



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 13, 2015

Karen L. Smith, M.D., MPH
Director
California Department of Public Health
1615 Capitol Avenue
Sacramento, CA 95899-7377

Dear Dr. Smith:

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 5–9, 2015. The review team's preliminary findings were discussed with your staff 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, and compatible with the NRC's program. The review team also recommends that the period of monitoring initiated during the 2008 IMPEP review and continued following the 2011 review be discontinued.

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. Our preliminary scheduling places the California MRB meeting in mid-January. I will coordinate with you to establish the date for the MRB review of the California report. 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

K. Smith

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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 (301) 415-5422

Thank you for your cooperation.

Sincerely,

/RA/

Christian E. Einberg, Chief
Agreement State Programs Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Draft California IMPEP Report

cc w/encl: Mark Starr, 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 5 – 9, 2015

DRAFT REPORT

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the California Agreement State Program. The review was conducted during the period of October 5-9, 2015, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), and the States of Florida and Texas.

Based on the results of this review, California's performance was found satisfactory for all indicators reviewed.

The review team made three recommendations (see Section 5.0) regarding the California Agreement State Program performance in Sealed Source and Device evaluation, and determined that the recommendation from the 2011 IMPEP review, regarding regulation adoption, should be closed (see Section 2.0).

Accordingly, the review team recommends that the California Agreement State Program is adequate to protect public health and safety and is compatible with the NRC's program. The review team also recommends that the period of monitoring be discontinued and the next IMPEP review take place in approximately four years.

1.0 INTRODUCTION

This report presents the results of the review of the California Agreement State Program radioactive materials safety program. The review was conducted during the period of October 5-9, 2015, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), and the States of Florida and Texas. The review 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 (MD 5.6), "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of October 22, 2011, to October 9, 2015, were discussed with State managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the State on April 29, 2015. The State provided its response to the questionnaire on September 18, 2015. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML15267A261.

The California Agreement State Program (the 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 Center for Environmental Health which is located within the Department of Public Health (the Department). Organization charts for the State can be found in ADAMS using the Accession Number ML15267A069.

At the time of the review, the Program regulated 1,795 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.

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.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on October 21, 2011. The final report is available in ADAMS (Accession Number ML120120373). The results of the previous review and the status of the recommendation are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory
Recommendation: None

Technical Quality of Incident and Allegation Activities: Satisfactory
Recommendation: None

Compatibility Requirements: Unsatisfactory

Recommendation: 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.

Status: To address the recommendation, the Program made several changes to the process it uses to develop and track regulations equivalent to the NRC's regulation amendments. In early 2012, the Program started developing rulemaking packages that address individual NRC amendments instead of developing packages by Parts of Title 10 of the Code of Federal Regulations (CFR), as was the practice previously. The Program also developed and implemented a detailed rulemaking process flowchart and an NRC amendment adoption tracking chart to closely track and gauge progress toward regulation adoption. The success of the Program in adopting regulation amendments during the review period demonstrates the effectiveness of the Program's approach to addressing this recommendation. The review team recommends that this recommendation be closed.

Sealed Source and Device Evaluation Program: Satisfactory
Recommendation: None

Overall finding of the previous review: Adequate to Protect Public Health and Safety and Not Compatible. The period of monitoring was continued until significant progress is made in the regulation promulgation area.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the 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

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical

personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and thus could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires a consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

The review team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated California's performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to NRC's Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Materials and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are being followed or that qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

The California Agreement State Program is budgeted for 40 full-time equivalents (FTE), which includes management and staff. An additional two FTE are provided by four Regulation Unit staff members who support the Program through regulation development. Inspection activities are conducted out of two State regional offices (Richmond and Brea), and two county offices (San Diego County and Los Angeles County). Inspection activities in the county offices are conducted under a contract with the State.

Currently the Program has three vacancies, all of which have been vacant since July 2015. Over the review period a total of 8 staff left the Program and 10 were hired. Each of the vacancies was open on average for six to nine months before they were filled.

