November 10, 2011

Ron Chapman, M.D.
Director
California Department of Public Health
1615 Capitol Avenue
Sacramento, CA 95899-7377

Dear Dr. Chapman:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report that documents the results of the Agreement State review held in California on October 17-21, 2011. I was the team leader for the review. The review team's preliminary findings were discussed with you on the last day of the review. The review team's proposed recommendations are that the California Agreement State Program be found adequate to protect public health and safety, but not compatible with NRC's program. The review team also recommends that the period of Monitoring initiated during the 2008 IMPEP review be continued. Monitoring is an informal process that allows the NRC to maintain an increased level of communication with an Agreement State program.

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

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

The team will review your response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Coordinating with your staff, I scheduled the California MRB meeting for Thursday, January 5, 2012, from 1:00 p.m. to 3:00 p.m. EST. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. The NRC has video conferencing capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

If you have any questions regarding the enclosed report, please contact me at (630) 829-9661.

Thank you for your cooperation.

Sincerely,

***/RA/***

James L. Lynch
State Agreements Officer
Division of Nuclear Materials Safety

Enclosure:
Draft California IMPEP Report

cc w/encl: Rufus Howell, Director
Center for Environmental Health

Stephen Woods, Chief
Division of Food, Drug, and Radiation Safety

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE CALIFORNIA AGREEMENT STATE PROGRAM

OCTOBER 17-21, 2011

# DRAFT REPORT

Enclosure

# EXECUTIVE SUMMARY

This report documents the results of the IMPEP review of the California Agreement State Program. The review was conducted during the period of October 17-21, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the States of Alabama and Ohio.

Based on the results of this review, California's performance was found unsatisfactory for the indicator, Compatibility Requirements, and satisfactory for the six remaining performance indicators reviewed. The finding for the Compatibility Requirements indicator remains unchanged from the previous IMPEP review. Progress has been made on the indicator, but the State has not yet addressed a large number of outstanding NRC comments regarding earlier regulation packages. The review team determined that one recommendation from the 2008 IMPEP review, regarding inspection frequency, should be closed. The other recommendation from the 2008 IMPEP review, regarding regulation adoption, was modified to require a specific action plan to resolve the backlog of overdue regulations.

Accordingly, the review team recommends that the California Agreement State Program is adequate to protect public health and safety but is not compatible with NRC's program. The review team also recommends that the period of Monitoring currently in place for California continue until significant progress is made in the regulation promulgation process.

The review team recommends that the next IMPEP review take place in approximately four years, with an early Periodic Meeting scheduled in one year and an additional Periodic Meeting in approximately 2.5 years.

## 1.0 INTRODUCTION

This report presents the results of the review of the California Agreement State Program. The review was conducted during the period of October 17-21, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the States of Alabama and Ohio. 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 April 5, 2008, to October 21, 2011, were discussed with California managers on the last day of the review.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

The California Agreement State Program is administered by the Radiologic Health Branch (the Branch), which is located within the Division of Food, Drug, and Radiation Safety (the Division). The Division is part of the Department of Public Health (the Department). Organization charts for the Department, Division, and the Branch are included as Appendix B.

At the time of the review, the California Agreement State Program regulated 1,853 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of California.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Branch on June 23, 2011. The Branch provided its response to the questionnaire on October 1, 2011. A copy of the questionnaire response may be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML11279A020.

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

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on April 4, 2008, the review team made two recommendations regarding the California Agreement State Program's performance. The status of the recommendations is as follows:

1. The review team recommends that the State reevaluate its justification for inspecting HDR licensees on a 3-year interval and demonstrate that the health, safety, and security of HDR devices are not compromised. (Section 3.2 of the 2008 IMPEP report)

   Status: California modified the inspection frequency for HDR licensees to a 2-year interval, consistent with NRC's inspection frequency. This recommendation is closed.

2. The review team recommends that the Branch develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 4.1.2 of the 2008 IMPEP report)

   Status: The State developed an action plan and has made considerable progress in the adoption of regulations, however, a significant backlog of uncompleted regulation packages remains. The review team modified the 2008 recommendation to require a specific plan, with actions, tasks and milestones, to resolve the backlog of overdue regulations, as described in Section 4.1 below. This recommendation remains open.

## 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 Branch'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 Branch's questionnaire response relative to this indicator, interviewed Branch managers and staff, and reviewed job descriptions, training plans, and training records. The review team also considered any possible workload backlogs in evaluating this indicator.

At the time of the previous review, the Branch was comprised of five Sections, all reporting to the Branch Chief. During the review period, the Branch added a sixth Section to allow each Section to have a more focused approach to the Branch's business. The Financial Operations and Analysis Section support program infrastructure and human resources. The Registration and Certification Section, and the Inspection, Compliance, and Enforcement Section, Radiation Machines, deal primarily with machine-made radiation. The Radioactive Materials Licensing Section (the Licensing Section) performs all of the Agreement State licensing functions. The

Inspection, Compliance, and Enforcement (ICE) Section, Radioactive Materials, is the inspection arm of the Branch for the materials program; and, the new Strategic Planning & Quality Assurance Section handles special projects and strategic planning for the Branch.

The Licensing Section employs three Senior Health Physicists as Unit Supervisors and has staff positions for 15 Associate Health Physicists, one Assistant Health Physicist, and two Junior Health Physicist positions. Most licensing functions are performed in the Sacramento office by three Units in the Licensing Section. A previous fourth Licensing Unit was moved from the Licensing Section to the Strategic Planning & Quality Assurance Section. This Unit, in part, performs radiological assessments.

The ICE Section is operated out of the Sacramento office and two regional offices, one in Richmond (Northern California), and one in Brea (Southern California). Both of the regional offices have a Senior Health Physicist as a supervisor. The Northern California Office has six Associate Health Physicists and two support staff, while the Southern California Office has four Associate Health Physicists. In addition, the Branch has contracts with Los Angeles and San Diego Counties to perform radioactive material inspections. Three full-time equivalents for radioactive materials inspections are currently contracted in the County programs. At the time of the review, the total number of health physicist positions dedicated to radioactive materials in the ICE Section was 12, not including contractor support. The review team found that the balance in staffing between the licensing and inspection programs was effective.

A separate unit, the Regulations Unit, is staffed by a Senior Health Physicist and an Associate Health Physicist that maintain the State's radioactive materials regulations. These individuals previously reported to the Branch Chief but now report to the Strategic Planning & Quality Assurance Section Chief.

The Branch Chief position is vacant due to a retirement and is in the process of being filled, and is currently staffed by Section Chiefs rotating through the position. Discussions with Divisional managers indicated that the Branch Chief position would be permanently filled in the near future. The current Acting Branch Chief is also the Section Chief for the Licensing Section. The Section Chief for the ICE Section will act in the Branch Chief position beginning December 1, 2011. The review team noted that the Branch had two vacancies in the materials program at the time of the review. One position was being permanently held open due to personnel issues, and a selection and job offer had been made for the second vacant position. The review team determined that actions taken by the Branch in reorganizing and recruiting qualified individuals for vacancies have proven effective. Despite being subject to a fragile economy, staff departures are promptly filled, helping to keep up with the high volume of work produced by the Branch.

