration.

The Program receives laboratory and sample analysis support from the State laboratory located near the Program office. The laboratory is an accredited, full service radiochemistry laboratory, and has a wide array of analytical equipment capable of detailed radiochemistry analysis.

The review team accompanied five of the Program's radioactive materials inspectors during the week of February 22-26, 2010. The inspectors conducted inspections at a gamma knife facility, an industrial radiography office, a hospital performing radioiodine therapy, a hospital utilizing a high dose-rate remote afterloader (HDR) and a PET production facility. The inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety and security programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations in progress, conducted confirmatory measurements, and utilized good health physics practices. The inspectors held entrance and exit meetings with the appropriate level of licensee management. The review team determined that the inspections were adequate to assess radiological health, safety, and security 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 Technical Quality of Licensing Actions

The review team examined the casework and interviewed license reviewers for 21 licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation and data, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included four new licenses, four renewals, seven amendments, four license terminations, one license application denial, and actions associated with decommissioning of a complex site formerly managed by NRC's Site Decommissioning Management Plan (SDMP) and transferred to Colorado. Files reviewed included a cross-section of license types, including: medical diagnostic and therapy, brachytherapy, gamma knife, industrial radiography, nuclear pharmacy, research and development, and industrial licensees. The casework sample represented work from each of the Program's license reviewers. A listing of the licensing casework reviewed, with case-specific comments, can be found in Appendix D.

The Program assigns a tracking number and logs all licensing actions into a computer tracking system. The action is then given to a license reviewer. The license reviewer can make notations of needed information and comments about the licensing action on a tracking sheet. If needed, the reviewer generates a deficiency letter. Once any deficiency items are resolved, the license reviewer produces a draft licensing action. The draft licensing action is forwarded to a person with signature authority for final approval. Corrections are made, as needed, and the licensing action is issued. The license reviewers have guidance documents for use in preparing medical, industrial, and laboratory licenses.

The review team noted the licensing actions were of high technical quality and consistent with NRC's NUREG-1556 series guidance, the State's regulations, and good health physics practices. The review team noted that some supporting documentation and data that was needed to support the licensing action was missing from the license file. In two cases, the basis for financial assurance levels was missing from the respective files. The review team also found that one file was missing the current license and another file was missing some of the pages of the licensee's application. In determining the extent of condition, the review team found that critical documentation was missing from files in the areas of incidents, allegations, sealed source and device evaluations, and uranium recovery. In some cases, the documentation was no longer available due to State-wide guidance to periodically delete old e-mails and computer files. The review team believes that the missing documentation existed at one time; however, the Program failed to include the documentation file or filed the documentation improperly. The review team believes that the Program's lack of guidance that clearly defines the roles and

responsibilities of staff and expectations for document retention as the underlying cause for the missing documentation. The review team recommends that the State development and implement guidance that outlines the roles and responsibilities for staff and the expectations regarding record retention to ensure that the Program's files are complete and comprehensive.

The review team evaluated the State's actions implemented through NRC's Grant Program, for sites that were formerly managed by NRC. The State of Colorado had one location for which it managed decommissioning activities, using NRC's grant funding. During the review period, the Program produced a final report entitled, "George E. Davis Mill remediation Project HMWMD-RAD-01, Gateway Mesa County, Colorado, Project Completion Report, September 2006", that details the site characterization and remediation performed. All of the grant money was exhausted through the remediation efforts; however, there was not sufficient funding to perform full remediation. The property owners signed an environmental covenant placing restrictions on land use. With the restrictions in place, the dose to the property owners and the public is less than 25 millirem per year from the site. This was the final formerly licensed site under NRC's Grant Program.

The review team assessed the Program's implementation of the pre-licensing guidance. The review team noted that the Program performs pre-licensing checks of all new applicants and new authorized users in accordance with the original pre-licensing guidance, but has not yet implemented all of the essential elements of the revised pre-licensing guidance that was issued on September 22, 2008, and transmitted to the Agreement States via Office of Federal and State Materials and Environmental Management Programs (FSME) Letter RCPD-08-020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will Be Used as Specified on a License and the Checklist for Risk-significant Radioactive Material." FSME Letter RCPD-08-020 required implementation of the essential elements of the pre-licensing guidance by March 22, 2009. The review team examined two new licenses issued since March 22, 2009, in which the applicant would be classified as an "unknown entity" in accordance with the guidance. The Program performed a pre-licensing visit of one of the applicants, but not the other. The review team discussed with Program managers the essential elements of the revised pre-licensing guidance and several strategies that other Agreement States have used to satisfy the essential elements. The review team recommends that the State review its implementation of the pre-licensing guidance to ensure that all of the essential elements of the guidance are consistently met.

The review team examined the Program's licensing practices regarding the Increased Controls, Fingerprinting, and National Source Tracking System requirements. The review team noted that the Materials Section added legally binding license conditions to the licenses that met the criteria for implementing the Increased Controls, Fingerprinting, and National Source Tracking System requirements. The review team confirmed that Program evaluates new license applications and license amendments using the same criteria.

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 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Program's actions in responding to incidents and allegations, 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 Program's files, and evaluated the casework for 14 radioactive materials incidents. A listing of the casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Program's response to nine allegations involving radioactive materials, including three that NRC referred to the State during the review period.

When notified of an incident, the Program performs preliminary evaluations of the events to determine the appropriate response based on its emergency response procedure. The Program maintains a database for tracking the status of all incidents and allegations. If the incident meets the reportability thresholds, as established in FSME Procedure SA-300, "Reporting Material Events," the Program promptly notifies the NRC Headquarters Operations Center, typically by e-mail, using the information template established for NMED. If the investigation is complex and extends over a period of time, NMED is appropriately updated, using the NMED software. Of the incidents evaluated by the review team, all had been reported to NRC within the required timeframe and had been properly submitted to NMED.

The incidents selected for review included both medical and industrial events involving lost or stolen radioactive material, overexposure, damaged equipment, contamination, radioactive material release, and equipment failure. The review team determined that the Program's responses to incidents were thorough, 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 immediately dispatched inspectors to a site when the possibility of an immediate threat to public health and safety existed. When no immediate threat was present and the Program determined that the licensee had qualified, competent individuals investigating the incident, the Program generally responded by telephone or e-mail, with an on-site followup at a later date depending on the nature of the incident.

