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

November 21, 2019

Gonzalo L. Perez, Branch Chief
Radiologic Health Branch
Division of Radiation Safety and Environmental Management
Department of Health Services
P.O. Box 997414, MS-7610
Sacramento, CA 95899-7414

Dear Mr. Perez:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State and NRC radioactive materials programs. Enclosed for your review is the draft IMPEP report, which documents the results of the Agreement State review held in California on October 21-25, 2019. The team's preliminary findings were discussed with you and your staff on the last day of the review. The 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 NRC conducts periodic reviews of radioactive materials 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 IMPEP process uses a team comprised of NRC and Agreement State staff to perform the reviews. All reviews use common criteria in the assessment and place primary emphasis on performance. The final determination of adequacy and compatibility of each program, based on the 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 draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 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 the response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. The MRB meeting is scheduled for January 16, 2020, at 1:30 pm ET. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at the NRC Headquarters in Rockville, Maryland. The NRC has Skype capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to participate in the meeting using Skype.

If you have any questions regarding the enclosed report, please contact me at 301-415-5804 or Lance Rakovan at 301-415-2589.

Thank you for your cooperation.

Sincerely,

/RA/

Paul Michalak, Chief
State Agreement and Liaison Program Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

Enclosure:
NRC FY20 Draft IMPEP Report

SUBJECT: CALIFORNIA FY2020 DRAFT IMPEP REPORT

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE CALIFORNIA PROGRAM

OCTOBER 21-25, 2019

DRAFT REPORT

Enclosure

EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the California Agreement State Program are discussed in this report. The review was conducted during the period of October 21-25, 2019.

Based on the results of this review, California's performance was found satisfactory for all indicators. The team did not make any new recommendations and determined that the recommendations from the 2015 IMPEP review should be closed (see Section 2.0).

Accordingly, the team recommends that the California Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Since this was the second consecutive IMPEP review with all performance indicators being found satisfactory, the team recommends that the next IMPEP review take place in approximately 5 years with a periodic meeting in approximately 2.5 years.

1.0 INTRODUCTION

The California Agreement State Program review was conducted during the period of October 21-25, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the State of Louisiana, and the Commonwealth of Pennsylvania. Team members are identified in Appendix A. The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* on October 18, 2017 (82 FR 48535), and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of October 10, 2015, to October 25, 2019, were discussed with California managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and applicable non-common performance indicators was sent to California on August 7, 2019. California provided its response to the questionnaire on October 7, 2019. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML19283A827.

The California Agreement State Program is administered by the Radiologic Health Branch (the Branch), which is located within the Division of Radiation Safety and Environmental Management (the Division). The Division is part of the Center for Environmental Health (Center). The Center is part of the California Department of Public Health (the Department). The previous IMPEP review was conducted the week of October 5-9, 2015. Organization charts for California are available in ADAMS (Accession Number ML19283A680).

At the time of the review, California regulated 1,708 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of California.

The team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicators and made a preliminary assessment of the California's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on October 10, 2015. The final report is available in ADAMS (Accession Number ML16019A265). The results of the review and the status of the associated recommendations 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: Satisfactory
Recommendation: None

Sealed Source and Device Evaluation Program: Satisfactory

Recommendation: 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.).

Status: The Branch responded by developing and implementing an action plan to address the nine remaining SS&D transfers in a timely manner. The actions had been pending transfer from another jurisdiction and required a new evaluation. At that time, the requests had been pending for five to six years. Each SS&D action was assigned to a pair of reviewers for processing. All transfer actions were completed by November 8, 2016.

The team determined that this recommendation should be closed.

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

Status: The Branch responded by developing a Quality Assurance/Quality Control supplemental procedure. Additionally, staff modified the routine inspection procedure used for inspections of nonmedical manufacturers to include checking if an SS&D existed for the licensee and use the SS&D supplemental inspection procedure, if appropriate. Training was provided to Branch staff. The team was impressed with the SS&D supplemental inspection procedure.