California has a training and qualification program equivalent to the requirements in IMC 1248.

c. Evaluation

The team determined that during the review period the California program met the performance indicator objectives listed in Section 3.1.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that California's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.2 Status of the Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The review team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated California's performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3, licensees are performed at the frequency prescribed in IMC 2800.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports").

b. Discussion

California performed 1,003 Priority 1, 2, 3, and initial inspections during the review period, of which 38 inspections (3.8 percent) were conducted overdue according to the inspection frequencies prescribed in IMC 2800. A sampling of 30 inspection reports indicated that one inspection report was communicated to the licensee beyond the Program's goal of 30 days after the inspection exit. California performed 40 percent of candidate reciprocity inspections in 2011, 50 percent in 2012, 50 percent in 2013, 9 percent in 2014, and 27 percent in 2015 through August. In 2014, an error in the tracking sheet used to track reciprocity inspections caused the percentage of candidate reciprocity inspections conducted to be over-represented until the error was discovered in preparation of the 2015 IMPEP questionnaire response.

c. Evaluation

The team determined that during the review period California met the performance indicator objectives listed in Section 3.2.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that California's performance with respect to the indicator, Status of the Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing inspections, and the critical evaluation of inspection records are used to assess the technical quality of a program's inspection capability.

a. Scope

The review team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated California's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, to verify that procedures

- are established and followed to provide feedback information to license reviewers.
- For Agreement States, to determine if inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The review team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 32 materials inspections conducted during the review period. The casework reviewed included inspections conducted by 12 of California's inspectors and covered medical, industrial, commercial, academic, research, and service licenses. The inspection casework and inspector accompaniments were also assessed for implementation of security requirements for risk significant material, as applicable.

Review team members accompanied eight program inspectors on August 3-5 and September 21-25, 2015. The inspectors were found to be well-prepared, thorough, and conducted performance-based inspections. The inspections were adequate to assess radiological health, safety and security. The inspector accompaniments are identified in Appendix B.

The review team noted the Program performed annual supervisory accompaniments for each of the inspectors throughout the review period.

c. Evaluation

The team determined that during the review period California met the performance indicator objectives listed in Section 3.3.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, 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 quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, and security. An assessment of licensing procedures, actual implementation of these procedures, and documentation of communications and associated actions between the California licensing staff and regulated community will be a significant indicator of the overall quality of the program.

a. Scope

The review team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated California's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements meet current regulatory guidance (e.g. financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and are inspectable.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled and secured.

b. Discussion

During the review period, California performed 7,693 radioactive materials licensing actions. The review team evaluated 41 radioactive materials licensing actions. The licensing actions selected for review included 6 new applications, 21 amendments, 8 renewals, and 6 terminations. The review team evaluated casework which included the following license types and actions: broad scope, medical diagnostic and therapy, accelerator, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, panoramic and self-shielded irradiators, well-logging, service providers, waste brokers, decommissioning actions, financial assurance, and bankruptcies. The casework sample represented work from 18 license reviewers.

Licenses are issued for a ten-year period under a timely renewal system. The review team noted that the Program's backlog for license renewals (pending greater than one year) had reduced significantly from 370 during the last IMPEP review period to 209 licenses during this review period. The team noted that 76 percent of the current license renewal backlog was received in the last 3 years. The Program continues to issue amendments to licenses in timely renewal in order to address health, safety, and security significant issues. Based on a review of the completed licensing actions, the

review team determined that health and safety and security were not impacted by the backlog in renewal actions.

c. Evaluation

The team determined that during the review period California met the performance indicator objectives listed in Section 3.4.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, 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

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and follow-up procedures and actions will be a significant indicator of the overall quality of the program.

a. Scope

The review team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated California's performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety or security significance.
- Appropriate follow-up actions are taken to ensure prompt compliance by licensees.
- Follow-up inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED).
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 494 incidents were reported to NMED by California of which the majority of these were landfill trips involving diagnostic medical waste. The review team selected 20 of the remaining events for review. These included radioactive materials incidents, lost/stolen radioactive materials, potential overexposures, medical events, damaged equipment and leaking sources. The team found that California dispatched inspectors for onsite follow-up for each of the cases reviewed by the team.