The 2006 review team noted in its report a commitment from the former Compliance Lead to document the Program's incident response procedures and make them available to staff. During this review, the review team examined the Program's incident response guidance, which is part of the Program's emergency response procedure. The review team noted that the guidance included a prioritization for on-site investigations; however, the prioritization does not specifically address loss, thefts, and abandonment of risk-significant quantities of radioactive material or recurring events, especially at medical facilities. The review team discussed with Program managers the importance of conducting on-site investigations for significant or repetitive incidents. The Unit Leader committed to evaluate the on-site investigation priorities and to consider separating the incident response guidance into its own procedure.

In evaluating the effectiveness of the Program's response to allegations, the review team evaluated the casework for nine allegations. The review team concluded that the Program consistently took prompt and appropriate action in response to concerns raised. The Program notified the allegers of the conclusion of their investigation, when possible. The review team

determined that the Program has the ability to adequately protect the identity of allegeders that request anonymity.

As noted in earlier sections of the report, the review team identified issues regarding sensitive information and documentation with respect to incident and allegation files. The review team identified sensitive information that was not appropriately marked in incident and allegation files. The review team also noted that some incident and allegation files were missing essential documentation of the Program's responses.

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

Four non-common performance indicators are used to review 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. NRC's Agreement with Colorado relinquishes regulatory authority for all four program areas covered by the non-common performance indicators.

4.1 Compatibility Requirements

To assess Colorado's status with respect to this performance indicator, the review team examined the Program's response to the questionnaire relative to this indicator; reviewed Colorado's State Regulation Status Data Sheet (SRS), as maintained by FSME; and conducted interviews with managers and staff responsible for this program area.

4.1.1 Legislation

Colorado became an Agreement State on February 1, 1968. The Department is designated as the State's radiation control agency under the Colorado Revised Statutes (CRS) Title 25, Article 11, "The Radiation Control Act." These statutes also authorize the Governor to enter into agreements with the federal government in matters relating to radiation safety.

During the review period, the State did not pass any legislation that had a direct impact on the Colorado Agreement State Program. The review team reviewed and discussed with the Program Manager the effects of several bills passed during the Colorado Legislature's 2008 Session that amended the Colorado Mined Land Reclamation Act. The bills enhanced the Department of Natural Resources' Division of Reclamation, Mining, and Safety's oversight of certain aspects of in situ uranium mining, but did not create any conflicts with the Program's statutory authority or responsibilities under NRC's Agreement with the State of Colorado.

The review team also reviewed two pieces of pending legislation that will impact the Agreement State program if passed. The first would strengthen the Program's enforcement process and would increase the maximum penalty from \$5,000 per day per violation to \$15,000 per day per violation. The second piece of pending legislation would require uranium recovery facilities in standby to remediate any existing environmental contamination prior to restarting operations.

4.1.2 Program Elements Required for Compatibility

The review team examined the procedures used in the Program's regulation promulgation 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 Program provides NRC a draft of the rules for a compatibility review. Once the preliminary comments from the Committee, NRC, and the affected community are received, the Program requests a public hearing with the State's Board of Health (the Board) to formally present and discuss the proposed rules. Once a hearing date is established, the Board issues a notice requesting public comments on the proposed rules. 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 2 months after the hearing. On average, the State can promulgate final effective regulations in 4 to 6 months, depending on the resolution of comments received during the various comment periods. The Program's rules and regulations are exempt from the State's "sunset" law.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after the effective date of NRC's regulations. The review team identified one regulation amendment that was overdue for adoption at the time of the review:

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40 and 70 amendment (71 FR 15005), that was due for Agreement State adoption on March 27, 2009.

The review team identified the following NRC regulation amendments that the State will need to address in future rulemakings or by the adoption of alternate legally binding requirements:

- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendment (72 FR 45147 and 72 FR 54207), that is due for Agreement State adoption by October 29, 2010.
- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.
- "Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32 and 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.
- "Medical Use of Byproduct Material – Authorized User Clarification," 10 CFR Part 35 amendment (74 FR 33901), that is due for Agreement State adoption by September 28, 2012.

At the time of the review, the Program was in the process of addressing all overdue and upcoming regulation amendments. The Program had several rulemaking packages at various

stages in their rule promulgation process that will address these regulation amendments. The Program anticipates these rulemaking packages to be finalized in summer or fall 2010.

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 Sealed Source and Device Evaluation Program

In reviewing this indicator, the review team used three subelements to evaluate the Program's performance regarding the SS&D evaluation program. These subelements were: (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 the information provided in response to the IMPEP questionnaire and evaluated the SS&D registry sheets and supporting documents processed during the review period. The review team also evaluated SS&D staff training records, the use of guidance documents and procedures, and interviewed the staff currently conducting SS&D evaluations.

4.2.1 Technical Staffing and Training

SS&D evaluation responsibilities are mainly distributed between senior license evaluators who are fully qualified to perform SS&D evaluations. Since the last review, three individuals have been trained to perform SS&D evaluations and have attended NRC's SS&D Workshop. During the review period, one of the fully qualified SS&D evaluators retired from the program.

At the time of the review, the Program had five reviewers who are qualified to perform safety evaluations of SS&D applications. The review team interviewed staff members involved in the reviews and determined that they were familiar with the procedures used in the evaluation of a source/device and had access to applicable reference documents. The review team determined that the Program's staffing and training with respect to SS&D evaluations is adequate based on the Program's SS&D workload.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Program conducted 2 new evaluations, issued 8 amendments to existing registrations, and inactivated 13 registrations. The review team evaluated 7 of the 23 SS&D actions, including custom evaluations issued by the Program during the review period. The selected casework represented the work of all the individuals involved with SS&D evaluations during the review period. During the review, the Program compiled an updated list of registrations and determined that there are currently eight active SS&D registrations in the State of Colorado. A list of SS&D casework examined, with the case-specific comments, can be found in Appendix F.