One area the review team noted where staffing was an issue was in the area of regulation development. As discussed later in this report, regulation development has continued to be an ongoing problem for the Branch. California has a long process for rule adoption which commences after regulations are drafted by the Branch. That initial drafting of regulations was an area of concern for the review team. For several years, the Branch has had one individual primarily responsible for all rule development (materials, X-ray and other areas). Because this individual is primarily responsible for all regulation development, the time allocated to each type of regulation development is limited. This splitting of time has resulted in the Branch often being

several years behind in regulation development and ultimately being placed on different forms of increased surveillance by the NRC. Department managers are committed to applying additional resources to address this problem.

The review team also reviewed job descriptions, qualification matrixes, and training records maintained by the inspection and licensing sections. The training policy for inspectors is contained in the ICE Section manual 17.0, "Qualification of Inspectors". Inspectors are permitted to independently perform inspections for those categories of licenses for which training was completed. The Branch documents the training requirements for license reviewers in Procedure 07-01, "Training Program for Radioactive Materials Licensing Health Physicists." Qualifications for both license reviewers and inspectors are consistent with those found in NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Program Area." Currently, all license categories are covered by trained inspectors or license reviewers as indicated by the Branch's qualification records.

Based on the IMPEP evaluation criteria, the review team recommends that California's performance with respect to the indicator, Technical Staffing and Training, be found 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 Branch's questionnaire response relative to this indicator, data gathered from the Branch's database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that California's inspection frequencies for all types of radioactive material licenses are at the same frequency as similar license types listed in IMC 2800, "Materials Inspection Program."

The review team determined that during the review period, the Branch conducted approximately 685 Priority 1, 2, and 3 inspections, based on the inspection frequencies established in IMC 2800. Seventy-three of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. The review team identified nine current overdue inspections at the time of the review.

The Branch performed approximately 153 initial inspections during the review period, of which 19 were conducted overdue. As required by IMC 2800, initial inspections should be conducted within 12 months of license issuance.

Branch supervisors stated the inspections were sometimes conducted late due to changing inspection priority codes, database issues and lack of management monitoring of overdue inspections. The Branch self-identified the issues and developed a plan to better monitor the inspections due dates. Overall, the review team calculated that the Branch performed 9.8 percent of the total Priority 1, 2, and 3 and initial inspections overdue during the review period.

The review team evaluated the Branch's timeliness in providing inspection findings to licensees. The review team's evaluation of 22 inspection reports identified only two inspection findings letters were communicated to the licensees beyond the Branch's goal of 30 days post-inspection. The two late inspection letters were issued 45 and 68 days after the inspections.

During the review period, the Branch granted 104 reciprocity permits, 36 of which were candidate licensees, based upon the criteria in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." The review team determined that the Branch met or exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

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

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 29 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by 15 Branch inspectors and covered inspections of various license types, including: medical broad scope, medical institutions, medical private practice, portable gauges, industrial radiography, well logging, research and development, veterinary use, gamma knife, nuclear pharmacy, mobile nuclear medicine, service providers, reciprocity and Increased Controls. The evaluation also included a review of documentation of decommissioning inspections and confirmatory surveys performed by the Radiological Assessment Unit. Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of licensed radiation programs. The review team found that compliance inspection reports were generally complete and consistent, 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 licensees, unresolved safety issues, and discussions held with licensees during exit interviews. The reports used for Increased Controls inspections were properly marked with "Official Use Only - Security Related Information" and correspondence to licensees pertaining to those inspections was also found to be properly marked.

The review team determined that inspectors conducted field inspections, as appropriate, to evaluate a licensee's program. The review of the casework did note one instance where an unqualified inspector performed an inspection of a nuclear pharmacy. This was brought to the Division management's attention by the review team and based on the circumstances, a decision was made by Branch managers to consider the inspection incomplete. The inspection was rescheduled to be performed by a qualified inspector.

The inspection procedures utilized by the Branch are generally consistent with the inspection guidance outlined in IMC 2800. The Branch has a goal of performing 90 percent of its

inspections as unannounced, but allows one-day announced inspections to increase inspector efficiency. The compliance inspection reports used by the inspectors are detailed with opportunities for the inspector to add comments as needed to describe items noted during the inspection. For the inspections, the inspector has the option to provide inspection results to the licensee utilizing the Branch 2514 "short" form, which requires signature by the licensee and inspector, and is left with the licensee at the completion of the onsite inspection. This method can be used for an inspection where no violations or only minor items of concern are identified. The ICE Section supervisors review and sign all inspection reports. Supervisory accompaniments were conducted annually for all inspectors.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. All inspection findings were clearly stated and documented in the reports and communicated to the licensees. The Branch issues to the licensee either a letter indicating a clear inspection or a letter with a Notice of Violation which details the results of the inspection. These letters are routinely sent within 30 days of the inspections with a few exceptions noted. When the Branch issues a Notice of Violation, the licensee is required to provide a written corrective action plan within 30 days. The licensee's corrective measures are evaluated by the inspector and an ICE Section supervisor, and if found satisfactory, an acknowledgement letter is sent to the licensee. After all actions are completed, an inspection packet that includes a compliance inspection code sheet, inspection report and enforcement documentation, is sent to the Sacramento office where it is filed and the inspection database is updated.

The review team noted that the Branch has an adequate supply of survey instruments to support their inspection program. Inspectors are assigned appropriate, calibrated survey instrumentation, such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, micro-R meters and portable multichannel analyzers. The Branch also has neutron detectors and a wide array of survey and analysis equipment to support the inspection program and the Radiological Assessment Unit. Instruments are calibrated annually by an approved vendor in the Sacramento area.

A review team member visited the State laboratory facility to evaluate its support to the Branch. The State laboratory is located adjacent to the Branch's Northern California Office and performs sample analysis for multiple programs within the Branch. The laboratory has four staff positions which are dedicated to radiochemistry analysis, two of which are funded entirely by the Branch. The laboratory has a wide array of analytical equipment capable of detailed radiochemistry analysis. The equipment includes multiple high purity germanium detectors, several gamma counters, and various scintillation counters.

The review team accompanied nine of the Branch's inspectors in September 2011. The inspectors conducted inspections at industrial radiography facilities, a nuclear pharmacy, a gamma knife, medical facilities, a pool irradiator, and a research facility. Three of the inspections included a review of the licensees' implementation of the Increased Controls. Appendix C lists the inspector accompaniments. The inspectors demonstrated 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 programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, 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 recommends that California's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

### 3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 34 specific 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, 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 3 new licenses, 4 renewals, 3 decommissioning or termination actions, 2 bankruptcy actions, and 22 amendments. Files reviewed included a cross-section of license types, including: broad scope, medical diagnostic and therapy, brachytherapy, industrial radiography, research and development, nuclear pharmacy, gauges, manufacturers, panoramic and self-shielded irradiators. The casework sample represented work from 23 license reviewers. A listing of the licensing casework evaluated is provided in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records. All licensing actions are maintained in the Branch's electronic database and files. License reviewers use the Branch's licensing guides, policies, checklists, and standard license conditions, specific to the type of licensing actions, to ensure consistency in licenses.

Incoming actions are processed by the Special Projects Unit, which logs them in and delivers to the appropriate unit. Unit chiefs assign actions to the reviewers, who then take the actions for review. If other areas apply, such as financial assurance, increased controls or need for a pre-licensing visit, the action is forwarded to the appropriate person or group for additional review or attention. Once completed, each licensing action undergoes a peer review before going to the Unit chief for final review and signature.