During the review period, 73 allegations were received by California. The review team evaluated 12 allegations, including 6 of 10 allegations that the NRC referred to the State during the review period.

c. Evaluation

The team determined that during the review period California met the performance indicator objectives listed in Section 3.5.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, 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

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as

necessary for maintenance of an adequate and compatible program should be adopted and implemented by an Agreement State within 6 months following NRC designation.

a. Scope

The review team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated California's performance with respect to the following performance indicator objectives.

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.
- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Impact of sunset requirements, if any, on the State's regulations.

b. Discussion

California became an Agreement State on September 1, 1962. The California Agreement State Program's current effective statutory authority is contained in the Radiation Protection Act of 1999, Containment of Radioactive Materials Law, and Radiation Control Law under Division 104 of the California Health and Safety Code. The Department is designated as the State's radiation control agency. There were two legislative amendments passed during the review period that minimally affect California's rulemaking process. Senate Bills 617 and 1099 added provisions that adjust the economic impact analysis conducted during the pre-notice stage of rulemaking and require all regulations filed with the Secretary of State to be posted to the internet. Neither of the legislative amendments, enacted in 2013, has impacted the Program's rulemaking process significantly.

The State's administrative rulemaking process takes approximately 25 months from drafting to finalizing a rule. The public, NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved by the Center. The review team noted that the State's rules and regulations are not subject to "sunset" laws.

During the review period, California submitted 16 final regulation amendments to the NRC for compatibility review, and all of the submitted regulations were determined to be compatible without comment. California addressed 10 of the 12 overdue amendments identified in the 2011 IMPEP report and is analyzing whether their current regulations appropriately address the remaining 2 longstanding overdue amendments identified below. Additionally, two regulation amendments became overdue in August 2015. California has drafted a rulemaking package to address these amendments that is currently in the State's rulemaking process. A complete list of NRC's regulation amendments can be found on the NRC website at the following address: https://scp.nrc.gov/rss_regamendments.html.

At the time of this review, the following four amendments were overdue:

- "Timeliness in Decommissioning Material Facilities," 10 CFR Parts 30, 40, and 70 amendment (59 FR 36026), that was due for Agreement State adoption by August 15, 1997.
- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendment (62 FR 39057), that was due for Agreement State adoption by August 20, 2000.
- "Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste," 10 CFR Part 71 amendment (77 FR 34194), that due for Agreement State adoption by August 10, 2015.
- "Technical Corrections," 10 CFR Parts 30, 34, 40 and 71 amendment (77 FR 39899), that was due for Agreement State adoption by August 6, 2015.

The two longstanding overdue amendments listed above, "Timeliness in Decommissioning Material Facilities" and "Radiological Criteria for License Termination," are related to each other. The "Radiological Criteria for License Termination" portion of 10 CFR Part 20 was previously adopted by California and subsequently challenged in State court by "The Committee to Bridge the Gap, et al." The challenge was successful, and the license termination portion of 10 CFR Part 20 was repealed on August 8, 2002. The review team identified that California has not adopted the portions of these amendments that are not associated with 10 CFR Part 20. The review team and the Program discussed that California may be able to document that the State's current regulations are compatible with these portions of the two amendments. The Program is analyzing whether their current regulations appropriately address these longstanding overdue amendments and has committed to submit regulations to the NRC to document that the portions of these amendments not associated with 10 CFR Part 20 have been adopted.