The team determined that this recommendation should be closed.

Overall finding: Adequate to protect public health and safety and compatible with the NRC's program.

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 could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires 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 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 Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are followed, or 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

California's Agreement State Program is comprised of 61 positions which equals 58 full time equivalents (FTE) for the radioactive materials program when fully staffed. There were 3 vacancies at the beginning of the review period and 14 staff members left the program during the review period. Ten staff members were hired over the course of the review period. Positions were vacant from 4 to 9 months, with one exception of 22 months as discussed below. Additionally, four staff were re-assigned to other duties and

two staff were re-assigned to radioactive material duties. At the time of the review, there were nine vacancies, three of which occurred within a month prior to the IMPEP review. The remainder have been open for 10 to 29 months. The Branch left three positions open for extended periods (one was open 22 months, two have been open 27 and 29 months and continue to be open) after determining that the existing workload in certain units did not justify filling those positions.

The licensing section continues to experience an imbalance between staffing and workload, as exhibited by a continued backlog of pending renewal actions. The Branch is actively monitoring this backlog and evaluates incoming requests for significant impacts on health, safety, and security. The Branch has allocated available resources throughout the review period in an effort to address the backlog and has demonstrated an ability to diminish the size of the backlog in the absence of extenuating demands on its resources.

California has a training and qualification program compatible with the NRC's IMC 1248. Staff are trained and qualified in a reasonable period of time and management commitment to staff is apparent.

c. Evaluation

The team determined that, except as noted below, during the review period California met the performance indicator objectives listed in Section 3.1.a.

- There is an imbalance in staffing of the licensing and inspection programs.

The licensing section continues to experience an imbalance between staffing and workload, as exhibited by a continued backlog of pending renewal actions. At the time of the review, the Branch was in the process of reallocating one vacancy to the licensing section to help address an existing backlog of pending renewal actions. This reallocation should help restore balance between staffing and workload levels in the licensing section.

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

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

3.2 Status of 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 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 944 Priority 1, 2, and 3, and initial inspections during the review period. California conducted 12 of these inspections overdue for a total of approximately 1 percent of Priority 1, 2, and 3, and initial inspections being conducted overdue during the review period, well below the target of less than 10 percent being conducted overdue.

California's inspection frequencies are the same for similar license types in IMC 2800. The Branch can also use codes to temporarily change the inspection priority for any licensee under "unusual circumstances," for example, following a major incident. The "Temp code" is used, and thus the licensee is inspected more frequently, until Branch staff and management agree that the licensee has proven the typical inspection frequency can be reinstated.

The Branch tracks the issuance of inspection findings using a database. Per the database, 27 inspection findings, or approximately 3 percent, were communicated to the licensees beyond California's goal of 30 days after the inspection exit.

Each year of the review period, California inspected greater than 20 percent of candidate reciprocity licensees. For example, 47 percent of candidates were inspected in 2016 and 33 percent were inspected in 2018.

c. Evaluation

The team determined that, during the review period, California met the performance indicator objectives listed in Section 3.2.a. Based on the criteria in MD 5.6, the team recommends that California's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

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 an Agreement State's inspection program.

a. Scope

The 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, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, procedures are established and followed to provide feedback information to license reviewers.
- Inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors involved in 34 materials inspections conducted during the review period. The casework reviewed included inspections conducted by 14 of the Branch's inspectors and covered medical, industrial, commercial, academic, research, and service licenses.

Team members accompanied seven program inspectors on September 12-13, and September 24–27, 2019. No performance issues were noted during the inspector accompaniments. Inspectors were well-prepared and thorough, and assessed the impact of licensed activities on health, safety, and security. The inspector accompaniments are identified in Appendix B.