In assessing the Program's SS&D evaluation activities, the review team examined information contained in the Program's response to the IMPEP questionnaire for this indicator, evaluated casework, and interviewed program staff and managers. The review team verified that the

Program's SS&D reviewers had access to the guidance in NRC's SS&D Workshop; NUREG-1556, Volume 3, Revision 1; and applicable and pertinent American National Standards Institute standards, when conducting SS&D evaluations. The review team found that these documents were generally used and followed during SS&D reviews.

The review team noted that the Program's practice is to print e-mail correspondence and any associated attachments and include the documents in the registry file; however, the review team found cases where the application or attachments containing critical information; such as engineering drawings, radiation profiles, and results of tests conducted by the applicant; for the evaluation were not retained or printed out for future reference. This documentation issue is consistent with the review team's observations under other performance indicators.

The Program uses the manufacturer's radioactive materials possession license for legal means to enforce commitments that a manufacturer makes in its SS&D applications. Without the appropriate documentation, the manufacturers' commitments may not be legally enforceable. During the casework evaluations, the review team also noted that the license conditions tying the manufacturer to its commitments were inconsistently worded and did not include all the registries issued to the manufacturer. The review team concluded that the consistency of the wording of the license condition varied between SS&D reviewers and was dependent on the reviewer's experience with SS&D registries.

Based on casework evaluations and interviews with staff, the review team identified Program practices that differ from those specified in NUREG-1556, Volume 3, Revision 1. The review team's observations of these differing practices are noted in Appendix F as comments for each of the cases that were reviewed. Some of these issues were repetitive, such as documentation of items reviewed when transferring a registry to inactive status, lack of protection of proprietary information, and inconsistent issuance dates and review dates. The review team determined that the technical quality of the safety evaluations was not compromised by any of these administrative issues and practices; however, the review team recognized the potential for the Program to experience difficulty in recreating the evaluations to support its regulatory decisions if generic health or safety issues with any of the devices for which the Program issued certificates are identified. The review team attributed the Program's infrequency of performing reviews as an underlying cause of the observed administrative issues and practices. The review team discussed with Program managers the importance of retention of all necessary documentation for legal enforceability and adherence to the guidance in NUREG-1556, Volume 3, Revision 1, for consistency in registry quality and content across the nation. The review team recommends that the State establish a means to ensure that SS&D evaluations are appropriately documented and conducted with thoroughness; consistency with the current version of NUREG-1556, Volume 3; and adherence to existing guidance in product evaluations.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No incidents related to SS&D defects involving sources or devices registered by the State of Colorado were reported during the review period. Incident procedures are in place should an SS&D-related incident occur. The Program is aware of the need to review such incidents as potentially generic in nature with possible wide-ranging effects.

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, but needs improvement.

4.3 Low-level Radioactive Waste Disposal Program

In 1981, 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 low-level radioactive waste (LLRW) as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although the Colorado Agreement State Program has authority to regulate a LLRW disposal facility, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatibility LLRW program. There are no plans for a commercial LLRW disposal facility in Colorado. Accordingly, the review team did not review this indicator.

4.4 Uranium Recovery Program

In reviewing this indicator, the review team used five subelements to evaluate the Program's performance regarding the uranium recovery program. These subelements were: (1) Technical Staffing and Training, (2) Status of the Uranium Recovery Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

At the time of the IMPEP review, Colorado's uranium recovery program had regulatory oversight of six licenses (one site in standby and five sites in closure). Three of the five sites in closure have been remediated and are in the process of NRC concurrence for license termination and/or appropriate transfer to the U.S. Department of Energy's long-term care program. The Program was also in the process of reviewing an application for a new facility. The license in standby and the new facility application are for conventional mills. The Program anticipates an application for an in-situ recovery facility in the near future.

During the IMPEP period, the Program terminated two additional licenses. One license expired after the licensee abandoned the site prior to providing financial assurance. The other license, a conventional mill, was terminated and the property transferred to U.S. Department of Energy for long-term care.

4.4.1 Technical Staffing and Training

In reviewing this subelement, the review team considered staffing level, technical qualifications of the staff, staff training, and staff turnover.

At the time of the review, the Program had two technical personnel who perform the vast majority of the project management, inspections, and licensing action reviews or Colorado's uranium recovery licensees. The Program has dedicated 1.5 FTE to the uranium recovery

program between these two individuals. The staff has training in health physics or geology/geophysics. Technical staff members from the Unit assist with inspection and licensing activities at the sites. The Program also has access to individuals from other programs in the Division for technical support.

An equivalent of 1.2 FTE assigned to the uranium recovery program was lost through retirement of personnel since the 2006 IMPEP. As noted in Section 3.1 of this report, the Program is evaluating its staffing needs in preparation of an anticipated retirement to see if additional support is needed in the uranium recovery area given the potential for new sites to come under their regulatory purview.

The review team examined staff training records as well as interviewed various staff members regarding training efforts. During the IMPEP review period, the training attended by uranium recovery staff was equivalent to two NRC-sponsored courses for each staff member. In addition, Colorado will host NRC's Health Physics for Uranium Recovery (F-104) course in July 2010.

The review team determined that the Program's staffing levels and qualifications for the uranium recovery program were adequate for the Program's workload at the time of the review.

4.4.2 Status of the Uranium Recovery Inspection Program

In reviewing this subelement, the review team evaluated the Program's inspection frequency for uranium recovery licensees and the Program's timeliness of communicating inspection findings to the licensees. The review team's evaluation is based on Colorado's response to the questionnaire relative to this indicator, the uranium recovery inspection schedule, selected inspection casework files, and interviews with inspection staff and managers.

During the review period, Colorado performed 18 license inspections at 7 licensees. The inspections were performed in accordance with frequencies prescribed by NRC's IMC 2801, "Uranium Mill and 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program." The inspection reports were generally completed within 45 days of the inspection, as expected for team inspections. Three inspection reports were completed outside of the 45-day period (49, 53, and 74 days).

4.4.3 Technical Quality of Inspections

In reviewing this subelement, the review team examined inspection reports for six inspections conducted by Colorado during the review period and accompanied inspectors on an inspection at one licensed facility. The uranium recovery program inspection files evaluated by the review team, as well as the inspector accompaniment, are listed in Appendix C. The cases selected for review represented a range of uranium recovery activities in different stages of operation. The review team interviewed inspectors and managers to assess the adequacy of their preparation for the inspections, guidance and/or protocols for inspection procedures, the depth and content of the actual inspections, and the appropriateness of inspection findings.

