



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

January 10, 2018

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

Dear Mr. Perez:

A periodic meeting with you and your staff was held on October 18, 2017. The purpose of this meeting was to review and discuss the status of the California Agreement State Program. The U.S. Nuclear Regulatory Commission (NRC) was represented by Mark Shaffer, Director, Division of Nuclear Materials Safety (DNMS) and me.

I have completed and enclosed a general meeting summary, including any specific actions resulting from the discussions. A Management Review Board (MRB) meeting to discuss the outcome of the periodic meeting will be scheduled and the date and time will be provided to you in a separate transmission.

If you feel that our conclusions do not accurately summarize the meeting discussion, or have any additional remarks about the meeting in general, please contact me at (817) 200-1143 or via e-mail at Randy.Erickson@nrc.gov to discuss your concerns.

Sincerely,

/RA/

Randy R. Erickson
State Agreements Officer
Division of Nuclear Materials Safety

Enclosure:
Periodic Meeting Summary

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR
 CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
 DATE OF MEETING: OCTOBER 18, 2017

U.S. Nuclear Regulatory Commission (NRC) Attendees	California Department of Public Health Attendees
Mark Shaffer, Director, Division of Nuclear Materials Safety, Region IV	Anthony Chu, Chief Division of Radiation Safety and Environmental Management
Randy Erickson, State Agreements Officer, Region IV	Gonzalo Perez, Environmental Program Manager II Chief, Radiologic Health Branch
	John Fassell, Supervising Health Physicist Inspection Compliance and Enforcement Section
	Ira Schneider, Supervising Health Physicist Radioactive Materials Licensing Section
	Ronald Rogus, Senior Health Physicist Licensing Projects Unit
	Phillip Scott, Senior Health Physicist Regulations Unit
	Robert Greger, CHP Senior Health Physicist

DISCUSSION:

The California Agreement State Program is administered by the Radiologic Health Branch (Branch), which is located within the Division of Radiation Safety and Environmental Management (Division). The Division is part of the California Department of Public Health. The previous IMPEP review was conducted the week of October 5-9, 2015.

During the 2015 review of the California Program, the team found the Program's performance satisfactory for all indicators reviewed. The team did make two recommendations specific to their performance in the Sealed Source and Device evaluation indicator. These included developing and implementing an action plan to complete pending transfer actions in a timely manner as to ensure consistency and clarity in the licensing of the registered sources and devices across all jurisdictions; and, developing and implementing a procedure for reviewing the implementation of the manufacturer or distributor's quality assurance and quality control program commitments during onsite inspections. Each is discussed later in this summary.

The team also recommended, and the Management Review Board (MRB) agreed, that the California Agreement State Program was adequate to protect public health and safety, was compatible with the Nuclear Regulatory Commission's (NRC) program; and, that the next IMPEP review should take place in approximately four years.

TOPICS COVERED DURING THE MEETING INCLUDED:

Program Challenges

- California noted that travel restrictions to other states, including Tennessee, is negatively impacting staff training. When the travel restrictions were implemented, California reported this to NRC and with the assistance of the Office of Nuclear Material Safety and Safeguards (NMSS), a letter was generated which has allowed California to take advantage of certain exemptions to the California travel restrictions. While this has helped, travel restrictions continue to present challenges to the Program.
- Given the travel challenges noted above, California has asked if it would be possible that they could host additional NRC training classes in California. They have hosted NRC training classes in the past, they have adequate training facilities and equipment available to them to do so in the future, and are willing to host NRC training classes. They believe that this could help alleviate some of the issues associated with travel restrictions.
- California has been experiencing challenges to hiring qualified health physicist candidates from outside the agency. This is primarily due to the salaries that they are allowed to pay. It has resulted in most of their candidates promoting or transferring from within the Branch which in some cases may not allow them to reach the most qualified individuals.