The review team also reviewed a known compatibility issue regarding low-level radioactive waste (LLRW) disposal requirements found in Section 115261 of California's "Health and Safety Code – Radiation Control Law" and NRC's 10 CFR Part 61. This incompatibility was initially noted in the NRC's response to California's amendment submitted for review on July 25, 2007. At that time, NRC notified the State that a portion of its statute was more restrictive than 10 CFR 61.41, and therefore did not meet the Compatibility Category "A" designation assigned to the rule. To date, this compatibility

issue has not been resolved, and California is uncertain when this issue can be resolved. The Program is not aware of any prospective applicant for a LLRW disposal facility license in California; consequently, California's requirements that are more restrictive than 10 CFR 61.41 are not currently in use by the State. If someone were to express interest in applying for a LLRW disposal facility license in California, the State appears to have sufficient time to adopt compatible LLRW facility requirements before those requirements are needed to license a facility.

c. Evaluation

Since the 2011 IMPEP review, the Program has modified its approach to the process used to adopt NRC regulations. The Program moved from its long standing practice of processing rule packages by "Parts", such as Part 20 or Part 35 of CFR, to adopting regulations by amendments, which is similar to the manner in which NRC promulgates rules. The Program also added additional staff to the Regulations Unit to rule development activities. The success of the Program in adopting 16 regulation amendments during the review period demonstrates the effectiveness of the Program's approach to improve upon the unsatisfactory ratings from the previous two IMPEP reviews.

The Program has committed to submit regulations to the NRC to document that the applicable portions of the two longstanding overdue amendments are appropriately addressed. The two newly overdue amendments are already contained in a rulemaking package that is currently in California's rulemaking process. In addition to the regulation packages submitted to the NRC during the review period, the Program has also initiated the rulemaking process for amendments coming due in the next several years. In summary, the Program has adopted all but a few program elements essential for compatibility and meets all the other evaluation criteria for this performance indicator.

The team determined that during the review period California met the performance indicator objectives listed in Section 3.4.1.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that California's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

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

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides information on conducting SS&D reviews and establishes useful guidance for review teams. Three sub elements, technical staffing and training, technical quality of the product evaluation program, and evaluation of defects and incidents regarding SS&D's, will be evaluated to determine if the SS&D program is satisfactory. Agreement States

with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The review team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated California's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Qualification criteria for new technical staff are established and are being followed or that qualification criteria will be established if new staff members are hired.
- Any vacancies are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

Technical Quality of the Product Evaluation Program

- SS&D evaluations are adequate, accurate, complete, clear, specific, and consistent with NUREG 1556, Volume 3.

Evaluation of Defects and Incidents

- SS&D incidents are reviewed to detect possible manufacturing defects and the root causes of these incidents.
- Incidents are evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to NRC, Agreement States, and others, as appropriate, should occur in a timely manner.

b. Discussion

Technical Staffing and Training

The Branch has five individuals that are fully qualified SS&D reviewers with full signature authority to perform concurrence reviews. There are eight additional reviewers that are either partially qualified reviewers or are reviewers in training with limited initial reviewer signature authority. Currently, there are no vacancies in the SS&D program. The State has a training program equivalent to NRC training requirements listed in IMC 1248, Appendix D.

Technical Quality of the Product Evaluation

California has 26 Manufacturer/Distributor licensees with 227 active SSD registrations. The review team evaluated 14 of 105 SS&D actions processed during the review period. These actions included amendments, new applications, inactivations, and one reactivation.

Evaluation of Defects and Incidents Regarding SS&Ds

The review team evaluated one of three incidents involving SS&D registered products during the review period. One of the incidents was related to manufacturing or design of the sources/devices manufactured or distributed by a licensee with a SS&D registered by California.

c. Evaluation

The review team identified three areas for improvement in the California SS&D evaluation program. Those areas are described below.