The inspector accompaniments and casework reviews confirmed that Colorado inspections were thorough, of good quality, and included operational and record reviews. The inspectors

communicated findings and violations to the licensee during the inspection and exit interviews. The inspectors focused on compliance issues, adherence to procedures, and protection of public and worker health and safety. The inspectors concentrated on worker's health and health physics monitoring and environmental monitoring during records reviews. Due to time limitations, not all records were reviewed at each inspection; however, the Program's procedures require that records not reviewed for one inspection will be reviewed during the next inspection. The Program took appropriate enforcement actions based on the severity of violations observed during inspections.

4.4.4 Technical Quality of Licensing Actions

For this subelement, the review team examined files and associated documentation related to licensing of in-situ and conventional mill facilities, license amendment files, and other licensing documentation. Appendix D lists the licensing files reviewed. Based on the casework evaluated, the review team concluded that the licensing actions were of high technical quality and were consistent with Program procedures, State regulations, and good health physics practices.

The licensing actions during the review period consisted of a completeness review of a new application, license renewals and various amendments, decommissioning plans, annual financial assurance updates, compliance monitoring, and post-decommissioning monitoring for groundwater compliance. The Program reported over 300 licensing actions completed during the review period and 15 licensing actions still open at the time of the IMPEP. Of the 15 licensing action not completed, the delay for only one action was attributed to staffing levels. That action was reassigned and was expected to be completed shortly after the time of the review.

A large portion (133 actions) of the licensing actions consisted of document reviews for one licensee, the Cotter Corporation Canon City Mill. In some cases, the review documents did not include a decision of record, final evaluation report, or similar documentation with the final conclusions of the staff's evaluation of the proposed action. Intermediate reviews (e.g., request for additional information) and final detailed letters of approval did exist for most of the more significant licensing actions. The review team concluded that the lack of documentation was administrative, as noted in earlier sections of this report, and did not affect the technical quality of the Program's licensing. The review team discussed with Program managers and staff the importance of documenting final decisions to instill public confidence in that decision and to support requests for technical assistance from Federal or other State agencies.

In regard to the new application, the review team looked at Colorado's process for issuing a new license. Colorado's procedure for reviewing an application for a new source and 11e.(2) byproduct material license consists of a completeness review, two public meetings by the licensee, funding for the county in which the proposed facility is located to provide comments on the applicant's environmental report, a minimum 270-day period for staff review of the application and publication of a final licensing decision, and an opportunity for hearing following publication of the decision document and issuance of the license. The Program informed the review team that the public has the opportunity to submit comments throughout the new application's review period. The Program also informed the review team that any "affected party" can request a hearing after the decision document is published and the license is issued.

4.4.5 Technical Quality of Incident and Allegation Activities

For this subelement, the review team examined files and associated documentation related to incident and allegation activities, response timeliness, and inspection reports; and interviewed the inspection personnel involved with incident and allegation activities.

The review team evaluated the Program's response to three incidents involving uranium recovery operations. A listing of the incident casework examined can be found in Appendix E. The review team concluded that the Program's investigations were thorough and adequately determined the root causes for the three incidents. The Program took appropriate enforcement actions based on the severity of the violations noted.

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

5.0 SUMMARY

As noted in Sections 3.0 and 4.0, Colorado's performance was found satisfactory for seven of the eight performance indicators review and satisfactory, but needs improvement, for the performance indicator, Sealed Source and Device Evaluation Program. The review team made four recommendations regarding program performance by the State and kept open one recommendation from the previous review. Overall, 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. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years.

Below are the recommendations, as mentioned in an earlier section of the report, for evaluation and implementation by the State:

1. The review team recommends that the State develop and implement a policy and procedure for the handling, marking, transmitting, and storing of documents containing sensitive information. (Section 3.3) (Recommendation also applies to Sections 3.4 and 3.5)
2. The review team recommends that the State evaluate its license termination and decommissioning processes to ensure that reviews are appropriate, thorough, and consistent. (Section 3.4 of the 2006 IMPEP Review) (Modified in 2010)
3. The review team recommends that the State development and implement guidance that outlines the roles and responsibilities for staff and the expectations regarding record retention to ensure that the Program's files are complete and comprehensive. (Section 3.4) (Recommendation also applies to Sections 3.5 and 4.4.2)

(Continued on next page.)

4. The review team recommends that the State review its implementation of the pre-licensing guidance to ensure that all of the essential elements of the guidance are consistently met. (Section 3.4)
5. The review team recommends that the State establish a means to ensure that SS&D evaluations are appropriately documented and conducted with thoroughness; consistency with the current version of NUREG-1556, Volume 3; and adherence to existing guidance in product evaluations. (Section 4.2.2)

LIST OF APPENDIXES AND ATTACHMENT

Appendix A	IMPEP Review Team Members
Appendix B	Colorado Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source & Device Casework Reviews
Attachment	May 27, 2010 Letter from Gary W. Baughman Colorado's Response to the Draft Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Aaron McCraw, FSME	Team Leader Technical Staffing and Training Technical Quality of Incident and Allegation Activities Compatibility Requirements
Randy Erickson, Region IV	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Dennis Lawyer, Region I	Technical Quality of Licensing Actions
Tristan Timm, Florida	Technical Quality of Incident and Allegation Activities Sealed Source and Device Evaluation Program
John Saxton, FSME	Uranium Recovery Program Inspector Accompaniments

APPENDIX B

COLORADO ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML101180112

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: Swedish Medical Center
Inspection Type: Special, Announced
Inspection Date: 2/22/10
License No.: 251-02
Priority: 2
Inspector: ES

File No.: 2
Licensee: Acuren Inspection, Inc.
Inspection Type: Special, Announced
Inspection Date: 2/23/10
License No.: 997-01
Priority: 1
Inspectors: MD

File No.: 3
Licensee: Medical Center of the Rockies
Inspection Type: Routine, Announced
Inspection Date: 2/24/10
License No.: 1112-01
Priority: 3
Inspectors: JG

File No.: 4
Licensee: Lutheran Medical Center
Inspection Type: Routine, Announced
Inspection Date: 2/25/10
License No.: 227-02
Priority: 3
Inspector: JJ

File No.: 5
Licensee: PETNET Solutions, Inc.
Inspection Type: Routine, Announced
Inspection Date: 2/26/10
License No.: 990-02
Priority: 2
Inspector: CE

File No.: 6
Licensee: Western Cardiology Nuclear Imaging Labs
Inspection Type: Routine, Announced
Inspection Dates: 5/12/06
License No.: 641-01
Priority: 3
Inspector: ES

Comments:

- a) The Program performed the inspection 108 days overdue.
- b) The Program issued the inspection findings to the licensee 54 days after the inspection.

