



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV  
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ARLINGTON, TEXAS 76011-4125

May 28, 2009

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 April 29, 2009. The purpose of this meeting was to review and discuss the status of the California Agreement State Program. The NRC was represented by Mr. Arthur Howell from NRC's Region IV office, Mr. William Rautzen from NRC's 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,

*/RA/*

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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AGREEMENT STATE PERIODIC MEETING SUMMARY FOR  
THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DATE OF MEETING: APRIL 29, 2009

<b>NRC Attendees</b>	<b>California Attendees</b>
Randy Erickson, RSAO	Robert Schlag, Division Chief
Arthur Howell, Division Director	Gary Butner, Branch Chief
William Rautzen, FSME	Gonzalo Perez, Senior Health Physicist
	Victor Anderson, Senior Health Physicist
	Phillip Scott, Health Physicist
	Marilyn Willis, Regulation Services
	Peter Sapunor, Senior Staff Council

**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 program 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. The MRB also concluded that the next full IMPEP review should take place in 4 years and that a periodic meeting be held in 1 year.

The current 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)

Current Status: 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)

**ENCLOSURE**

Current Status: 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 the process 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. 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 and progressive staff that has approximately 2000 licensees. As a result of the Heightened Oversight process, funding has not been a problem, even with the State's well publicized financial issues. Management support to the Branch is outstanding and access to senior management is unencumbered. Two 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.

While the Branch had experienced some staff losses, it has successfully filled those positions with talented individuals bolstering the Program's already broad knowledge base. The Branch supports staff involvement in NRC working groups and encourages participation on IMPEP teams. The Branch has successfully integrated the added workload associated with Increased Controls and Fingerprinting 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 program.

Program Weaknesses: The Branch noted issues with obtaining training for the newly hired staff. Because of staff depth within the program, newly hired individuals often have to wait to get into classes because other programs with less depth have been identified as having a more serious need. They identified this as an issue, but have been able to manage staff training successfully.

#### Feedback on NRC's Program:

The Branch discussed issues associated with clean up of Department of Defense facilities; low level radioactive waste disposal including questions associated with the jurisdiction of mixed waste from Antarctica returning to the United States; issues associated with NRC review of regulation packages, and compatibility questions regarding a burial site that communicates with the Colorado River; and, questions about what NRC public meetings would be beneficial for the Branch to listen to. These questions are being answered separately.

Staffing and training:

The California Program is a large program which is divided into several program areas. The Branch has an average of 147 total staff members with approximately 50 of those being associated with the radioactive materials program. At the time of the meeting, the Branch reported they were fully staffed. They have aggressively recruited from local universities in addition to hiring experienced staff. The Branch recently lost the senior member in the Brea office, but has recently filled that position. The Branch continues to assess their staffing needs which tend to be dependent on additional requirements placed upon them by NRC.

Program reorganizations:

The Branch has not experienced any program reorganizations since the previous IMPEP review and none are expected.

Changes in Program budget/funding:

The Branch has not experienced any problems with budgeting or funding. The Branch is fee funded. The only issue that has affected the program irrespective of their funding levels is the overriding requirement that all state government offices close 2 days per month, which has had a net effect of a 10 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 a 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. At the time of the 2008 IMPEP review, the Branch still had 12 of these inspections to perform but now report that all Increased Controls inspections have been completed. The Branch also reported that all but three licensees have completed the fingerprinting implementation. Increased Controls/Fingerprinting files are locked in uniquely keyed file cabinets and are not subject to release under FOIA.

The Branch reported they have a process in place for addressing pre-licensing guidance requirements and are currently developing a formal procedure. The Branch stated that at the present time only new Increased Controls licensees currently receive a site visit.

Regulations and Legislative changes:

During the 2008 IMPEP review, the Branch was found to not be compatible with NRC's program due to number of late regulations. The period of heightened oversight was terminated and a period of monitoring had been initiated. Over the successive months, calls with the Branch have been held to update NRC on their compatibility with NRC's

program. The most recent call with the Branch occurred on February 17, 2009. At the time of the call, the Branch still had 13 outstanding regulations. During the periodic meeting, the Branch confirmed that two regulations were scheduled to become effective on May 24, 2009. The remaining regulations continue to work their way through the process.

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

The Branch had reported 129 events to NMED since the 2008 IMPEP review with 72 still open. The majority of events are landfill alarm trips. The Branch is monitoring the open events and closing them as information to close them becomes available.

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. Staff is dispatched to perform onsite investigations when necessary. The Branch Manager has placed a high emphasis on maintaining an effective response to incidents and allegations.

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

While the Branch processed several allegations since the 2008 IMPEP review, no allegations were formally referred by NRC during the same period.

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.

Current State Initiatives:

The Branch noted that furloughs continue. No specific end date has been identified. Due to budget shortfalls, the State has begun a round of layoffs. The Branch is uncertain if the layoffs will affect them.

Emerging Technologies:

None noted.

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

The Branch identified pipeline decommissioning work on Bureau of Land Management lands as a non-standard project they are working.

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 initiatives with the Branch. These included pre-licensing guidance, fingerprint orders, national source tracking, web based licensing, generally licensed devices, and the issues associated with tritium exit signs.

Summary:

The Branch appears to have spent a significant amount of time and effort to correct the issues that were initially facing the Program. The remaining recommendation involving Compatibility Requirements continues to be a challenge for the Branch. While a cumbersome and often difficult regulatory process is being revised, the Branch has not demonstrated a sustained period of success in implementing regulations. For that reason, it is recommended that the MRB consider continuing the period of monitoring for the California Agreement State Program and have another periodic meeting with the Program in approximately 18 months.

Schedule for the next IMPEP review:

It is recommended that the next IMPEP review to be held on schedule in 3 years.