Licenses are issued for a five-year period under a timely renewal system. The review team noted that the Branch's backlog for license renewals (pending greater than one year) had significantly increased over the review period. This has resulted in approximately 20 percent of

licensees operating under timely renewal. The review team, based on its assessment of the licensing program, believed safety was maintained through the amendment process and inspection program, in spite of the backlog. Branch management indicated that they intend to focus on the backlog in the future, as resources allow.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the NUREG-1556 guidance documents, the State's regulations, and good health physics practices. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

The Branch's pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All new licensees receive a pre-licensing site visit which includes an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license. In fact, the Branch performs pre-licensing checks of all significant licensing actions. This approach is more restrictive than NRC policy and requires significant resources to accomplish. Branch management indicated during the review that they were revising the pre-licensing procedures to align more closely to current NRC policy.

The review team examined the Branch's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the Branch uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, including fingerprinting, as appropriate. The review team analyzed the Branch's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Branch requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The review team noted that sensitive, unclassified, non-safeguards information (SUNSI) related to security and Increased Controls, was properly controlled and protected to prevent unauthorized access. However, the Branch does not mark documents as suggested by NRC Regulatory Issue Summary (RIS) 2005-31, "Control of Security-Related SUNSI Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 22, 2005. Discussions with Branch management indicated that since all documents are withheld from public disclosure, they felt this eliminated the need to further mark documents.

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

### 3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Branch's actions in responding to incidents and allegations, the review team examined the Branch's response to the questionnaire relative to this indicator, evaluated selected incidents reported for California in the Nuclear Material Events Database (NMED) against those contained in the Branch's files, and evaluated the casework for 20 radioactive materials incidents. A listing of the incident casework examined, with case-

specific comments, may be found in Appendix E. The review team also evaluated the Branch's response to 19 allegations involving radioactive materials, including 17 allegations referred to the State by the NRC during the review period.

When the Branch is notified of an incident or allegation, the staff member who receives the notification records the information in a Form 5010, "Matter Requiring Investigation/Inspection." A supervisor assigns responsibility for initial response to incidents and allegations involving radioactive material, to a technical staff member. The Branch has comprehensive written procedures for handling investigations. Once the investigation is completed, a "Materials Investigation Closing Memo" is generated, signed off by the appropriate supervisor, and placed in the investigation file.

The incidents selected for review included the following categories: medical events, lost/stolen material, leaking sources, damaged equipment, and transportation. The review team determined that the Branch's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Branch dispatched inspectors for on-site investigations when appropriate and took suitable enforcement and follow-up actions. If the incident met the reportability thresholds, as established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events," the State notified the NRC Headquarters Operations Center and entered the information into NMED in a prompt manner. The NRC's contractor that runs the NMED database stated that California did an outstanding job in providing initial and follow-up information for inclusion in the database.

The review team identified 237 radioactive material incidents in NMED for California during the review period. The review team evaluated the Branch's timeliness of reporting incidents and found that all incidents are reported in the required time frame, following the Branch's receipt of notification from the licensees.

In evaluating the effectiveness of California's actions responding to allegations, the review team evaluated the casework for the 17 allegations referred to the State by the NRC, as well as the casework for two additional allegations reported directly to the State. The Branch evaluated each allegation and determined the proper level of response. The casework review indicated that the Branch took prompt and appropriate action in response to all concerns raised. All of the allegations reviewed were appropriately closed, and appropriate parties were notified of the actions taken. The review team identified no performance issues from the review of the allegation casework.

The State has a Freedom of Information Act- equivalent law, the Public Records Act. The review team discussed the Branch's process for release of records under the Public Records Act and determined that the alleger's identities were adequately protected.

Based on the IMPEP evaluation criteria, the review team recommends that California's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found 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. The NRC's Agreement with California does not relinquish regulatory authority for a uranium recovery program; therefore, only the first three non-common performance indicators applied to this review.

### 4.1 Compatibility Requirements

#### 4.1.1 Legislation

California became an Agreement State on September 1, 1962. The statutory authority for the State's Radiation Control Program is found in Section 7.6 of the California Health and Safety Code. The Division is designated as the State's radiation control agency, and the Branch implements the radiation control program. The review team found that one piece of legislation was passed during the review period that will become effective in 2012. This legislation adds one additional step to the rule development process and requires a broader analysis of the economic impacts of rules being developed. The Branch is uncertain at this time how this State law will specifically affect their rule development process.

#### 4.1.2 Program Elements Required for Compatibility

The State's regulations for control of radiation are located in Title 17 of the California Code of Regulations and apply to all ionizing radiation, whether emitted from radionuclides or devices. California requires a license for possession and use of all radioactive materials. The review team also determined that the State is not subject to sunset regulations.

The review team evaluated the Branch's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status sheet that FSME maintains.

A review of the State's rulemaking process revealed that the process can take well over 600 days from the time a draft rule is placed in the system to the final filing with the Secretary of State. The rules then become effective in 30 days. The public, NRC, other State agencies, and all potentially impacted licensees and registrants are offered an opportunity to comment during the rulemaking review process. When a proposed rule is sent for public comment, it is also sent to NRC for a compatibility review. After resolution of any comments, the final rules are sent to the *California Register* as notification of adoption. Final rules are also sent to licensees and to the NRC.

With so much lead time required, the Branch must initiate its rulemaking process for those rules necessary for compatibility, immediately after NRC publishes its final rule, in order to meet the three-year compatibility requirement. This initiation of the rulemaking process and the timely drafting of regulations have been noted as an issue for the Branch since the 2004 IMPEP review, and continues to be an issue for the Branch in this review. The Branch only has one

staff member assigned to regulation development, including both materials and x-ray regulations. When this staff member is working to develop x-ray regulations, rules necessary for materials compatibility are not being developed. This staffing issue, as illustrated earlier in this report, was discussed with Division managers who agreed to consider additional resources to alleviate this problem.

The State reported they continue to make some progress on the regulation backlog. California processes rule packages by "Parts", such as Part 20 or Part 35, instead of by amendments that cross over several Parts as is done during NRC rule promulgation.

The review team found that the State can also adopt regulations by reference, but noted that State regulations need to pass a criterion called clarity, where the regulation needs to be clear, difficult to misunderstand, and be stand-alone, requiring no additional guidance. The State has difficulty at times incorporating NRC rules by reference because NRC regulations tend to be performance-based, with implementing guidance available in another document. The State would need to make the requirement specific and incorporate some of the guidance information in its regulations for them to pass the clarity criterion.

At the time of the 2008 IMPEP review there were 14 overdue regulations. During the review period, the Branch completed ten amendments; nine of which were overdue at the time of their completion. Currently the Branch has 12 overdue regulations with an additional 3 regulations coming due for adoption in the near future. The review team noted at the time of the review that no new amendments were being prepared by the Branch for processing, and the regulation development staff member indicated with the current workload, that amendment packages would likely not be processed for some time, likely a year.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they become effective. The following amendments are overdue, some significantly longer than three years from their effective date.

- "Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]," 10 CFR Parts 30, and 40 amendments (58 FR 39628), that was due for Agreement State implementation on October 25, 1996.

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026), that was due for Agreement State implementation on August 15, 1997.

  This rule is tied to the amendment "Radiological Criteria for License Termination." See below.

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71 and 150 amendments (62 FR 28947) that was due for Agreement State implementation on June 27, 2000.