File No.: 7
Licensee: Mallinckrodt, Inc.
Inspection Type: Routine, Announced
Inspection Date: 8/6/08
License No.: 859-01
Priority: 2
Inspector: JG

File No.: 8

Licensee: National Jewish Medical and Research Center
Inspection Type: Routine/Special, Announced
Inspection Dates: 3/7/07 and 3/19/07

License No.: 222-03
Priority: 1
Inspector: JO

File No.: 9

Licensee: St. Anthony North Hospital
Inspection Type: Routine, Announced
Inspection Date: 2/17/10

License No.: 152-02
Priority: 3
Inspectors: JD, ES

File No.: 10

Licensee: Aspen Valley Hospital
Inspection Type: Routine, Announced
Inspection Date: 3/23/06

License No.: 861-01
Priority: 3
Inspector: JJ

Comments:

- a) The Program performed the inspection 23 days overdue.
- b) The Program issued the inspection findings to the licensee 49 days after the inspection.

File No.: 11

Licensee: University of Colorado Health Science Center
Inspection Type: Special
Inspection Dates: 1/11/07

License No.: 835-01
Priority: 2
Inspector: TP

File No.: 12

Licensee: Halliburton Energy Services, Inc.
Inspection Type: Special, Announced
Inspection Date: 2/15/07

License No.: 120-01
Priority: 3
Inspectors: TB, PE

File No.: 13

Licensee: Schlumberger Technology Corporation
Inspection Type: Special, Announced
Inspection Date: 8/17/06

License No.: 039-01
Priority: 3
Inspector: TP

File No.: 14

Licensee: J-W Wireline Company
Inspection Type: Initial, Announced
Inspection Date: 7/23/08

License No.: 1138-01
Priority: 3
Inspectors: ES, MD

File No.: 15

Licensee: Radiation Therapy Center of Thornton
Inspection Type: Routine, Announced
Inspection Date: 4/4/08

License No.: 1134-01
Priority: 2
Inspector: JO

File No.: 16

Licensee: Utah Inspection, LLC
Inspection Type: Routine, Unannounced
Inspection Date: 12/18/07

License No.: 1043-01
Priority: 1
Inspector: PE

Comment:

The Program performed the inspection 288 days overdue.

File No.: 17

Licensee: Poudre Valley Hospital
Inspection Type: Special, Announced
Inspection Date: 8/16/06

License No.: 123-01
Priority: 5
Inspector: JJ

File No.: 18

Licensee: Lockheed Martin Space Systems
Inspection Type: Special, Announced
Inspection Date: 11/1/06

License No.: 012-12
Priority: 5
Inspector: JO

File No.: 19

Licensee: High Mountain Inspection Services
Inspection Type: Initial/Special, Announced
Inspection Date: 1/6/10

License No.: 1042-01
Priority: 1
Inspectors: ES, CE

File No.: 20

Licensee: High Mountain Inspection Services
Inspection Type: Routine, Announced
Inspection Date: 10/23/07

License No.: 1042-01
Priority: 1
Inspectors: TP, SL

Comment:

The Program performed the inspection 4 days overdue.

File No.: 21

Licensee: MDS Nordion
Inspection Type: Reciprocity, Unannounced
Inspection Date: 6/6/07

License No.: NRC 54-28274-01
Priority: 5
Inspectors: JO, JJ, MD

File No.: 22

Licensee: SABIA, Inc.
Inspection Type: Reciprocity, Unannounced
Inspection Date: 12/1/06

License No.: NRC 11-27727-01
Priority: 5
Inspector: PE

File No.: 23

Licensee: Olsson Associates
Inspection Type: Reciprocity, Unannounced
Inspection Date: 3/17/10

License No.: NE 59-08-01
Priority: 1
Inspector: MD

File No.: 24

Licensee: Nondestructive & Visual Inspection
Inspection Type: Reciprocity, Unannounced
Inspection Date: 7/25/07

License No.: LA-5601-L01
Priority: 1
Inspector: PE

File No.: 25

Licensee: Alpha Omega Services, Inc.
Inspection Type: Reciprocity, Unannounced
Inspection Date: 3/24/09

License No.: CA 3925-19
Priority: 5
Inspector: JJ

File No.: 26

Licensee: JL Shepherd & Associates
Inspection Type: Reciprocity, Unannounced
Inspection Dates: 1/27-28/09

License No.: CA 1779-19
Priority: 5
Inspector: MD

File No.: 27

Licensee: Littleton Equine Medical Center
Inspection Type: Routine, Announced
Inspection Date: 1/20/10

License No.: 1163-01
Priority: 3
Inspectors: CE, PP

File No.: 28

Licensee: Cardinal Health
Inspection Type: Routine, Announced
Inspection Dates: 10/19/09 and 10/22/09

License No.: 392-03
Priority: 2
Inspectors: JG, CE

File No.: 29

Licensee: Midwest Inspection Services
Inspection Type: Routine, Announced
Inspection Date: 8/7/08

License No.: 902-01
Priority: 1
Inspectors: MD, ES

File No.: 30

Licensee: Colorado Medical Cyclotron, Inc.
Inspection Type: Routine, Announced
Inspection Date: 12/4/08

License No.: 990-01
Priority: 2
Inspectors: JG, CE

Comment:

The Program performed the inspection 118 days overdue.