The team identified that California's inspection results were well documented and violations were well supported. The team noted that Branch inspectors obtained the licensee's inventory during inspections and included this with the scanned report as a reference tool for future inspections, licensing actions, and related matters. Branch inspectors also coordinated with licensing staff on any issue(s) that were identified during inspections for appropriate action. The team noted the Branch developed and used a common inspection checklist in all regions across the State to help ensure consistency.

The Branch performed annual supervisory accompaniments for each inspector throughout the review period.

The team noted that California has ample supplies of radiation survey instruments such as Geiger-Mueller meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors to support its inspection program. The portable instruments used during the inspector accompaniments were operational and calibrated.

c. Evaluation

The team determined that, during the review period, California met the performance indicator objectives listed in Section 3.3.a. Based on the criteria in MD 5.6, the team recommends that California's performance with respect to the indicator, Technical Quality of Inspections be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

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, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the California licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The 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 are consistent with current regulatory guidance (e.g., financial assurance, 10 CFR Part 37, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- 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 10 CFR Part 37 equivalent.
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, California performed 7,981 radioactive materials licensing actions. The team evaluated 59 of those actions. The actions selected for review included 4 new applications, 37 amendments, 6 renewals, 4 terminations, 1 bankruptcy, and 7 financial assurance actions. The 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, veterinary services, gauges, panoramic and self-shielded irradiators, well-logging, service providers, waste brokers, decommissioning actions, financial assurance, and bankruptcy. The casework sample represented work from 21 license reviewers, whose program responsibilities include work in other areas, such as sealed source and device reviews, financial assurance reviews, and peer reviews.

The team found that licensing actions were complete, consistent, and of acceptable quality with health, safety, and security concerns addressed. All licensing actions are reviewed by an assigned license reviewer from either the Medical Unit, Licensing Projects Unit, or the Industrial and General Licensed Devices Unit. The license reviewers use up-to-date guidance. Each action then undergoes a documented peer review prior to approval and signature by the respective unit senior health physicist. Each unit under the Radioactive Materials Licensing Section (Medical, Licensing

Projects, Industrial & General Licensed Devices, and Special Projects and Support), meets weekly to address workflow volume and timeliness concerns.

Licenses are issued for a 10-year period under a timely renewal system. Based on a review of the completed licensing actions, the team determined that health and safety and security were not impacted by the backlog in renewal actions. The team noted that the Branch's backlog for license renewals (pending greater than 1 year) dropped from 209 during the last IMPEP review period to 198 during this review period. The team believes that the drop would have been more substantial in the absence of extenuating external demands on the Branch's resources during the review period (i.e., Hunter's Point), as the licensing section continued to maintain a high level of productivity, notably in the last few years. The team also noted that 51 percent of the current license renewal backlog was received in the last 3 years. The Branch Chief and Supervising Health Physicists met and established the priority for which licensing actions should be processed with respect to health, safety, and security risks, as well as the licensee's inspection interval. Based on this continued prioritizing, management ensures that licensees listed in the backlog continue to be inspected at their routine inspection intervals and that staff continues to confirm that the safe and secure use of radioactive materials remains in accordance with regulatory guidelines. The Branch continues to issue amendments to licenses within established timeframes to address health, safety, and security issues.

c. Evaluation

The team determined that, during the review period, California met the performance indicator objectives listed in Section 3.4.a. Based on the criteria in MD 5.6, the team recommends that California's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

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 actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The 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, 1,340 incidents were reported to California of which the majority of these were landfill trips involving diagnostic medical waste. Of the 1,340 incidents reported to California, 521 were reported to the NRC. Of the 521 reported by California, 119 were required to be reported for inclusion in NMED and the rest included items such as landfill alarm monitor trips involving diagnostic medical waste and tritium exit sign incidents. The team evaluated 13 radioactive materials incidents which included 3 lost/stolen radioactive materials, 3 medical events, 2 damaged equipment, 2 leaking sources, and 3 equipment malfunctions. The State of California dispatched inspectors for onsite follow-up for 7 of the 13 cases reviewed.