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057), that was due for Agreement State implementation on

August 20, 2000.

The 10 CFR Part 20 portion of the regulation was adopted and then challenged in State court by "The Committee to Bridge the Gap, et al." The challenge was successful, and the "Radiological Criteria for License Termination" portion of the regulation was repealed on August 8, 2002. The Branch is currently terminating licenses on a case-by-case basis. This amendment remains open.

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32, 35, 36, and 39 amendments (63 FR 39477 and 63 FR 45393), that was due for Agreement State implementation on October 26, 2001.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162), that was due for Agreement State implementation on February 16, 2004.

- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendments (67 FR 20249), that was due for Agreement State implementation on October 24, 2005.

- "Medical Use of Byproduct Material - Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that was due for Agreement State implementation on April 29, 2008.

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

- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendments (72 FR 45147, 72 FR 54207), that was due for Agreement State implementation by October 29, 2010.

- "Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, 150 amendments (72 FR 58473), that was due for Agreement States implementation by December 17, 2010.

- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864), that was due for Agreement State implementation by November 30, 2010.

The review team identified the following regulation changes and adoptions that will be needed in the future, and the State related that the regulations would be addressed in upcoming rulemaking or by adopting alternate legally binding requirements:

- "Medical Use of Byproduct Material – Authorized User Clarification," 10 CFR Part 35 amendment (74 FR 33901), that is due for Agreement State implementation by September 28, 2012.

- "Decommissioning Planning," 10 CFR Parts 20, 30, 40, and 70 amendments (76 FR 35512), that is due for Agreement State implementation by December 17, 2015.

- "Licenses, Certifications, and Approvals for Materials Licensees," 10 CFR Parts 30, 36, 39, 40, 70, and 150 amendments (76 FR 56591), that is due for Agreement State implementation by November 14, 2014.

The review team also noted little progress on an issue noted during the 2008 review, and discussed with the Branch during subsequent Periodic Meetings and Monitoring calls. This involves the incompatibility of legislation found in Section 115261 of California's "Health and Safety Code – Radiation Control Law" to NRC's 10 CFR Part 61 with regard to low-level radioactive waste disposal. This incompatibility was initially noted in an amendment submission to NRC on June 25, 2007. At that time, NRC notified the State that their statute was more restrictive than 10 CFR 61.41, and therefore did not meet the Compatibility "A" designation assigned to the rule. To date, this compatibility issue has not been resolved. Branch supervisors were uncertain when this issue will be resolved.

Considering the continued number of overdue regulation changes and the lengthy process to complete regulation development, the review team was again not able to find that the California Agreement State Program was meeting the compatibility requirements as identified in the IMPEP evaluation criteria. As noted during previous reviews, the review team believes that additional time and resources will be needed before the State can adopt all overdue regulations required for compatibility.

At the time of the 2008 review, the team made a recommendation that the Branch develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. The review team concluded that the Branch did develop and implement a general action plan for adoption of NRC regulations; however, the team believes that the Branch's plan is not specific enough to transition them through the regulation development process in a timely manner. Therefore, the review team is modifying the previous recommendation to include greater specificity. The review team recommends that the State develop and implement a detailed action plan that fully documents actions, tasks, and milestones associated with each regulation package, to better track adoption of required regulations in accordance with the current NRC policy on adequacy and compatibility.

Based on the IMPEP evaluation criteria, the review team recommends that California's performance with respect to the indicator, Compatibility Requirements, be found unsatisfactory.

## 4.2 Sealed Source and Device Evaluation Program

In reviewing this indicator, the review team used three subelements to evaluate the Branch's performance regarding the Sealed Source and Device (SS&D) Evaluation Program. The sub-elements are: (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 Branch's SS&D evaluation activities, the review team examined information provided by the Branch in response to the IMPEP questionnaire for this indicator. The review team conducted a review of all new, amended, and inactivated SS&D evaluations and

supporting documents covering the review period. The review team noted the staff's use of guidance documents and procedures, interviewed the staff 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 Technical Staffing and Training

The Branch has three individuals that are fully qualified SS&D reviewers with full signature authority to perform concurrence reviews. There are 12 other reviewers that are either partially qualified reviewers or are reviewers in training, and they have limited initial reviewer signature authority, in accordance with the Branch's documented training program. The supervisor assigning the SS&D reviews makes the assignments based on the extent of reviewer's training and experience relative to the complexity of the review required. The Branch uses the concurrence reviewer as the final technical quality reviewer.

The Branch's comprehensive training program is discussed in detail in Section 3.1 of this report. The Branch has a documented qualification program for SS&D reviewers as a subsection of its qualification procedure. The Branch maintains a qualification journal for all reviewers, which lists the completed course work relevant to SS&D evaluations.

The Branch had a list of 62 cases pending review. The breakdown of the cases is six amendments, 20 inactivations, and 36 transfer amendments from one manufacturer to another. The review team determined that the nature and number of open cases does not present a health and safety concern. The Branch has committed to assigning appropriate staff to clear out the backlog of cases.

Consequently, the review team determined that the staffing level dedicated to performing SS&D evaluations is adequate.

### 4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Branch completed 92 SS&D actions, which included one new source and device evaluation, with the balance evenly split between amendments of previously issued registrations, and inactivations of registration certificates. The casework reviewed included 21 of these actions. The cases selected for review were chosen to be representative of the work performed by the Branch during the review period, taking the following factors into account: the types of actions performed; the pool of licensees; the types of products evaluated; and the different reviewers who performed SS&D evaluations. A listing of the SS&D certificates evaluated, with case-specific comments, can be found in Appendix F.

Analysis of the casework and interviews with the staff confirmed that the Branch follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, Revision 1, "Consolidation Guidance About Materials Licenses: Application for Sealed Source and Device Evaluation and Registration." The Branch used appropriate review checklists to ensure all relevant materials were submitted and reviewed. The review team verified that pertinent American National Standards Institute standards, Regulatory Guides, and applicable references were available and were used when Branch staff performed SS&D reviews.

The review team noted some administrative issues and practices that differ from those used in the SS&D community in general. These issues and practices were shared with Branch staff members. The review team noted that safety issues were not affected by any of these administrative issues and practices.

The review team noted that typed names were used in lieu of handwritten signatures on the SS&D registrations. A Branch supervisor had an informal email from their legal representative indicating that the typed signature was acceptable for electronic documents.

The review team noted in registration number CA-406-S-238-S for a line source that the registration did not indicate how the singly vs. doubly or triply encapsulated sealed sources could be distinguished from one another. The issue being that the singly encapsulated sealed source is not robust enough to be used in the gamma gauge applications, as is with the double and triple encapsulated sources. Once this was brought to the Branch's attention, they committed to contacting the vendor to clarify the issue.

The review team determined that the registration files contained all correspondence, photographs, engineering drawings, radiation profiles, and details of the applicant's quality assurance and quality control program. The registrations clearly summarized the product evaluation to provide license reviewers with adequate information to license the possession and use of the product. Deficiency letters clearly stated regulatory positions and all health and safety issues were properly addressed. The review team found that the evaluations were of high quality with health and safety issues properly addressed.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The review team examined a selected sample of incidents or failures regarding SS&D registered products that occurred during the review period. The review team examined incidents that occurred within the State of California, as well as incidents nationwide that occurred within the review period involving equipment or sources registered by the Branch. The review team determined that the Branch followed their procedures, analyzed the events and evaluated the issues, followed up on the incidents that were relevant to SS&D issues, and documented the issues.