File No.: 31

Licensee: Parkwest Medical Imaging
Inspection Type: Initial, Announced
Inspection Date: 10/5/07

License No.: 1114-01
Priority: 5
Inspector: ES

Comment:

The Program performed the inspection 51 days overdue.

File No.: 33
Licensee: Barry Smith, M.D.
Inspection Type: Initial, Announced
Inspection Date: 8/1/07

License No.: 1110-01
Priority: 3
Inspector: JJ

Comment:

The Program performed the inspection 174 days overdue.

File No.: 34
Licensee: Cotter Corporation, Canon City
Inspection Type: Routine, Announced
Inspection Date: 5/6/09

License No.: 369-01
Priority: 2
Inspectors: PE, EE, MD, JD

Comment:

The Program issued the inspection findings to the licensee 49 days after the inspection.

File No.: 35
Licensee: Cotter Corporation, Canon City
Inspection Type: Routine, Announced
Inspection Date: 5/14/08

License No.: 369-01
Priority: 2
Inspector: JG

Comment:

The Program issued the inspection findings to the licensee 74 days after the inspection.

File No.: 36
Licensee: UMETCO Maybell
Inspection Type: Routine, Announced
Inspection Date: 10/15/08

License No.: 660-01
Priority: 2
Inspector: PE

File No.: 37
Licensee: UMETCO Maybell
Inspection Type: Routine, Announced
Inspection Date: 4/26/06

License No.: 660-01
Priority: 2
Inspectors: PE, EE

File No.: 38
Licensee: UMETCO Uravan
Inspection Type: Routine, Announced
Inspection Date: 8/13/09

License No.: 660-02
Priority: 2
Inspectors: PE, ES

File No.: 39
Licensee: CSMRI - Creekside
Inspection Type: Routine, Announced
Inspection Date: 2/25/09

License No.: 617-01
Priority: 2
Inspector: EE

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Swedish Medical Center
Inspection Type: Special, Announced
Inspection Date: 2/22/10

License No.: 251-02
Priority: 2
Inspector: ES

Accompaniment No.: 2

Licensee: Acuren Inspection, Inc.
Inspection Type: Special, Announced
Inspection Date: 2/23/10

License No.: 997-01
Priority: 1
Inspector: MD

Accompaniment No.: 3

Licensee: Medical Center of the Rockies
Inspection Type: Routine, Announced
Inspection Date: 2/24/10

License No.: 1112-01
Priority: 3
Inspector: JG

Accompaniment No.: 4

Licensee: Lutheran Medical Center
Inspection Type: Routine, Announced
Inspection Date: 2/25/10

License No.: 227-02
Priority: 3
Inspector: JJ

Accompaniment No.: 5

Licensee: PETNET Solutions, Inc.
Inspection Type: Routine, Announced
Inspection Date: 2/26/10

License No.: 990-02
Priority: 2
Inspector: CE

Accompaniment No.: 6

Licensee: Cotter Corporation, Canon City
Inspection Type: Routine, Announced
Inspection Dates: 3/29-31/10

License No.: 369-01
Priority: 2
Inspectors: PE, EE, JG, CE

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Colorado State University, Environmental Health Services
Type of Action: Amendment
Date Issued: 10/5/09
License No.: 002-27
Amendment No.: 19
License Reviewer: JJ

File No.: 2
Licensee: University of Colorado
Type of Action: Renewal
Date Issued: 4/6/09
License No.: 082-08
Amendment No.: 44
License Reviewer: CE

Comment:

The Program has required the licensee to provide financial assurance; however, the basis for the amount of financial assurance was not documented in the file.

File No.: 3
Licensee: Red Hill Forest Property Owner's
Mutual Water & Cattle Assoc.
Type of Action: Renewal
Date Issued: 10/27/06
License No.: 794-1
Amendment No.: 03
License Reviewer: EE

File No.: 4
Licensee: Presbyterian/St. Luke's Medical Center
Type of Action: Renewal
Date Issued: 7/19/06
License No.: 632-06
Amendment No.: 14
License Reviewer: JO

File No.: 5
Licensee: American Piping Inspection, Inc.
Type of Action: New
Date Issued: 12/17/09
License No.: 1169-01
Amendment No.: 00
License Reviewer: JD

Comment:

Part of the licensee's application was missing from the file.

File No.: 6
Licensee: National Inspection Services, LLC
Type of Action: New
Date Issued: 7/24/09
License No.: 1159-01
Amendment No.: 00
License Reviewer: JG

File No.: 7

Licensee: Baker Hughes Oilfield Operations
Type of Action: Renewal
Date Issued: 10/30/09

License No.: 1072-01
Amendment No.: 11
License Reviewer: JD

Comment:

The current license (Amendment No. 11) was not in the file.

File No.: 8

Licensee: Presbyterian/St. Luke's Medical Center
Type of Action: Amendment
Date Issued: 11/4/09

License No.: 632-06
Amendment No.: 20
License Reviewer: JJ

File No.: 9

Licensee: Isogenis, Inc.
Type of Action: Denial
Date Issued: 5/22/08

License No.: N/A
Amendment No.: N/A
License Reviewer: JG

File No.: 10

Licensee: Quinn Testing, LLC
Type of Action: Termination
Date Issued: 7/10/09

License No.: 1137-01
Amendment No.: 01
License Reviewer: JD

File No.: 11

Licensee: Gilead Colorado, Inc.
Type of Action: Termination
Date Issued: 2/19/10

License No.: 1002-01
Amendment No.: 17
License Reviewer: CE

Comment:

The Program did not request the licensee to submit all applicable information prior to terminating the licensee.

File No.: 12

Licensee: Conoco Phillips Pipeline Company
Type of Action: Termination
Date Issued: 4/10/09

License No.: 238-01
Amendment No.: 15
License Reviewer: JJ

Comment:

The Program did not request the licensee to submit all applicable information prior to terminating the licensee.