Feedback on NRC's Program

- California is requesting final resolution of a transportation question involving the legal interpretation of 10 CFR 71.5(a) and 71.5(b) as it relates to a U.S. Department of Transportation (DOT) exemption found in 49 CFR 171.1(d)(5). That DOT exemption in part, exempts any local, state or federal government employee while using a government owned vehicle to transport hazardous materials for noncommercial government purposes, from complying with DOT shipping requirements.
- California is also requesting final resolution of an issue concerning the regulatory applicability of Part 37 to individuals who have job responsibility to issue PINs, access cards and keys to allow access to security zones.

Program Reorganizations

At the time of the 2015 IMPEP review, the Branch was located within the Division of Food, Drug, and Radiation Safety. In November 2016 the Department underwent a reorganization and the Branch is now within the Division of Radiation Safety and Environmental Management.

Program Budget/Funding

The Branch is fee funded. On September 1, 2017, the Branch received a 26.76 percent fee increase. The last fee increase was in 2015.

Technical Staffing and Training (2015 IMPEP: Satisfactory)

At the time of the periodic meeting, the Branch had a total of 42 full time equivalent (FTE) positions which includes management and staff. Two additional individuals support the Branch with regulation development. All licensing staff are located in Sacramento, and inspection staff are located in Sacramento and in regional offices across the state.

Of the 42 FTE noted, five inspectors work in the Richmond office in northern California and five inspectors work in the Brea office in southern California. California also contracts with Los Angeles County who has four inspectors and San Diego County who has two inspectors.

Since the 2015 IMPEP review five staff have left the Branch for various reasons with each being quickly replaced. At the time of the Periodic Meeting (meeting) the Branch had one vacancy. They were conducting interviews to fill that position two days after the meeting.

At the time of the 2015 IMPEP review, the Branch had a documented training plan consistent with NRC's Inspection Manual Chapter (IMC) 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs." The Branch is working to complete the 24 hour continuing education requirement now found in IMC 1248.

Status of Materials Inspection Program (2015 IMPEP: Satisfactory)Technical Quality of Inspections (2015 IMPEP: Satisfactory)

The Branch reported they conducted 306 Priority 1, 2, and 3 inspections since the 2015 IMPEP review. They also performed an additional 67 initial inspections. Of the 373 total inspections performed, 7 were conducted overdue (1.9 percent). At the time of the meeting, none were overdue.

The Branch reported they had granted 94 reciprocity authorizations since the 2015 IMPEP review. The Branch further reported they had performed a total of 38.9 percent of candidate reciprocity inspections in 2015, 47.1 percent in 2016, and 27.8 percent from January 1, 2017 through the date of the meeting.

The Branch continues to perform annual supervisor accompaniments of each inspector with none being missed since the 2015 IMPEP review.

The Branch assesses timeliness goals for forwarding inspection findings to licensees following an inspection and discuss those findings with inspectors. The Branch reported that since the 2015 IMPEP review, they exceeded the 30 day goal in 25 out of 344 total reports issued (7.3 percent).

Technical Quality of Licensing Actions (2015 IMPEP: Satisfactory)

The Branch currently has 1733 specific licensees. License reviewers completed a total of 3637 licensing actions since the 2015 IMPEP review. License renewals occur at 10 year intervals. At the time of the 2015 IMPEP review, the Branch had 209 licenses under timely renewal for a period of greater than one year. At the time of the meeting, that number had increased to 279 licenses under timely renewal for a period of greater than one year.

At the time of the 2015 IMPEP review, the Branch was following NRC's revised pre-licensing guidance. The Branch reported that they perform pre-licensing inspections on all new licensees, all ownership changes and all Part 37 licensees. No licenses are delivered at the time of pre-licensing inspections.

Technical Quality of Incidents and Allegations (2015 IMPEP: Satisfactory)

At the time of the meeting the Branch had reported 204 total events to the NMED database since the 2015 IMPEP review. Those included landfill trips as well as general license reports. At the time of the meeting 23 events remained open. Of those, five were recent events in the process of review, three needed additional information to close and 15 others were completed and ready to close. The Branch reported that all HOO reportable events had been conveyed to the NRC in accordance with the established guidance in SA-300, "Reporting Materials Events".

Since the 2015 IMPEP review the Branch directly received 14 allegations. NRC also referred eight allegations to the Branch, two came from Region IV and six from NMSS. All but three allegations from NMSS have been closed. Those three are in the process of closure and involve exempt distribution issues.

