



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
612 E. LAMAR BLVD., SUITE 400  
ARLINGTON, TEXAS 76011-4125

November 10, 2010

Gary W. Butner, Branch Chief  
Radiological Health Branch  
Division of Food, Drug & Radiation Safety  
California Department of Health Services  
P.O. Box 997414, MS-7610  
Sacramento, California 95899-7414

Dear Mr. Butner:

A periodic meeting with you and your staff was held on October 13, 2010. The purpose of this meeting was to review and discuss the status of the California Agreement State Program. The NRC was represented by Dr. Janine Katanic from the Office of Federal and State Materials and Environmental Management Programs (FSME), and me. I have completed and enclosed a general meeting summary, including any specific actions resulting from the discussions.

In addition to a discussion of general topics associated with your program, discussions to ascertain the status of overdue regulations specific to your status under Monitoring was performed. This will replace your upcoming Monitoring call with NRC and the next call will be held in 4 months.

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) 860-8143 or e-mail [Randy.Erickson@nrc.gov](mailto:Randy.Erickson@nrc.gov) to discuss your concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Randy Erickson", written in a cursive style.

Randy Erickson  
Regional State Agreements Officer

Enclosure:  
Periodic Meeting Summary for California

California Department of Health Services

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cc w/enclosure:

Robert Schlag, M.Sc.

California Department of Public Health

Division of Food, Drug & Radiation Safety

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 Final:

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<i>RRE</i>	<i>JFK</i>			
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AGREEMENT STATE PERIODIC MEETING SUMMARY FOR THE  
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DATE OF MEETING: OCTOBER 13, 2010

<b>NRC Attendees</b>	<b>California Attendees</b>
Randy Erickson, RSAO	Robert Schlag, Division Chief
Janine Katanic, FSME	Gary Butner, Branch Chief
	Gonzalo Perez, Senior Health Physicist
	John Fassell, Senior Health Physicist
	Phillip Scott, Health Physicist
	Ron Rogus, Health Physicist
	Steve Hsu, Health Physicist

**DISCUSSION:**

The Radiological Health Branch (the Branch), located within the Division of Food, Drug, and Radiation Safety (the Division), administers the California Agreement State Program. The Division is a part of the Department of Public Health (the Department).

The previous IMPEP review was conducted the week of March 31 – April 4, 2008. At the conclusion of the review the team found California's performance to be satisfactory for six performance indicators and unsatisfactory for the performance indicator Compatibility Requirements. The review team made two recommendations regarding Branch performance and identified one good practice. Accordingly, the review team recommended and the MRB agreed that the California Program is adequate to protect public health and safety and not compatible with NRC's program. The MRB also concluded that the period of Heightened Oversight should end and a period of Monitoring should be initiated. Additionally, the MRB agreed with the team's recommendation that the next full IMPEP review should take place in four years and that a Periodic Meeting be held within one year.

The initial Periodic Meeting was held on April 29, 2009 (ML091480762). This Periodic Meeting covers the period from April 30, 2009 through October 13, 2010. The meeting was conducted in lieu of a scheduled Monitoring call with the Branch and therefore includes additional specific details of the Branch's progress on completing each of the recommendations from the 2008 follow-up IMPEP review.

The proposed status of the recommendations from the 2008 California final IMPEP report is summarized below.

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

**ENCLOSURE**

Status on April 29, 2009: The Branch has changed the frequency of HDR inspections from a 3-year interval to a 2-year interval to be compatible with NRC's frequency. This recommendation should be verified and closed at the next IMPEP review.

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

Status on April 29, 2009: The Department recognized that the rulemaking process in place at the time of the 2008 IMPEP review was inefficient and needed revision. In response to that need, the Department hired a consulting firm to assess the rulemaking process and make recommendations on how to improve it within the confines of state law. The consulting firm made recommendations to the Department, and in December 2008 the Branch in coordination with the Office of Regulations, drafted an Action Plan to streamline the Branch's rulemaking process. Additionally, they implemented a team approach to development and promulgation of regulations and are now just beginning to follow the Action Plan. More time will be needed to fully evaluate the effectiveness of this approach.

Current Status: The Department reported they continue to make progress on the regulation backlog. California processes rule packages by "Parts", such as Part 20 or Part 35, instead of by amendments containing several smaller parts similar to the manner in which NRC promulgates rules. This method of rule promulgation gives the impression that the California program remains seriously behind on regulation development, when in fact they continue to steadily implement regulations. The Branch completed and filed Part 35 regulations (including some subsequent amendments) with the California Secretary of State on the date of the meeting. They will become effective on January 1, 2011. The Branch also reported that the Department's new rule development and promulgation process is working well. The process hasn't significantly reduced the amount of time it takes to promulgate new rules, but it has brought efficiencies to the process that have helped the Branch, primarily in the area of concurrent processing of rule packages. This recommendation remains open and should be evaluated at the next IMPEP review.