File No.: 13

Licensee: Greeley X-Ray Group, P.C.
Type of Action: Termination
Date Issued: 10/2/08

License No.: 1074-01
Amendment No.: 06
License Reviewer: CE

File No.: 14

Licensee: Aeroflex Colorado Springs, Inc.
Type of Action: Amendment
Date Issued: 11/03/08

License No.: 468-01
Amendment No.: 05
License Reviewer: CE

File No.: 15

Licensee: Little Equine Medical Center
Type of Action: New
Date Issued: 7/21/09

License No.: 1163-01
Amendment No.: 00
License Reviewer: CE

Comment:

The Program did not perform a pre-licensing visit prior to issuing this license to an "unknown" entity.

File No.: 16

Licensee: ALS Laboratory Group, Environmental Division
Type of Action: Amendment
Date Issued: 3/29/10

License No.: 847-02
Amendment No.: 14
License Reviewer: EE

Comment:

The Program increased the amount of financial assurance required by this licensee; however, there was not supporting documentation in the file.

File No.: 17

Licensee: Forney Acquisitions, LLC
Type of Action: New
Date Issued: 3/18/10

License No.: 1172-01
Amendment No.: 00
License Reviewer: PP

File No.: 18

Licensee: Mallinckrodt, Inc.
Type of Action: Amendment
Date Issued: 7/21/09

License No.: 859-01
Amendment No.: 29
License Reviewer: MD

File No.: 19

Licensee: Rocky Mountain Gamma Knife Center, LLC
Type of Action: Amendment
Date Issued: 8/20/09

License No.: 857-01
Amendment No.: 20
License Reviewer: JJ

File No.: 20

Licensee: University and Colorado Hospital
Type of Action: Amendment
Date Issued: 3/12/09

License No.: 828-01
Amendment No.: 27
License Reviewer: MD

File No.: 21

Site: George E. Davis Mill Remediation Project
Type of Action: Decommissioning
Date Issued: N/A

License No.: N/A
Amendment No.: N/A
License Reviewer: N/A

File No.: 22

Licensee: Cotter Corporation, Canon City
Type of Action: Document Review – 2008 Annual Report
Date Issued: 11/4/09

License No.: 369-01
Amendment No.: N/A
License Reviewer: PE

Comment:

An Evaluation Summary Report for this action was not in the file.

File No.: 23

Licensee: Cotter Corporation, Canon City
Type of Action: Amendment
Date Issued: 10/6/08

License No.: 369-01
Amendment No.: 52
License Reviewer: EE

File No.: 24

Licensee: Cotter Corporation, Canon City
Type of Action: Document Review – Impoundment Dewatering
Date Issued: 8/1/08

License No.: 369-01
Amendment No.: N/A
License Reviewer: PE

Comment:

An Evaluation Summary Report for this action was not in the file.

File No.: 25

Licensee: Cotter Corporation, Canon City
Type of Action: Document Review – Alternatives Analysis
Date Issued: 5/2/08

License No.: 369-01
Amendment No.: N/A
License Reviewer: ST

File No.: 26

Licensee: Cotter Corporation, Canon City
Type of Action: Document Review – Security Procedures
Date Issued: 8/27/08

License No.: 369-01
Amendment No.: N/A
License Reviewer: ST

File No.: 27

Licensee: Cotter Corporation, Schwartzwalder Mine
Type of Action: Document Review – Decommissioning Plan
Date Issued: 8/27/08

License No.: 369-02
Amendment No.: N/A
License Reviewer: EE

Comment:

Final decision documentation was not in the file.

File No.: 28

Licensee: Cotter Corporation, Schwartzwalder Mine
Type of Action: Amendment
Date Issued: 10/7/09

License No.: 369-02
Amendment No.: N/A
License Reviewer: EE

Comment:

Final decision documentation was not in the file.

File No.: 29

Licensee: Cotter Corporation, Schwartzwalder Mine
Type of Action: Document Review – Occupational Dose Assessment
Date Issued: 3/31/08

License No.: 369-02
Amendment No.: N/A
License Reviewer: EE

Comment:

Evaluation or decision-supporting documentation was not in the file.

File No.: 30

Licensee: Umetco Minerals Corporation, Uravan
Type of Action: Trip Report
Date Issued: 4/10/06

License No.: 660-02
Amendment No.: N/A
License Reviewer: PS

File No.: 31

Licensee: Energy Fuels Resources
Type of Action: New – Completeness Review
Date Issued: 12/18/09

License No.: 1170-01
Amendment No.: N/A
License Reviewers: ST, PE, JG, EE,
LB, CT, NC

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Colorado State University
Date of Incident: 8/31/09
Investigation Date: None
License No.: 002-19
NMED No.: 090740
Type of Incident: Lost/Stolen Material
Type of Investigation: Licensee Report

File No.: 2
Licensee: Colorado State University
Date of Incident: 7/11/07
Investigation Date: 7/11/07
License No.: 002-19
NMED No.: 070442
Type of Incident: Equipment Failure
Type of Investigation: E-mail

File No.: 3
Licensee: Suncor Energy USA
Date of Incident: 8/19/09
Investigation Date: 8/19/09
License No.: 615-02
NMED No.: 090680
Type of Incident: Equipment Failure
Type of Investigation: Phone/E-mail

File No.: 4
Licensee: Schlumberger
Date of Incident: 4/9/09
Investigation Date: 4/10/09
License No.: 39-01
NMED No.: 090533
Type of Incident: Abandoned Source
Type of Investigation: Licensee Report

File No.: 5
Licensee: St. Mary-Corwin Hospital
Date of Incident: 3/18/09
Investigation Date: 3/23/09
License No.: 235-02
NMED No.: 090646
Type of Incident: Contamination
Type of Investigation: Phone/E-mail

File No.: 6
Licensee: Cardinal Health
Date of Incident: 2/20/09
Investigation Date: 2/20/09
License No.: 392-03
NMED No.: N/A
Type of Incident: Compounding/Dispensing Error
Type of Investigation: E-mail

File No.: 7
Licensee: Skyridge Medical Center
Date of Incident: 3/4/08
Investigation Date: 3/4/08
License No.: 1053-01
NMED No.: 080146
Type of Incident: Medical Event
Type of Investigation: E-mail

File No.: 8

Licensee: Non-licensee
Date of Incident: 10/6/08
Investigation Date: 10/6/08

License No.: Non-Licensee
NMED No.: N/A
Type of Incident: Public survey request
Type of Investigation: Site

