



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BLVD
ARLINGTON, TEXAS 76011-4511

February 22, 2013

Gonzalo Perez, 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. Perez:

A periodic meeting with you and your staff was held on January 24, 2013. The purpose of this meeting was to review and discuss the status of the California Agreement State Program. The NRC was represented by Anton Vogel and Linda Gersey from the Division of Nuclear Materials Safety (DNMS) in NRC Region IV, 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 meeting will replace your upcoming Monitoring call with NRC and the next call will be held in approximately 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) 200-1143 or e-mail Randy.Erickson@nrc.gov to discuss your concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Randy Erickson".

Randy Erickson
Regional State Agreements Officer

Enclosure:
Periodic Meeting Summary for California

bcc (via e-mail distribution):
 Anton Vogel, DNMS
 Vivian Campbell, DNMS
 Brian McDermott, FSME
 Pamela Henderson, FSME
 Duncan White, FSME
 Binesh Tharakan, SAO
 Randy Erickson, SAO
 Linda Gersey, DNMS
 Lisa Dimmick, FSME
 Michelle Beardsley, FSME
 Karen Meyer, FSME

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 Final:

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Publicly Available	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Non Sensitive		
RIV: RSAO				
RRErickson				
				
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AGREEMENT STATE PERIODIC MEETING SUMMARY FOR THE
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DATE OF MEETING: JANUARY 24, 2013

NRC Attendees	California Attendees
Randy Erickson, SAO	Steve Woods, Division Chief
Anton Vegel, RIV	Gonzalo Perez, Branch Chief
Linda Gersey, SAO	Steve Hsu, Senior Health Physicist
Janine Katanic, FSME	John Fassell, Senior Health Physicist
	Jerry Hensley, Senior Health Physicist
	Robert Greger, Senior Health Physicist
	Phillip Scott, Health Physicist
	Ron Rogus, Health Physicist
	Ira Schneider, Health Physicist
	Brandy Pena, Health Program Specialist

DISCUSSION:

The California Agreement State program is administered by the Radiologic Health Branch (the Branch), which is located within the Division of Food, Drug, and Radiation Safety (the Division). The Division is part of the Department of Public Health (the Department). The previous IMPEP review was conducted the week of October 17-21, 2011.

At the conclusion of the review, the team found California's performance to be unsatisfactory for the indicator, Compatibility Requirements, and satisfactory for the remaining performance indicators reviewed. The review team also modified one recommendation from the 2008 IMPEP review regarding the timely promulgation of regulations.

Accordingly, the review team recommended, and the MRB agreed, that the California Agreement State program was adequate to protect public health and safety, but not compatible with NRC's program, and that the period of Monitoring currently in place for California be continued until significant progress was made in the regulation promulgation process.

Lastly, the review team also recommended that a Periodic Meeting be held one year following the MRB, that a second Periodic Meeting take place in approximately 2.5 years, and that the next IMPEP review take place in approximately four years.

The status of the one remaining recommendation from the 2011 California final IMPEP report is summarized below.

- The review team recommends that the State develop and implement a detailed action plan that fully documents actions, tasks, and milestones associated with each regulation package, to better track adoption of required regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 4.1.2)

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Status: Immediately following the October 2011 IMPEP review, the Branch developed a detailed action plan to track the progress of regulation packages through the system. Once developed, they began using this document to track regulation packages and where they were in process.

During the first Monitoring call in May 2012, the Branch reported they were making changes to the manner in which they processed regulations. They planned to move from their long standing practice of processing rule packages by "Parts", such as Part 20 or Part 35, to a method that would parallel NRC's adoption process. The Branch believed this change would improve efficiency and help in the elimination of their long standing regulation backlog. Branch managers indicated they would also be adding staff in an effort to eliminate the backlog.

During the most recent Monitoring call with the Branch in November 2012, the Branch reported that they hired two additional staff members to assist in the development of California regulations. They reported they also have an Attorney assigned to also assist with regulation development. The Branch also noted that all but two overdue regulations have been completed and were entered into the Department's internal regulation approval process in Department Regulation Package DPH11-024.

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 approximately 1900 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.

While the Branch has experienced minor staff losses, they have been very successful in filling positions with talented individuals. The Branch noted that recruitment is going well and they have been successful in hiring Health Physicists as well as individuals with physics majors. The Branch noted that the size and depth of their program allows for specialization and expertise. It also allows them to rapidly respond to issues such as Fukushima, contaminated products entering the State, decommissioning of contaminated sites and their SS&D program.