Other topics covered at the meeting included.

Program Strengths: The California Program is a large and busy program with a highly motivated staff that at the time of the meeting had responsibility for 1913 specific materials licensees. Management support to the Branch is outstanding and access to senior management is unencumbered. Senior managers have offices on the same floor as the Branch. The close physical location allows easy access to both Branch and Division management and allows managers to be more intimately involved in staff activities.

ENCLOSURE

While the Branch continues to experience minor staff losses, they have been very successful in filling positions with talented individuals bolstering the Branch's already broad knowledge base. The Branch has successfully integrated the added workload associated with Increased Controls, as well as fingerprinting and NSTS requirements. Staff members work well together providing a high level of customer service to their licensees, and Branch management has worked diligently to ensure that a proper balance is achieved within the Branch.

Program Weaknesses: The Branch was previously a strong supporter of staff involvement in NRC working groups and participation on IMPEP teams; however, due to the state's economic downturn and the high negative visibility associated with sending staff out of state to participate in these activities, senior management has restricted travel for both. Additionally, for approximately the last year, staff has been restricted from traveling out of state to attend NRC training courses. Because of this, Region IV has coordinated with TTC to bring the licensing and inspection procedures courses to California. Additionally, furloughs have now been in place for over a year and continue for the staff at the rate of three days per month.

Feedback on NRC's Program:

The Branch discussed issues associated with environmental remediation of several Department of Defense facilities located in California, but the majority of the Branch's concerns are focused on clean-up activities at the former Treasure Island Naval Station (Treasure Island), a Base Realignment and Closure (BRAC) site undergoing decommissioning. The Branch discussed their concerns about jurisdiction of Treasure Island both prior to and during the Periodic Meeting. The Branch has experienced difficulty in determining who (the State, the NRC or someone else) is responsible for oversight of ongoing environmental remediation activities involving byproduct materials at the site, and has also experienced difficulties in obtaining access to the site.

Subsequent to the meeting, Region IV staff was able to confirm with the Navy Master Materials License (MML) Project Manager that NRC has no jurisdiction on the site at this time. This is because the only material identified at Treasure Island thus far has been radium, and due to current NRC policy regarding military use. This was conveyed to the Branch telephonically on October 20, 2010. The Branch reported that on October 27, 2010, staff members from the Branch would be provided escorted access to the site by members of the Naval Radiological Affairs Support Office (RASO) and BRAC so that the Branch could perform independent radiological surveys.

The Branch expressed their concerns about requests by the Domestic Nuclear Detection Office (DNDO) for access to licensee information contained in the Branch's licensee database. DNDO provided the Branch with a Memorandum of Understanding (MOU) detailing the access needed. As of the date of the meeting, the Branch has not responded to DNDO's request. They are uncomfortable providing specific licensee information to anyone outside of direct coordination with, or working through NRC.

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Staffing and training:

The California Program is a large program which is divided into several program areas. The Branch has an average of 150 total staff members with approximately one third of those being associated with the radioactive materials program. At the time of the meeting, the Branch reported they were fully staffed but anticipated losing one licensing reviewer in the near future. In addition to hiring experienced staff, the Branch also aggressively recruits from local universities, and continue to do so. The Branch continues to assess their staffing needs which are in part, dependent on additional requirements placed upon them by NRC.

The status of Agreement State staff members who fail NRC core training courses was discussed. Branch managers indicated it is their policy to provide other forms of remedial training whenever this might occur. They discussed one staff member who recently failed NRC's "Transportation of Radioactive Materials" course (H-308). They worked with this individual, providing alternate methods of training until they were satisfied the individual was sufficiently capable of understanding and applying DOT regulations.

Program reorganizations:

The Branch has not been subject to reorganization since the last meeting. A change in the Governor's office will occur with the upcoming election, but this is not expected to result in Department reorganization. Since the last meeting, the Branch rotated the individuals occupying the positions of Chief of the Radioactive Materials Inspection, Compliance and Enforcement Section, and Chief of the Strategic Planning and Quality Assurance Section to each other's position.

Changes in Program budget/funding:

The Branch has not experienced any problems with budgeting or funding. The Branch is fee funded. The FY11 budget has been passed by the legislature. The only issue that has affected the Branch irrespective of their funding levels is the overriding requirement that all state government offices close three days per month which has had a net effect of an approximate 15 percent pay cut to all employees.