File No.: 9

Licensee: Denver Heath Medical Center
Date of Incident: 2/29/08
Investigation Date: 2/29/08

License No.: 97-04
NMED No.: 080164
Type of Incident: Contamination
Type of Investigation: Licensee Report

File No.: 10

Licensee: Suncor Energy USA
Date of Incident: 11/8/07
Investigation Date: 11/8/07

License No.: 615-02
NMED No.: 080050
Type of Incident: Exposure to Public
Type of Investigation: Licensee Report

File No.: 11

Licensee: Rocky Mountain Cancer Center
Date of Incident: 11/28/06
Investigation Date: 9/28/08

License No.: 1012-01
NMED No.: N/A
Type of Incident: Potential Overexposure
Type of Investigation: Licensee Report

File No.: 12

Licensee: Protechnics
Date of Incident: 4/12/07
Investigation Date: 4/13/07

License No.: 545-01
NMED No.: 070228
Type of Incident: Contamination
Type of Investigation: Site

File No.: 13

Licensee: Conam Inspection
Date of Incident: 10/30/07
Investigation Date: 10/30/07

License No.: 963-01
NMED No.: N/A
Type of Incident: Loss of control
Type of Investigation: Telephone/Interviews

Comments:

- a) The Program did not appropriately mark or secure sensitive information in the file.
- b) The documentation of the interview with the radiation safety officer was not in the file.

File No.: 14

Licensee: Centura Health Penrose – St. Francis
Date of Incident: 7/21/09
Investigation Date: 7/21/09

License No.: 197-02
NMED No.: 090668
Type of Incident: Medical Event
Type of Investigation: Telephone/Interviews

File No.: 15

Licensee: Cotter Corporation, Canon City

Date of Incident: 12/26/05

Investigation Date: 1/12/06

License No.: 369-01

NMED No.: N/A

Type of Incident: Employee Acid Burn

Type of Investigation: Site

File No.: 16

Licensee: Cotter Corporation, Canon City

Date of Incident: 3/2/06

Investigation Date: 5/31/06

License No.: 369-01

NMED No.: N/A

Type of Incident: Yellowcake Drum Burst

Type of Investigation: Record Review

File No.: 17

Licensee: Cotter Corporation, Canon City

Date of Incident: 2/15/06

Investigation Date: 2/18/06

License No.: 369-01

NMED No.: N/A

Type of Incident: Ore Truck Accident

Type of Investigation: Site

APPENDIX F

SEALED SOURCE & DEVICE CASEWORK REVIEWS

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

File No.: 1

Registry No.: CO-1012-D-103-S

Manufacturer: Thermo MF Physics Corporation

Date Issued: 6/1/09

SS&D Type: (T) Other

Model No.: A-3031

Type of Action: New

SS&D Reviewers: ES, JJ

Comments:

- a) The application and its attachments were not in the file or available for review.
- b) The issuance date (June 1, 2009) was prior to the date of the secondary review (signed on June 9, 2009).

File No.: 2

Registry No.: CO-1012-D-101-S

Manufacturer: Thermo MF Physics Corporation

Date Issued: 6/8/09

SS&D Type: (T) Other

Model No.: A-3000 Series

Type of Action: Amendment

SS&D Reviewers: ES, N/A

Comment:

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

File No.: 3

Registry No.: CO-1230-D-101-S

Manufacturer: Hazen Research, Inc.

Date Issued: 6/16/09

SS&D Type: (T) Other

Model No.: NEM 16 Series Models

Type of Action: Amendment

SS&D Reviewers: JJ, ES

Comments:

- a) The amended text was not shown in bold, which is the conventional method to show changes.
- b) First page of the certificate lists "Custom Source" instead of "Custom Device."
- c) The issuance date (June 16, 2009) was prior to the date of the secondary review (signed on June 19, 2009).

File No.: 4

Registry No.: CO-1217-D-102-G

Manufacturer: Particle Measuring Systems

Date Issued: 3/5/07

SS&D Type: (N) Ion Generator

Model No.: Ion Mobility Spectrometry (IMS)

Type of Action: New

SS&D Reviewers: MD, JJ

Comment:

The first page lists the sealed source and model number designation on the same line as the isotope and maximum activity, which is not in accordance with the standard format in NUREG-1556, Vol. 3, Rev. 1.

File No.: 5

Registry No.: CO-1113-S-801-S

Manufacturer: Syncor Pharmaceuticals, Inc.

Date Issued: 9/25/07

SS&D Type: (V) General Medical Use

Model No.: IBT-125-1

Type of Action: Inactivation

SS&D Reviewers: ES, TP

Comment:

No documentation in the file covering the items reviewed for "Transfer to Inactive Status" in accordance with the guidance in Section 13.4, NUREG-1556, Vol. 3, Rev. 1.

File No.: 6

Registry No.: CO-8187-D-801-E

Manufacturer: Statitrol Corporation

Date Issued: 9/19/06

SS&D Type: (P) Ion Generators, Smoke Detectors

Model No.: A-403, A-405, 1503, 1600, 1602

Type of Action: Inactivation

SS&D Reviewers: ES, JJ

Comments:

- a) No documentation in the file covering the items reviewed for "Transfer to Inactive Status" in accordance with the guidance in Section 13.4, NUREG-1556, Vol. 3, Rev. 1.
- b) The issuance date (September 19, 2006) was prior to the date of the secondary review (signed on October 3, 2006).

File No.: 7

Registry No.: CO-8184-D-801-G

Manufacturer: Lear Sigler, Inc.

Date Issued: 9/19/06

SS&D Type: (T) Other

Model No.: Argos I

Type of Action: Inactivation

SS&D Reviewers: ES, JJ

Comments:

- a) No documentation in the file covering the items reviewed for "Transfer to Inactive Status" in accordance with the guidance in Section 13.4, NUREG-1556, Vol. 3, Rev. 1.
- b) The issuance date (September 19, 2006) was prior to the date of the secondary review (signed on October 3, 2006).

ATTACHMENT

May 27, 2010 Letter from Gary W. Baughman
Colorado's Response to the Draft Report

ADAMS Accession No.: ML101540293