The review team evaluated the Branch's response to three separate event or allegation issues regarding a high dose rate remote afterloader. These included sources sticking in the unit during servicing, transfer guide tube length changes, and failure of an extension adapter during prostate treatment. The review team determined the incident investigations were complete, thorough, and fully addressed the issues.

The review team also analyzed the Branch's response to multiple incidents involving a radiography camera in which the locking mechanism prematurely tripped and locked the source outside of the secured (safe) position. Based on the Branch's root cause analysis, the manufacturer revised the device instruction manual and the Branch issued an information notice regarding user maintenance issues. The review team identified design issues that the Branch's initial investigation did not address, such as a potential device modification to alleviate malfunction causative factors. During the review, the Branch reopened the investigation and contacted the manufacturer to schedule a meeting to address the additional design issues at the

manufacturer's facility.

The Branch's evaluation of defects and incidents regarding sealed source and device registrations were resolved in accordance with the regulatory requirements and the relevant guidance documents and procedures. In cases affecting other Agreement States or the NRC, the Branch took the appropriate action to contact the States or the NRC and requested follow-up action.

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

4.3 Low-level Radioactive Waste Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory 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. Although the California Agreement State Program has LLRW disposal authority, the NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in California. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, California's performance was found unsatisfactory for the indicator, Compatibility Requirements, and satisfactory for the remaining performance indicators reviewed. The review team modified a recommendation from the 2008 IMPEP review regarding the timely promulgation of regulations.

Accordingly, the review team recommends that the California Agreement State Program is adequate to protect public health and safety but is not compatible with NRC's program. The review team also recommends that the period of Monitoring currently in place for California, be continued until significant progress is made in the regulation promulgation process.

The review team recommends that the next IMPEP review take place in approximately four years, with a Periodic Meeting scheduled in one year and an additional Periodic Meeting in approximately 2.5 years.

The current review team recommendation, modified from the 2008 IMPEP review, is as follows:

The review team recommends that the State develop and implement a detailed action plan that fully documents actions, tasks, and milestones associated with each regulation package, to better track adoption of required regulations in accordance with the current NRC policy on adequacy and compatibility.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

| **Name** | **Area of Responsibility** |
|---|---|
| Jim Lynch, Region III | Team Leader<br>Technical Quality of Incident & Allegation Activities<br>Inspector Accompaniments |
| Randy Erickson, Region IV | Technical Staffing and Training<br>Compatibility Requirements<br>Inspector Accompaniments |
| Vanessa Cox, FSME | Status of Materials Inspection Program |
| Bryan Parker, Region I | Technical Quality of Licensing Actions |
| David Turberville, Alabama | Technical Quality of Inspections |
| Karl Von Ahn, Ohio | Sealed Source and Device Evaluation Program |

APPENDIX B

CALIFORNIA ORGANIZATION CHARTS

ADAMS ACCESSION NO.:  ML112790126

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Cardinal Health — License No.: 6925-19
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 8/26/10 — Inspectors: DK, JD

File No.: 2
Licensee: Cardinal Health — License No.: 3822-19
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 8/26/10 — Inspector: DK

File No.: 3
Licensee: Kaiser Permanente Medical Center — License No.: 3653-21
Inspection Type: Routine, Announced — Priority: 3
Inspection Date: 9/15/11 — Inspector: KAH

File No.: 4
Licensee: Geo Environ — License No.: 6636-30
Inspection Type: Routine, Unannounced — Priority: 5
Inspection Date: 3/3/11 — Inspector: AR

File No.: 5
Licensee: Industrial Nuclear Co., Inc. — License No.: 2229-01
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 5/10/11 — Inspector: KAH

File No.: 6
Licensee: Seton Medical Center — License No.: 1391-41
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Dates: 4/28-5/3/11 — Inspector: GF

File No.: 7
Licensee: Triad Isotopes, Inc. — License No.: 3219-19
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 6/2/11 — Inspector: JD

Comment: Inspector determined to be not qualified to perform inspection.

File No.: 8
Licensee: Qal-Tek Associates — License No.: NRC 11-27610-01
Inspection Type: Routine, Announced - Reciprocity — Priority: 3
Inspection Date: 3/28/11 — Inspector: RO

File No.: 9
Licensee: TechCorr Inspection & Engineering
License No.: NRC 42-29261-01
Inspection Type: Routine, Unannounced - Reciprocity
Priority: 1
Inspection Date: 7/14/10
Inspector: AT

File No.: 10
Licensee: University of the Pacific
License No.: 0840-39
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Date: 1/7/11
Inspector: KF

File No.: 11
Licensee: Southern California Edison
License No.: 5244-30
Inspection Type: Routine, Announced
Priority: 1
Inspection Dates: 6/9-15/11
Inspector: KH

File No.: 12
Licensee: Corona Regional Medical Center
License No.: 1550-33
Inspection Type: Routine, Announced
Priority: 3
Inspection Date: 4/20/11
Inspector: KH

File No.: 13
Licensee: TC Inspection, LLC
License No.: 5299-07
Inspection Type: Routine, Unannounced
Priority: 1
Inspection Dates: 6/15-7/11/11
Inspector: RO

File No.: 14
Licensee: San Diego Gamma Knife Center
License No.: 6072-37
Inspection Type: Routine, Unannounced
Priority: 2
Inspection Dates: 3/9-13/11
Inspector: RY

File No.: 15
Licensee: Mercy Imaging Center
License No.: 7809-34
Inspection Type: Initial, Unannounced
Priority: 3
Inspection Date: 1/4/11
Inspector: KF

File No.: 16
Licensee: Medi-Physics, Inc.
License No.: 5796-37
Inspection Type: Routine, Unannounced
Priority: 2
Inspection Date: 3/11/11
Inspector: RY

File No.: 17
Licensee: Newport Imaging Center
License No.: 7144-30
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Date: 4/28/11
Inspector: AT

File No.: 18
Licensee: CY Geotech, Inc. License No.: 6617-19
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 5/12/11 Inspector: AR

File No.: 19
Licensee: City of Alameda Health Care District License No.: 1948-01
Inspection Type: Routine, Announced Priority: 3
Inspection Dates: 10/29-11/4/10 Inspector: EM

File No.: 20
Licensee: CA Foundation for Health License No.: 4000-15
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 11/29/10 Inspector: AT

File No.: 21
Licensee: Pengo Wireline of California License No.: 3943-15
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 11/18/10 Inspector: KF

File No.: 22
Licensee: Rapiscan Laboratories License No.: 2484-43
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 1/3/11 Inspector: GF

File No.: 23
Licensee: Prime Health Care Management License No.: 0940-19
Inspection Type: Routine, Unannounced Priority: 3
Inspection Dates: 2/1-3/11 Inspector: JO

File No.: 24
Licensee: Golden Empire Cardiology License No.: 7456-15
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 11/17/10 Inspector: AT

File No.: 25
Licensee: Radiocat, Inc. License No.: 7255-41
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 6/15/10 Inspector: PL

File No.: 26
Licensee: North Oaks Radiation Center License No.: 3693-56
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 3/22/10 Inspector: DA

File No.: 27
Licensee: Halliburton Energy Services, Inc. License No.: 6481-57
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 12/10/10 Inspector: EM