Regulations and Legislative Changes (2015 IMPEP: Satisfactory)

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.

At the time of the 2015 IMPEP review the team found that the Branch had four overdue amendments. Of those four overdue amendments, two are longstanding overdue amendments due for adoption in 1997 and 2000 respectively, and both were identified in multiple previous IMPEP reviews. The amendments included, "Timeliness in Decommissioning Material Facilities" and "Radiological Criteria for License Termination," and 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." challenge was successful, and the license termination portion of 10 CFR Part 20 was repealed on August 8, 2002. California continues to terminate licenses on a case-by-case basis.

An additional issue was discussed with the Branch and involved 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 the 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, the 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.

At the time of the meeting the Branch had seven overdue amendments. Of those, five were in regulation packages working their way through the lengthy California rule adoption process. The remaining two amendments were the same two long standing overdue amendments described above. The Branch does not have a date when they will be through the process and finalized.

Sealed Source and Device Evaluation Program (2015 IMPEP: Satisfactory)

At the time of the 2015 IMPEP review the Branch had five individuals that were fully qualified sealed source and device evaluation (SS&D) reviewers with full signature authority to perform concurrence reviews. There were eight additional reviewers that are either partially qualified reviewers or are reviewers in training with limited initial reviewer signature authority. At the time of 2015 IMPEP review, the Branch had no vacancies in the SS&D program. There have been no changes in staffing in the SS&D program.

The Branch reported that since the 2015 IMPEP review, they have received 110 SS&D submittals including four new submittals, 70 amendments, 35 inactivations, and one correction. Of those, they have completed 55 actions including two new submittals, 16 amendments, 36 inactivations (one previously pending), and one correction.

The 2015 IMPEP 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. Because of this, the team made the following recommendation.

- The review team recommended 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 Branch responded by developing and implementing an action plan to transfer the nine remaining SS&D transfers in a timely manner. Each SS&D action was assigned to a pair of reviewers for processing. All transfer actions were completed by 11/8/16.

The 2015 IMPEP team also 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. Because of this, the team made the following recommendation.

- The review team recommended 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.

The Branch responded by developing a Quality Assurance/Quality Control supplemental procedure. Additionally, the routine inspection procedure used for inspections of non-medical manufacturers was modified to ask inspectors if an SS&D for sources or devices possessed existed for the licensee, and if so, inspectors are to also use the SS&D supplemental inspection procedure. The Branch is currently in the process of providing in-service training for the staff to ensure that each understands the procedure and how to use it.

State Initiatives

Some of the specific initiatives the State is involved in include:

- Governor Brown is working steadily towards the eventual elimination of all cesium-137 irradiators in California. As of the date of the meeting, two public meetings have been held regarding this issue in Irvine, California in March 2017 and in San Francisco, California in September 2017.
- The Branch has been coordinating with the National Nuclear Security Administration / Office of Radiological Security (NNSA/ORS) in an effort to harden all Part 37 licensee facilities. As of the date of the meeting, 39 of 110 Part 37 licensee facilities have been upgraded with enhanced security.
- The Branch continues to follow up on all non-military radium sites that NRC provided to them. California had a total of 66 sites, 14 have been completed and another 30-40 sites are currently in various stages of review.

Emerging Technologies

The Branch is working with NRC's medical team regarding the new MASEP Gamma Knife, manufactured in China and distributed in the United States. The company attempted to obtain an SS&D for the device in California, but instead obtained the SS&D sheet from Tennessee. The first unit is licensed and operating in Louisiana. The Branch is working with the medical team to determine the appropriate licensing guidance for this device.

CONCLUSIONS:

The Radiologic Health Branch continues to be an effective and vital part of the California Department of Health. They are currently fully staffed and have recently received an approximate 27 percent fee increase. The Program is effectively managing its licensing and inspection activities and is responding to incidents and allegations as appropriate. They have greatly reduced the number of past overdue regulation amendments and have addressed issues affecting their SS&D program.

NRC staff recommends that the next IMPEP review be conducted as scheduled in October 2019.