Materials Inspection Program:

The Branch reported that they currently have no overdue inspections. Routine inspections are generally performed by the due date, but occasionally inspections are performed within the allowed +25 percent window. Initial inspections are typically performed within 12 months of issuance. They continue to inspect reciprocity licensees and have not had difficulty performing inspections on at least 20 percent of candidate reciprocity licensees.

The Branch initially identified 140 licensees who were required to implement Increased Controls (IC). At the time of the meeting, the Branch reported they currently have 138 IC licensees. At the time of the 2008 IMPEP review, the Branch still had 12 of these

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inspections to perform but during the April 2009 meeting reported that all IC inspections had been completed. Also during that meeting the Branch noted that all but three licensees had completed the fingerprinting implementation. All fingerprinting requirements have now been implemented. IC inspections are now performed in conjunction with routine health and safety inspections. Fingerprinting and NSTS requirements are also reviewed at the time of inspection.

Increased Controls/Fingerprinting files are locked in uniquely keyed file cabinets and are not subject to release under FOIA.

The Branch reported they have developed and implemented a formal procedure on how they address pre-licensing guidance requirements including pre-licensing visits. At the time of the April 2009 meeting, the Branch stated that only new IC licensees received a site visit. During this meeting the Branch stated that all new licensees now receive a pre-licensing visit. Additionally, a non-IC licensee who requests an increase in license authorization that now subjects them to IC requirements also receives a pre-licensing visit, even though the Branch has a relationship with the licensee.

Regulations and Legislative changes:

During the 2008 follow-up IMPEP review, the Branch was found to not be compatible with NRC's program due to large number of overdue amendments. The period of Heightened Oversight was terminated and a period of Monitoring was initiated. Over the successive months, quarterly calls with the Branch were conducted to update NRC on the Branch's progress towards compatibility with NRC's program. The most recent Monitoring call with the Branch took place on June 9, 2010 (ML101660110). At the time of that call, the Branch reported on the remaining 11 out of the original 13 outstanding amendments.

During the Periodic Meeting, the Branch confirmed that on October 13, 2010, Part 35 (medical) regulations had been adopted and had been filed with the Secretary of State. These regulations will become effective for licensees on January 1, 2011, and licensee workshops for Part 35 are scheduled for early December 2010 in both northern and southern California. The adoption of Part 35 resulted in the completion of three amendments and the partial completion of four additional amendments. The remaining eight amendments continue to work their way through the rulemaking process.

The incompatibility of legislation found in Section 115261 of California's "Health and Safety Code – Radiation Control Law" to NRC's 10 CFR Part 61 with regards to low-level radioactive waste disposal was also discussed with the Branch. This incompatibility was initially noted in an amendment submission to NRC on June 25, 2007. At that time, NRC notified the Branch that their statute was more restrictive than 10 CFR 61.41, and therefore did not meet the Compatibility "A" designation assigned to the rule. To date this compatibility issue has not been resolved. On November 3, 2010, the Branch notified NRC by telephone and email that they will be requesting additional time to resolve the issue due to the upcoming change in administration following the 2010 elections (ML103140535).

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As noted in the Discussion section of this summary, a scheduled Monitoring meeting with the Branch was held in conjunction with the Periodic Meeting, and therefore this section includes additional specific details of the Branch's status of overdue amendments.

- "Quality Management Program and Misadministration," 10 CFR Part 35 amendment (56 FR 34104), that was due for Agreement State implementation on January 27, 1995.

Status: This amendment has been completed. It was adopted on October 13, 2010.

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

Status: This amendment remains open. This amendment is tied to the amendment, "Radiological Criteria for License Termination," noted below.

- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623), that was due for Agreement State implementation on October 20, 1998.

Status: This amendment has been completed. The Part 20 portion of this amendment was adopted on September 10, 1998. The Part 35 portion of this amendment was adopted on October 13, 2010.

- "Recognition of Agreement State Licenses in Areas under Exclusive Federal Jurisdiction within an Agreement State," 10 CFR Part 150 amendment (62 FR 1662), that was due for Agreement State implementation on February 27, 2000.

Status: This amendment remains open. The Branch has completed the 45-day public comment period. Based on comments received, they are about to place the amendment out for an additional 15-day comment period.

- "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Parts 20 and 35 amendments (62 FR 4120), that was due for Agreement State implementation on May 29, 2000.