File No.: 28
Licensee: Beverly Oncology and Imaging Centers Medical Group, Inc. License No.: 3666-19
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 12/13/10 Inspectors: JO, JD

File No.: 29
Licensee: North American Scientific License No.: 5537-19
Inspection Type: Special, Announced - Decommissioning Priority: 2
Inspection Dates: 12/15/09 - 1/27/10 Inspector: RL

## INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: IsoRx License No.: 6264-38
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 9/12/11 Inspector: EF

Accompaniment No.: 2
Licensee: Mistras Group, Inc. License No.: 4886-48
Inspection Type: Special, Unannounced Priority: 1
Inspection Date: 9/13/11 Inspector: EM

Accompaniment No.: 3
Licensee: Washington Hospital License No.: 1585-01
Inspection Type: Special, Unannounced Priority: 2
Inspection Date: 9/14/11 Inspector: RO

Accompaniment No.: 4
Licensee: Kaiser Permanente License No.: 3653-21
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 9/15/11 Inspector: NH

Accompaniment No.: 5
Licensee: St. Helena Hospital License No.: 3653-21
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 9/16/11 Inspector: KF

Accompaniment No.: 6
Licensee: Vertex Pharmaceuticals — License No.: 6336-37
Inspection Type: Routine, Announced — Priority: 5
Inspection Date: 9/26/11 — Inspector: RY

Accompaniment No.: 7
Licensee: Sterigenics US, LLC — License No.: 5956-33
Inspection Type: Routine, Announced — Priority: 2
Inspection Date: 9/27/11 — Inspector: DK

Accompaniment No.: 8
Licensee: Davis Laboratories, Inc. — License No.: 3951-30
Inspection Type: Special, Announced — Priority: 1
Inspection Date: 9/28/11 — Inspector: AT

Accompaniment No.: 9
Licensee: West Hills Hospital & Medical Center — License No.: 1388-19
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 9/29/11 — Inspector: JO

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: St. Francis Memorial Hospital — License No.: 0115-38
Type of Action: Amendment — Amendment No.: 68
Date Issued: 11/25/09 — License Reviewer: JH

File No.: 2
Licensee: El Camino Hospital — License No: 0312-43
Type of Action: Amendment — Amendment No.: 86
Date Issued: 9/2/08 — License Reviewer: IS

File No.: 3
Licensee: Chevron USA Product Co. — License No.: 0490-07
Type of Action: Amendment — Amendment No.: 57
Date Issued: 11/13/08 — License Reviewer: BB

File No.: 4
Licensee: L-3 Communications — License No.: 0553-01
Type of Action: Amendment — Amendment No.: 63
Date Issued: 5/4/11 — License Reviewer: TE

File No.: 5
Licensee: University of Redlands — License No.: 0824-36
Type of Action: Amendment (Decommissioning) — Amendment No.: 17
Date Issued: 10/22/09 — License Reviewer: JG

File No.: 6
Licensee: El Camino Hospital – Los Gatos — License No.: 1670-43
Type of Action: Amendment — Amendment No.: 50
Date Issued: 7/22/09 — License Reviewer: PL

File No.: 7
Licensee: Cemex, Inc. — License No.: 1947-44
Type of Action: Amendment — Amendment No.: 22
Date Issued: 9/9/11 — License Reviewer: KD

File No.: 8
Licensee: University of California – San Diego — License No.: 1339-37
Type of Action: Renewal — Amendment No.: 112
Date Issued: 7/7/11 — License Reviewers: IS, JG

File No.: 9
Licensee: Parkview Community Hospital — License No.: 2082-33
Type of Action: Amendment — Amendment No.: 49
Date Issued: 2/23/11 — License Reviewer: BG

File No.: 10
Licensee: Victor Valley Community Hospital — License No.: 2236-36
Type of Action: Amendment — Amendment No.: 43
Date Issued: 7/20/11 — License Reviewer: JC

File No.: 11
Licensee: MHM, Inc. — License No.: 2336-58
Type of Action: Amendment — Amendment No.: 13
Date Issued: 8/2/11 — License Reviewer: RB

File No.: 12
Licensee: Palmdale Regional Medical Center — License No.: 2649-19
Type of Action: Amendment — Amendment No.: 32
Date Issued: 6/3/11 — License Reviewer: CR

File No.: 13
Licensee: Philips Medical Systems, Inc. — License No.: 2760-43
Type of Action: Amendment — Amendment No.: 48
Date Issued: 3/24/11 — License Reviewer: ZG

File No.: 14
Licensee: Philips Medical Systems, Inc. — License No.: 2760-43
Type of Action: Amendment — Amendment No.: 47
Date Issued: 1/6/09 — License Reviewer: LL

File No.: 15
Licensee: Radiation Oncology Medical Group of So. Cal. — License No.: 2833-30
Type of Action: Amendment — Amendment No.: 28
Date Issued: 6/1/11 — License Reviewer: RC

File No.: 16
Licensee: Consolidated Testing Labs — License No.: 3277-54
Type of Action: Amendment — Amendment No.: 20
Date Issued: 2/18/10 — License Reviewer: BH

File No.: 17
Licensee: Sterigenics US, LLC — License No.: 3390-30
Type of Action: Amendment — Amendment No.: 45
Date Issued: 12/19/08 — License Reviewer: RR

File No.: 18
Licensee: Geocon, Inc. License No.: 3924-37
Type of Action: Amendment Amendment No.: 25
Date Issued: 3/12/09 License Reviewer: BH

File No.: 19
Licensee: Western University of Health Sciences License No.: 4288-31
Type of Action: Amendment Amendment No.: 31
Date Issued: 10/20/10 License Reviewer: PG

File No.: 20
Licensee: Western University of Health Sciences License No.: 4288-31
Type of Action: Renewal Amendment No.: 30
Date Issued: 6/18/08 License Reviewer: FT

File No.: 21
Licensee: Western Industrial X-Ray, Inc. License No.: 4424-48
Type of Action: Amendment Amendment No.: 42
Date Issued: 4/23/09 License Reviewer: LL

File No.: 22
Licensee: Kaiser Foundation Hospital License No.: 4484-34
Type of Action: Amendment Amendment No.: 23
Date Issued: 11/2/09 License Reviewer: HA

File No.: 23
Licensee: Cardinal Health License No.: 4999-30
Type of Action: Amendment Amendment No.: 61
Date Issued: 3/30/09 License Reviewer: DV

File No.: 24
Licensee: California Steel Industries, Inc. License No.: 4485-36
Type of Action: Amendment Amendment No.: 15
Date Issued: 4/6/11 License Reviewer: HA

File No.: 25
Licensee: AMEC Geomatrix, Inc. License No.: 4768-01
Type of Action: Amendment Amendment No.: 20
Date Issued: 11/1/10 License Reviewer: RB

File No.: 26
Licensee: Moore Twining Associates License No.: 7765-33
Type of Action: New Amendment No.: 0
Date Issued: 4/16/09 License Reviewer: DC

File No.: 27
Licensee: Orange Co. Comprehensive Radiation Oncology Ctr. License No.: 7791-30
Type of Action: New Amendment No.: 0
Date Issued: 2/8/10 License Reviewer: HA

File No.: 28
Licensee: AHMC International Cancer Center License No.: 7886-19
Type of Action: New Amendment No.: 0
Date Issued: 8/8/11 License Reviewer: BG