Program Weaknesses: The Branch also noted that while the size and depth of their program was a strength, they also identified it as a weakness in that the program is large, resulting in managerial challenges. The Branch also noted that while they are experiencing fewer problems with the unions, they are still challenged occasionally by union issues.

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Feedback on NRC's Program:

The Branch presented the following as feedback on NRC's program:

Notifications announcing class acceptance to NRC classes is typically made eight weeks in advance of the class. However, lately those class notifications have often been made with shorter lead time. At eight weeks, it's difficult to get staff through the approval process, but when shorter lead times occur, it's very difficult to get staff into the classes. The Branch asks that NRC keep those class notifications at eight weeks.

The Branch stated that it would be very helpful if NRC could resolve jurisdictional issues involving the military use of radium and the Department of Defense.

The Branch asked if would send electronic mail with the subject matter clearly identified instead of identifiers such as ML numbers.

The Branch expressed appreciation for the help that Kathy Schneider provides to them.

Staffing and Training:

The Branch noted that seven technical staff left the program since the 2011 IMPEP review, and five of them have been replaced. The inspection program is authorized for 18 technical positions, all of which are filled. The licensing program is authorized for 21 technical positions. Two licensing reviewers left the program since the previous IMPEP review and those positions are currently vacant. And the technical support program which includes the regulations program is authorized for 13 positions. It now has two more positions than it had at the time of the 2011 IMPEP review. All those positions are currently filled.

The Branch also contracts with Los Angeles and San Diego counties for inspections in those areas. Each of those contracts is fully staffed now (with one additional inspector than at the time of the 2011 IMPEP).

Program Reorganizations:

The Branch has not been subject to reorganization since the last meeting.

Changes in Program Budget/Funding:

The Branch has not experienced any problems with budgeting or funding. The Branch is fee funded with the last fee increase in 2005. Furloughs have been occurring for several years; however, they are currently down to only one furlough day per month and furloughs

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will cease to exist on July 1, 2013. Those individuals that are at the top of their pay scales will receive a three percent increase in pay when furloughs terminate.

Materials Inspection Program:

The Branch reported that they currently have no overdue Priority 1-3 or initial 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 noted that since the 2011 IMPEP review, they have performed 339 Priority 1-3 and initial inspections with only three being performed overdue. There continue to be some overdue Priority 5 inspections for the Los Angeles County office; however, the qualification of two additional inspectors in that office is expected to allow all overdue inspections to be eliminated during CY 2013.

Regulations and Legislative changes:

The Branch reported that two legislative changes affecting California's rulemaking process were adopted on January 1, 2013. These included SB 617 which added new provisions affecting policy development and economic impact analysis during the pre-notice stage of rulemaking. The second was SB 1099 requires in part, that agencies post on their internet website, regulations filed with the Secretary of State. Additionally, the Branch reported that they have proposed legislation to allow them to automatically adopt regulations by reference. The Branch is sending links to NRC so they can be reviewed.

During the 2011 IMPEP review, the Branch was found unsatisfactory for the indicator, Compatibility Requirements and found to be not compatible with NRC's program due to large number of overdue amendments. Monitoring was continued, and over the successive months, 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 November 8, 2012. During the Periodic Meeting, the Branch reported on the status of the 12 overdue amendments.

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). This incompatibility has been discussed with the Branch during each

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successive IMPEP review, Periodic Meeting and Monitoring call. The Branch reports that this legislation is not supported by the current Governor and will not be addressed during his administration.

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.

The following are regulation changes and adoptions that are currently open and will likely not be adopted in the near future:

- "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.

This rule is tied to the amendment "Radiological Criteria for License Termination." This amendment remains open.

- "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.

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. This amendment remains open.

The following are regulation changes and adoptions contained in Department Regulation Package DPH11-024, which have left the Branch and have entered the Department's internal regulation approval process:

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71 and 150 amendments (62 FR 28947) that was due for Agreement State implementation on June 27, 2000.
- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32, 35, 36, and 39 amendments (63 FR 39477 and 63 FR 45393), that was due for Agreement State implementation on October 26, 2001.
- "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.