Form 5010 "RAM – Matter Requiring Investigation/Inspection" is used to document incidents/events, investigations, and allegations.

The team evaluated four allegations, including the two allegations that the NRC referred to the State during the review period that were related to radioactive materials and required more than just a telephone call to follow-up. Unfortunately, the team was not provided a definite number of allegations that the State of California received during the review period because staff was unable to pull this information from the system.

The team determined the Branch followed its process and the follow-up of incidents and allegations was appropriate. Both are provided a detailed review to determine the appropriate response. The team noted that onsite response was thorough and high quality, and that incidents were followed-up on during the subsequent inspection.

c. Evaluation

The team determined that, during the review period, California met the performance indicator objectives listed in Section 3.5.a. Based on the criteria in MD 5.6, the team recommends that California's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

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 (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste Disposal (LLRW) Program; and (4) Uranium Recovery Program. The NRC's Agreement with California retains 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 the 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 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. A complete list of regulation amendments can be found on the NRC website at the following address: https://scp.nrc.gov/regtoolbox.html.

- 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.
- Sunset requirements, if any, do not negatively impact the effectiveness of 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. No legislative changes affecting the Branch have been passed since the 2015 IMPEP review.

California's administrative rulemaking process takes approximately 3 years from drafting to finalizing a rule. All proposed regulations must be approved by the Department's Office of Regulations and by a separate California state agency, the Office of Administrative Law (OAL). The Department's rulemaking process is detailed in its response to the questionnaire. Numerous state laws must also be considered during regulation promulgation including: the Public Records Act; the Information Practices Act; the Bagley-Keen Open Meeting Act; the State Records Management Act; the Government Code; and the State Building Standards Law.

As part of the adoption process, 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 OAL. The team noted that the State's rules and regulations are not subject to "sunset" laws.

During the review period, California submitted 14 proposed regulation amendments, 9 final regulation amendments, and 3 legally binding license conditions to the NRC for compatibility review. Three full amendments and one partial amendment were overdue for State adoption at the time of submission. Two of these amendments were identified as overdue during the previous IMPEP review period. The amendments were submitted approximately 2 years to 2.5 years overdue and were the final portions of the Department's initiative to regain compatibility with the NRC as detailed in the previous IMPEP review and periodic meeting. At the time of this review, no amendments were overdue.

The team noted the 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 the NRC's 10 CFR Part 61. The Branch has taken no action to resolve this compatibility issue, however at the time of the review, there is no prospective applicant for a LLRW disposal facility license in California. If a party 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

The team determined that, except as noted below, during the review period California met the performance indicator objectives listed in Section 3.5.a.

- 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.

The three full amendments and one partial amendment were overdue for State adoption at the time of submission were the final portions of the Department's initiative to regain compatibility with the NRC as detailed in the previous IMPEP review and periodic meeting. At the time of this review, no amendments were overdue.

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

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

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 teams. Under this guidance, three sub elements: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and Evaluation of Defects and Incidents Regarding SS&D's, are 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 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 qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, 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 the guidance in NUREG-1556, Volume 3.

Evaluation of Defects and Incidents

- SS&D incidents are reviewed to identify 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 the NRC, Agreement States, and others, as appropriate, occur in a timely manner.

b. Discussion

Technical Staffing and Training

California has 16 staff qualified to perform SS&D reviews at different levels. Seven individuals are fully qualified SS&D reviewers with full signature authority to perform concurring-level review. There are four staff qualified to perform first-line reviews, but not concurring signature level. There are five staff qualified to perform amendments with no radiological or engineering evaluation. One person was in training at the time of the review. During the review period, one SS&D staff member left the program and one staff member was hired. There was one vacancy for a senior supervisory staff position at the time of the review, although a staff member is acting in the position. The position became vacant on September 10, 2019, less than 2 months before the review. The Branch is taking steps to fill the position at the time of the review.