Status: This amendment remains open. The Part 35 portion of this amendment was adopted on October 13, 2010. The Part 20 portion of this amendment has been filed with the Office of Administrative Law for review. The review has a deadline of November 23, 2010.

**ENCLOSURE**

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057), that was due for Agreement State implementation on August 20, 2000.

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

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 35, and 36 amendments (63 FR 39777 and 63 FR 45393), that was due for Agreement State implementation on October 26, 2001.

Status: This amendment remains open. The Part 35 portion of this amendment was adopted on October 13, 2010. The Part 36 portion of this amendment was completed by License Condition. The Part 20 portion of this amendment has been filed with the Office of Administrative Law for review. The review has a deadline of November 23, 2010.

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

Status: This amendment remains open. The Branch has completed the 45-day public comment period. Based on comments received, they are about to place the amendment out for an additional 15-day comment period.

- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendments (67 FR 20250), that was due for Agreement State implementation on October 24, 2005.

Status: This amendment remains open. The Part 35 portion of this amendment was adopted on October 13, 2010. The Part 20 portion of this amendment has been filed with the Office of Administrative Law for review. The review has a deadline of November 23, 2010.

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

Status: This amendment has been completed. It was adopted on October 13, 2010.

**ENCLOSURE**

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

Status: This amendment remains open. The Part 35 portion of this amendment was adopted on October 13, 2010. The Part 20 portion of this amendment has been filed with the Office of Administrative Law for review. The review has a deadline of November 23, 2010. Changes for Parts 30, 40 and 70 are compatibility Category D so they are not being addressed. Change to Part 32 is already addressed through the licensing review process.

Event reporting, including follow-up and closure information in NMED.

Between the date of the 2008 IMPEP review and the April 2009 Periodic Meeting, the Branch had reported 129 events to NMED, with 72 remaining open. The majority of those events were landfill radiation monitor alarm trips. Between the April 2009 meeting and October 13, 2010, the Branch reported 143 events to NMED, with 56 remaining open. The Branch continues to monitor open events and closes them as rapidly as possible. Their goal for event closure is 120 days from the date of the event.

Response to incidents and allegations.

The Branch continues to be sensitive to notifications of incidents and allegations. Incidents are quickly reviewed for their affect on public health and safety. Incidents are evaluated for safety significance and staff is dispatched to perform onsite investigations whenever possible. The Branch has taken the position that if they demonstrate responsiveness to incidents and allegations, no matter how trivial they might be, licensees and individuals will realize that reporting incidents and allegations should be important to them as well.

Status of allegations and concerns referred by the NRC for action.

The Branch continues to process allegations as they are received. In addition to allegations received by the Branch directly, since the 2009 Periodic Meeting, NRC has referred two allegations to the Branch. One did not require a response to NRC; the other was immediately investigated by the Branch and a response to NRC was generated within a week. The Branch continues to be sensitive to issues of identity protection regarding alleged.

Significant events and generic implications.

While the Branch continues to monitor several significant events, they reported that no new significant events have originated following the 2008 IMPEP review. One specific issue noted was the Branch's tracking of radioactive materials being sold on Ebay.

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Current State Initiatives.

The Branch noted that furloughs continue. No specific end date has been identified.

The Branch also noted they continue to work with RASO and BRAC on the environmental remediation of various former military installations within the State. Specifically, the Branch is concerned with clean-up of Treasure Island, and to a lesser extent Hunter's Point.

Emerging Technologies.

Nothing specific noted.

Large, complicated, or unusual authorizations for use of radioactive materials.

Nothing specific noted.

State's mechanisms to evaluate performance.

Branch managers review performance reports involving licensing actions, inspections performed, incidents reported, and reports reviewed.

Inspector accompaniments are also performed to ensure they are performing at the expected level.

Current NRC initiatives:

NRC staff discussed ongoing NRC initiatives with the Branch. These included in part, NRC's draft safety culture policy statement, web based licensing, NSTS, the NUREG 1556 revision process, the revisions to IMC 2800, the proposed Part 37 and accompanying guidance document, and potential changes to Part 20.

Summary:

The Branch appears to have spent a significant amount of time and effort to correct the issues that were initially facing them. While the rulemaking process in California continues to be a cumbersome and sometimes difficult regulatory process, the Branch has taken advantage of some of the recent changes in the process that allow for concurrent streaming of regulations which allows them to get regulatory packages out sooner. While the Branch has completed several amendments and partially closed others, they still have several to complete. It is recommended that the Management Review Board consider continuing the period of Monitoring for the California Program until the next IMPEP review.

Schedule for the next IMPEP review:

It is recommended that the next IMPEP review to be held on schedule in April 2012.

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