File No.: 29
Licensee: Libertytown USA 2, Inc. License No.: 4182-15
Type of Action: Renewal Amendment No.: 92
Date Issued: 7/29/10 License Reviewer: JR

File No.: 30
Licensee: Northern California Veterinary Specialists License No.: 6417-34
Type of Action: Termination (Bankruptcy) Amendment No.: 7
Date Issued: 4/5/11 License Reviewer: JR

File No.: 31
Licensee: Spansion, LLC License No.: 7631-43
Type of Action: Amendment (Bankruptcy) Amendment No.: 1
Date Issued: 3/30/10 License Reviewer: RJ

File No.: 32
Licensee: Acadia Pharmaceuticals, Inc. License No.: 6451-37
Type of Action: Renewal Amendment No.: 14
Date Issued: 6/26/09 License Reviewer: PG

File No.: 33
Licensee: Hitachi Chemical Research License No.: 5524-30
Type of Action: Termination Amendment No.: 16
Date Issued: 8/4/10 License Reviewer: PG

File No.: 34
Licensee: Cardinal Health License No.: 5910-50
Type of Action: Termination Amendment No.: 23
Date Issued: 3/7/11 License Reviewer: JG

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: STERIS, Inc.
Date of Incident: 9/16/08
Investigation Date: 9/16/08
License No.: 6666-36
NMED Log No.: 080567
Type of Incident: Damaged Equipment
Type of Investigation: Telephone.

File No.: 2
Licensee: Schlumberger Technology Corporation
Date of Incident: 4/11/08
Investigation Date: 4/29/08
License No.: 0144-15
NMED Log No.: 080295
Type of Incident: Abandoned Source
Type of Investigation: Letter

File No.: 3
Licensee: Mission Hospital Regional Medical Center
Date of Incident: 6/10/11
Investigation Date: 6/14/11
License No.: 2278-30
NMED Log No.: 110302
Type of Incident: Medical Event
Type of Investigation: Telephone

File No.: 4
Licensee: General Atomics
Date of Incident: 8/19/10
Investigation Date: 8/19/10
License No.: 0145-37
NMED Log No.: 100446
Type of Incident: Damaged Sources
Type of Investigation: Site

File No.: 5
Licensee: ProTechnics
Date of Incident: 10/10/10
Investigation Date: 11/15/10
License No.: 6387-15
NMED Log No.: 110115
Type of Incident: Abandoned Sources
Type of Investigation: Telephone

File No.: 6
Licensee: Sutter General Hospital
Date of Incident: 6/17/10
Investigation Date: 6/18/10
License No.: 2964-34
NMED Log No.: 100320
Type of Incident: Medical Event
Type of Investigation: Telephone

File No.: 7
Licensee: General Nucleonics, Inc.
Date of Incident: 10/6/08
Investigation Date: 10/23/08
License No.: 1288-19
NMED Log No.: 080861
Type of Incident: Leaking Source
Type of Investigation: Telephone

File No.: 8
Licensee: Siemens Medical Solutions
Date of Incident: 1/27/09
Investigation Date: 4/20/09
License No.: 0218-19
NMED Log No.: 090379
Type of Incident: Lost Sources
Type of Investigation: Site

File No.: 9
Licensee: Regents of the University of California, Los Angeles
Date of Incident: 5/8/09
Investigation Date: 5/8/09
License No.: 1335-19
NMED Log No.: 090486
Type of Incident: Lost Sources
Type of Investigation: Telephone

File No.: 10
Licensee: J. L. Shepherd & Associates
Date of Incident: 1/18/10
Investigation Date: 1/19/10
License No.: 1777-19
NMED Log No.: 100058
Type of Incident: Leaking Source
Type of Investigation: Telephone

File No.: 11
Licensee: J. L. Shepherd & Associates
Date of Incident: 9/22/09
Investigation Date: 9/23/09
License No.: 1777-19
NMED Log No.: 090737
Type of Incident: Leaking Source
Type of Investigation: Telephone

File No.: 12
Licensee: CPN Instrotek
Date of Incident: 12/7/09
Investigation Date: 12/7/09
License No.: 1100-07
NMED Log No.: 090871
Type of Incident: Stolen Gauge
Type of Investigation: Telephone

File No.: 13
Licensee: University of California, San Diego
Date of Incident: 9/25/08
Investigation Date:
License No.: 1339-37
NMED Log No.: 080617
Type of Incident: Leaking Source
Type of Investigation: Telephone

File No.: 14
Licensee: Isotope Products Laboratories
Date of Incident: 7/24/09
Investigation Date: 7/24/09
License No.: 1509-19
NMED Log No.: 090765
Type of Incident: Lost Sources
Type of Investigation: Site

File No.: 15
Licensee: Furgo West, Inc.
Date of Incident: 1/5/11
Investigation Date: 1/5/11
License No.: 4377-01
NMED Log No.: 110041
Type of Incident: Damaged Equipment
Type of Investigation: Telephone

File No.: 16
Licensee: University of California at Berkeley
Date of Incident: 11/19/08
Investigation Date: 11/21/08
License No.: 1333-01
NMED Log No.: 080821
Type of Incident: Leaking Source
Type of Investigation: Telephone

File No.: 17
Licensee: University of California at Berkeley
Date of Incident: 11/1/10
Investigation Date: 11/3/10
License No.: 1333-01
NMED Log No.: 100555
Type of Incident: Leaking Source
Type of Investigation: Telephone

File No.: 18
Licensee: Hoag Memorial Hospital Presbyterian
Date of Incident: 3/20/09
Investigation Date: 6/22/09
License No.: 0272-30
NMED Log No.: 090565
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 19
Licensee: Cypress Surgery Center
Date of Incident: 6/3/08
Investigation Date: 6/3/08
License No.: 7342-54
NMED Log No.: 080319
Type of Incident: Transportation
Type of Investigation: Site

File No.: 20
Licensee: California Department of Public Health
Date of Incident: 4/19/08
Investigation Date: 4/28/08
License No.: 0377-01
NMED Log No.: 080265
Type of Incident: Lost Sources
Type of Investigation: Telephone

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Registration No.: CA-626-D-101-G — SS&D Type: (N) Ion Chromatography
Applicant Name: Lagus Applied Technology — Type of Action: Amendment
Date Issued: 6/13/11 — SS&D Reviewers: ZG, RR

File No.: 2
Registration No.: CA-406-S-239-S — SS&D Type: (F) Well Logging Source
Applicant Name: Eckert & Zeigler Isotope Products — Type of Action: New
Date Issued: 2/5/09 — SS&D Reviewers: ZG, RR

File No.: 3
Registration No.: CA-0406-S-828-U — SS&D Type: (U) X-Ray Fluorescence
Applicant Name: Eckert & Zeigler Isotope Products — Type of Action: Inactivation
Date Issued: 2/16/11 — SS&D Reviewers: CR, HA

File No.: 4
Registration No.: CA-0406-S-827-S — SS&D Type: (X) Medical Reference Source
Applicant Name: Eckert & Zeigler Isotope Products — Type of Action: Inactivation
Date Issued: 2/13/11 — SS&D Reviewers: DCT, HA

File No.: 5
Registration No.: CA-0406-S-238-S — SS&D Type: (AB) Medical Diagnosis Sources , (D) Gamma Gauge, (X) Medical Reference
Applicant Name: Eckert & Zeigler Isotope Products — Type of Action: Amendment
Date Issued: 5/29/09 — SS&D Reviewers: DCT, BH, JF

Comments:
a) The sealed sources can be singly, doubly, or triply encapsulated sources but there is no indication how they can be identified – have same model numbers
b) The Branch has committed to contacting the vendor to clarify how the different encapsulations can be distinguished, and update the SS&D registration to clarify issue

File No.: 6
Registration No.: CA-0406-S-196-S — SS&D Type: (A) Ind.Rad., (D) Gamma Gauge, (F) Well Logging
Applicant Name: Eckert & Zeigler Isotope Products — Type of Action: Amendment
Date Issued: 3/3/11 — SS&D Reviewers: HA, JF

Comment:
Description on Page 2 states “capsule is robust enough to retain buildup of Helium gas during working life of the device”, but the only radionuclides used are Cs-137 and Co-60, neither of which generate Helium gas.