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- “Medical Use of Byproduct Material,” 10 CFR Parts 20, 32, and 35 amendments (67 FR 20249), that was due for Agreement State implementation on October 24, 2005.
- “Medical Use of Byproduct Material - Recognition of Specialty Boards,” 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that was due for Agreement State implementation on April 29, 2008.
- “Minor Amendments,” 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendments (71 FR 15005), that was due for Agreement State implementation by March 27, 2009.
- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR Parts 32 and 35 amendments (72 FR 45147, 72 FR 54207), that was due for Agreement State implementation by October 29, 2010.
- “Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Parts 30, 31, 32, 150 amendments (72 FR 58473), that was due for Agreement States implementation by December 17, 2010.
- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864), that was due for Agreement State implementation by November 30, 2010.
- “Medical Use of Byproduct Material – Authorized User Clarification,” 10 CFR Part 35 amendment (74 FR 33901), that is due for Agreement State implementation by September 28, 2012.
- “Requirements for Distribution of Byproduct Material,” 10 CFR Parts 30, 31, 32, 40, and 70 amendments (77 FR 43666), that is due for Agreement State implementation by October 23, 2015.

The following are regulation changes and adoptions that will be needed in the future:

- “Decommissioning Planning,” 10 CFR Parts 20, 30, 40, and 70 amendments (76 FR 35512), that is due for Agreement State implementation by December 17, 2015.
- “Licenses, Certifications, and Approvals for Materials Licensees,” 10 CFR Parts 30, 36, 39, 40, 70, and 150 amendments (76 FR 56591), that is due for Agreement State implementation by November 14, 2014.
- “Change of Compatibility of 10 CFR 31.5 and 31.6 (See RATS ID: 2001-1 for Rule Text),” 10 CFR Part 31 amendment (77 FR 3640), that is due for Agreement State implementation by January 25, 2015.

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- "Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste," 10 CFR Part 71 amendment (77 FR 34194), that is due for Agreement State implementation by August 10, 2015.
- "Technical Corrections," 10 CFR Parts 30, 34, 40, and 70 amendments (77 FR 39899), that is due for Agreement State implementation by August 6, 2015.

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

From approximately November 1, 2011 to the date of the meeting, 116 events were reported to the Branch with eventual entry into NMED. Sixty six of those were reportable events. For those 66 events, NMED records are complete for 61 of them and are closed for 41 of them.

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 one allegation received directly by the Branch since the 2011 IMPEP review, NRC also referred 15 allegations to the Branch. Eight of the allegations remain open and are being processed. All of the allegations reviewed were appropriately closed, and appropriate parties were notified of the actions taken. The Branch continues to be sensitive to issues of identity protection regarding allegers.

The State has a Freedom of Information Act- equivalent law, the Public Records Act. The Branch stated that alleger's identities are adequately protected.

Significant events and generic implications.

While the Branch noted the following as examples of significant events:

- National coordination of PetCo contaminated dog bowls
- Fukushima debris expected to arrive in California this year
- Identification and follow-up of Bed, Bath and Beyond contaminated products

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Current State Initiatives.

The Branch noted the following as examples of current state initiatives:

- TENORM, excluding 11.e(3) byproduct material
- Legislation on the use of radioactive materials for formation fracturing in the oil and gas industry
- General License review for Increased Controls quantities
- Legislative proposal is pending for automatic adoption of NRC regulations

Emerging Technologies.

The Branch noted the following as examples of emerging technologies:

- MASEP Infini gamma knife

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

The Branch noted the following as examples of large, complicated, or unusual authorizations

- Petco Do-60 dog bowls
- Whitaker-Bermite (clean up of DU testing at an unlicensed facility)
- Viktor Bene Bakery (formerly licensed NRC site)
- Magnesium Allow Products (formerly licensed NRC site)
- Proposed SNM transfer from NRC to CA at GE-Hitachi
- Mare Island
- Hunters Point
- McClellan (including onsite RCRA facility)

State's mechanisms to evaluate performance.

The Branch noted the following as examples of mechanisms to evaluate performance

- Ongoing SPSU audits to verify correctness of the RAM database
- QA audits of selected activities
- Due inspection tracking/status reports
- Overdue inspection tracking/status reports
- Greater than 30 days to issue inspection letter tracking/status reports
- Greater than 90 days to close inspection tracking/status reports
- Reciprocity inspection tracking/status reports
- NRC allegation tracking
- Event tracking

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- License action tracking
- Radioactive waste tracking
- General License database
- License database
- Delinquent bill (potential MIA licensee) tracking
- Inspector accompaniments tracking

Current NRC initiatives:

Several NRC initiatives were discussed with the Branch including the status of Part 37 and the NUREG 1556 series. The status of changes to the medical Inspection Procedures as well as working groups were discussed with the Branch. The status of several of the most recent FSME letters was also discussed.

Schedule for the next IMPEP review:

It is recommended that a second Periodic Meeting be held as scheduled in July 2014 and that the next IMPEP review be held as scheduled in October 2015. Additionally, it is recommended that the period of Monitoring be continued.

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