California has a training program for SS&D reviewers equivalent to NRC training requirements listed in the NRC's IMC 1248, Appendix D. The Branch completed the requirement of the 24-hour refresher training every 2 years to enhance the training of the staff with online web-based training topics. Some of the topics covered were low cycle fatigue, stainless steel and stress strain, engineering drawing, welding and brazing, and 10 CFR Part 21.

Technical Quality of the Product Evaluation

The Branch has 197 SS&D licensees and 23 manufacturers. The team evaluated 55 of 97 SS&D actions processed during the review period. The actions evaluated included 25 amendments, 4 new applications, 24 inactivations, and 2 corrections. The team found that the registration sheets were complete, thorough and of acceptable technical quality. At the time of the review, California had 16 SS&D actions backlogged while waiting on additional information on 15 amendments and 1 new request. The Branch uses the NRC's NUREG-1556, Volume 3 as its standard operating procedure during reviews.

The Branch incorporated a good practice example from the State of Ohio by documenting the reasons why an SS&D license/registration was amended into the reviewers notes section as part of its SS&D registrations.

Evaluation of Defects and Incidents Regarding SS&Ds

The team evaluated three incidents involving SS&D-registered products during the review period. None of the incidents were related to manufacturing or design of the sources/devices manufactured or distributed by a licensee with an SS&D registered by California.

c. Evaluation

The team determined that, during the review period, California met the performance indicator objectives listed in Section 4.2.a. Based on the criteria in MD 5.6, the team recommends that California's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC 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 authority to regulate a LLRW disposal, the NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated

as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in California. Accordingly, the team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, California's performance was found to be satisfactory for all applicable performance indicators. The team did not make any new recommendations and determined that the recommendations from the 2015 IMPEP review should be closed (see Section 2.0).

Accordingly, the team recommends that California be found adequate to protect public health and safety, and compatible with the NRC's program. Since this was the second consecutive IMPEP review with all performance indicators being found satisfactory, the team recommends that the next IMPEP review take place in approximately 5 years with a periodic meeting in approximately 2.5 years.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Areas of Responsibility
Lance Rakovan, NMSS	Team Leader Status of Materials Inspection Program Compatibility Requirements
Jackie Cook, Region IV	Technical Quality of Incident and Allegation Activities
Latischa Hanson, Region IV	Technical Quality of Licensing Actions Inspector Accompaniments
Ryan Craffey, Region III	Team Leader-in-Training Technical Staffing and Training
Shawn Seeley, Region I	Technical Quality of Inspections Lead for Inspector Accompaniments
Lisa Forney, PA	Technical Quality of Licensing Actions
Jim Pate, LA	Sealed Source and Device Evaluation Program
Randy Erickson, Region IV	Inspector Accompaniments

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 5139-19
License Type: Mobile High Dose Remote Afterloader	Priority: 2
Inspection Date: 9/12/19	Inspector: AC

Accompaniment No.: 2	License No.: 1810-19
License Type: Portable Gauge	Priority: 5
Inspection Date: 9/13/19	Inspector: CH

Accompaniment No.: 3	License No.: 7214-48
License Type: Industrial Radiography	Priority: 1
Inspection Date: 9/24/19	Inspector: EM

Accompaniment No.: 4	License No.: 1065-34
License Type: Medical Institution WD Required	Priority: 3
Inspection Date: 9/25/19	Inspector: DA

Accompaniment No.: 5	License No.: 1078-43
License Type: Medical Institution WD Required	Priority: 2
Inspection Date: 9/26/19	Inspector: GC

Accompaniment No.: 6	License No.: 2483-37
License Type: Medical Institution WD Required	Priority: 2
Inspection Date: 9/26/19	Inspector: RY

Accompaniment No.: 7	License No.: 0389-37
License Type: Medical Institution WD Required	Priority: 2
Inspection Date: 9/27/19	Inspector: JT