File No.: 7
Registration No.: CA-8231-D-801-S SS&D Type: (H) General Neutron Source
Applicant Name: Thermo Gamma Metrics Type of Action: Inactivation
Date Issued: 3/28/11 SS&D Reviewers: VK, RR

File No.: 8
Registration No.: CA-8204-D-801-S SS&D Type: (H) General Neutron Source
Applicant Name: NOVA R&D Type of Action: Inactivation
Date Issued: 5/15/08 SS&D Reviewers: MG, JF

File No.: 9
Registration No.: CA-0406-S-180-S SS&D Type: (X) Medical Reference Source
Applicant Name: Eckert & Zeigler Isotope Products Type of Action: Amendment
Date Issued: 4/24/09 SS&D Reviewers: MG, JF

File No.: 10
Registration No.: CA-0638-D-801-S SS&D Type: (D) Gamma Gauge
Applicant Name: Level Link, Inc. Type of Action: Inactivation
Date Issued: 8/27/08 SS&D Reviewers: MG, JF

File No.: 11
Registration No.: CA-0406-S-240-S SS&D Type: (F) Well Logging
Applicant Name: Eckert & Zeigler Isotope Products Type of Action: New
Date Issued: 6/6/09 SS&D Reviewers: ZG, RR

Comment:
Maximum activity listed was 24 Ci ± 20%, maximum activity requested was 20 Ci ± 20%; maximum activity for radiation profile was 24 Ci.

File No.: 12
Registration No.: CA-1080-S-104-S SS&D Type: (AC) Photon Emitting Remote Afterloader
Applicant Name: Varian Medical Systems Type of Action: Amendment
Date Issued: 3/10/09 SS&D Reviewers: RR, JF

File No.: 13
Registration No.: CA-1259-D-101-S SS&D Type: (H) General Neutron Source
Applicant Name: Clear Path Technology Type of Action: Amendment
Date Issued: 3/2/10 SS&D Reviewers: VK, RR

File No.: 14
Registration No.: CA-0406-S-243-S SS&D Type: (D) Gamma Gauges, (I) Calib. Sources
Applicant Name: Eckert & Zeigler Isotope Products Type of Action: Amendment
Date Issued: 10/5/10 SS&D Reviewers: BG, HA

Comments:
a) Under “Isotope and Maximum Activity,” isotope listed as “Atomic Numbers 3-83”
b) External radiation levels only listed for three isotopes, not for Atomic Numbers 3-83

c) External radiation levels in units of “R/hr”, should have been mR/hr based on maximum activity

File No.: 15
Registration No.: CA-0406-S-106-S SS&D Type: (AB) Med. Diag., (D) Gamma Gauge, (I) Calibration Source
Applicant Name: Eckert & Zeigler Isotope Products Type of Action: Amendment
Date Issued: 4/14/11 SS&D Reviewers: ZG, RR

File No.: 16
Registration No.: CA-0406-S-244-S SS&D Type: (D) Gamma Gauge, (I) Calibration Source
Applicant Name: Eckert & Zeigler Isotope Products Type of Action: Amendment
Date Issued: 2/10/11 SS&D Reviewers: JR, JF

File No.: 17
Registration No.: CA-181-D-101-G SS&D Type: (T) Other
Applicant Name: Beckman Coulter Type of Action: Amendment
Date Issued: 2/17/10 SS&D Reviewers: MG, JF

Comments:
a) Licensee stated that device is no longer manufactured, amendment to add new sealed source model for servicing existing devices, should have queried on using inactive product registration code
b) Cannot verify that the general license label meets the labeling requirements of 10 CFR 32.51 (SS&D and application only reference a GL label)

File No.: 18
Registration No.: CA-1218-D-101-S SS&D Type: (D) Gamma Gauge
Applicant Name: RapidScan Systems Neutronics Type of Action: Amendment
Date Issued: 6/17/09 SS&D Reviewers: RR, JF

Comments:
a) Under “Limitations,” text states that the owners must possess an NRC license or foreign permit, but omit agreement state license
b) Source holder design referenced by name and SS&D registration number, no diagram of source holder

File No.: 19
Registration No.: CA-1046-D-101-B SS&D Type: (H) General Neutron Source Application
Applicant Name: Thermo Gamma Metrics Type of Action: Amendment
Date Issued: 3/4/11 SS&D Reviewers: VK, RR

File No.: 20
Registration No.: CA-0406-S-818-S SS&D Type: "General Medical Use"
Applicant Name: Eckert & Zeigler Isotope Products Type of Action: Inactivation
Date Issued: 3/26/09 SS&D Reviewers: ZG, JF

File No.: 21
Registration No.: CA-661-D-103-S SS&D Type: (AC) Photon Emitting Afterloader
Applicant Name: Varian Medical Systems Type of Action: Amendment
Date Issued: 1/30/08 SS&D Reviewers: RR, JF

Comments:
a) SS&D only reviewed in context of evaluating Part 21 device failure investigation with NRC Event Reports # 44774, 44790, and others for issues related to Varisource HDR device wedge block and sticking source [registration was issued prior to current IMPEP review period]
b) Incident status still open, closure pending on final life cycle testing by manufacturer prior to implementing design change
c) The SS&D was also evaluated for investigations on the transfer guide tube length changes and failure of an extension adapter.

File No.: 22
Registration No.: CA-0384-D-109-S SS&D Type: (A) Industrial Radiography
Applicant Name: Industrial Nuclear Type of Action: Amendment
Date Issued: 9/28/11 SS&D Reviewers: RR, JF

Comments:
a) SS&D reviewed in context of Part 21 device failure issues related to premature locking of source in radiography camera
b) Result of initial root cause analysis resulted in change to user manual, issuing regulatory information notice, and amended SS&D related to operator maintenance of device & locking mechanism
c) Locking mechanism is located at bottom of device, external to the camera, and is designed to be rinsed with solvent to wash out debris
d) Areas of product design review did not include location of drive cable attachment and locking mechanism, combined with open accessibility of locking mechanism to permit debris intrusion
e) The Branch has reopened incident review and made arrangements to further investigate design issues with the manufacturer at their facility

File No.: 23
Registration No.: CA-0406-S-813-U SS&D Type: X-Ray Fluorescence
Applicant Name: Eckert & Zeigler Isotope Products Type of Action: Inactivation
Date Issued: 3/23/09 SS&D Reviewers: ZG, JF