The review team identified a backlog of nine requests for new registration certificates, which were pending transfer from another jurisdiction and required a new evaluation. The majority of these requests were submitted to California in 2009 and 2010. The review team determined that the backlog was due to the prioritization of work on other SS&D actions (i.e., new registrations, amendments, etc.). Delay of the completion of transfer registrations may impact other regulatory agencies' ability to inactivate the associated registrations in their jurisdictions and could cause confusion regarding which regulatory authority has jurisdiction over the registrations. The review team recommends that the Program develop and implement an action plan to complete pending transfer actions in a timely manner to ensure consistency and clarity in the licensing of the registered sources/devices across all jurisdictions.

The review team identified that California did not have a formal process for identifying potential generic issues associated with sealed sources and devices registered by California. The review team recommends that the Program implement a process to ensure that radioactive material incidents involving sealed sources and devices registered by California are periodically and independently assessed by the State for generic issues and that any potential generic issues are communicated to licensees and fellow regulators in a timely manner.

The review team noted that the Program did not have a formal process to verify the implementation of manufacturer/distributor's quality assurance and quality control program commitments. The review team recommends that the Program develop and implement a procedure for conducting an inspection of the implementation of the manufacturer/distributor's quality assurance and quality control program commitments.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, 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 satisfactory for all seven performance indicators reviewed. The review team made three recommendations regarding program performance by the State and determined that the recommendation from the 2011 IMPEP review should be closed.

Accordingly, the review team recommends that the California Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review take place in approximately four years.

Below are the review team's recommendations, as mentioned in the report, for evaluation and implementation by California:

1. The review team recommends that the Program develop and implement an action plan to complete pending transfer actions in a timely manner to ensure consistency and clarity in the licensing of the registered sources/devices across all jurisdictions. (Section 4.2.c.)
2. The review team recommends that the Program implement a process to ensure that radioactive material incidents involving sealed sources and devices registered by other jurisdictions are periodically and independently assessed by the State for generic issues and that any potential generic issues are communicated to licensees and fellow regulators in a timely manner. (Section 4.2.c)

3. The review team recommends that the Program develop and implement a procedure for conducting an inspection of the implementation of the manufacturer/distributor's quality assurance and quality control program commitments. (Section 4.2.c)

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspection Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Donna Janda, Region I	Team Leader Technical Staffing and Training Inspector Accompaniments
Randy Erickson, Region IV	Technical Quality of Incident and Allegation Activities
David Spackman, NMSS	Status of Materials Inspection Program Compatibility Requirements
Lizette Roldan-Otero, NMSS	Technical Quality of Licensing Actions
Michelle Hammond, Region IV	Technical Quality of Licensing Actions
Leo Bakersmith, Florida	Technical Quality of Inspections
Jason Kelly, Texas	Sealed Source and Device Evaluation Program

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 1391
License Type: Medical Institution, Written Directive Required	Priority: 2
Inspection Date: 08/03/15	Inspector: KH
Accompaniment No.: 2	License No.: 0077
License Type: Medical Institution, WD Required	Priority: 3
Inspection Date: 08/04/15	Inspector: EM
Accompaniment No.: 3	License No.: 6408
License Type: Nuclear Pharmacy	Priority: 2
Inspection Date: 08/05/15	Inspector: EF
Accompaniment No.: 4	License No.: 2975
License Type: Medical Institution, WD Required	Priority: 3
Inspection Date: 09/21/15	Inspector: AT
Accompaniment No.: 5	License No.: 1880
License Type: Industrial Radiography	Priority: 1
Inspection Date: 09/22/15	Inspector: AR
Accompaniment No.: 6	License No.: 6885
License Type: Medical Private Practice, WD Required	Priority: 2
Inspection Date: 09/23/15	Inspector: TR
Accompaniment No.: 7	License No.: 2871
License Type: Medical Institution, WD Required	Priority: 3
Inspection Date: 09/24/15	Inspector: GTM
Accompaniment No.: 8	License No.: 3960
License Type: Medical Institution, WD Required	Priority: 3
Inspection Date: 09/25/15	Inspector: KH