State of California—Health and Human Services Agency
California Department of Public Health

RON CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN JR.
Governor

JAN 0 5 2012

Mr. James L. Lynch
State Agreements Officer
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Mr. Lynch:

Thank you for your recent letter regarding the U.S. Nuclear Regulatory Commission (NRC) draft Integrated Materials Performance Evaluation Program (IMPEP) report that documents the results of the Agreement State review held in California on October 17 through 21, 2011. According to the letter, the California Department of Public Health (CDPH) is being provided with an opportunity to review and comment on the draft IMPEP report prior to its submittal to the Management Review Board (MRB).

The Radiologic Health Branch (RHB) appreciates the IMPEP team's efforts in providing a rigorous and professional evaluation of the performance of California's Radiation Safety Program and the proposed recommendation that the program be found adequate to protect public health and safety. RHB concurs with the IMPEP team's recommendation that California continue under the monitoring program initially recommended during the 2008 IMPEP review. On January 5, 2012, Mr. Stephen A. Woods, Chief of the CDPH Division of Food, Drug, and Radiation Safety will meet via video conference with the NRC's MRB to discuss the IMPEP team's recommendations and the final report.

The IMPEP team noted under section 4.1.2, page 13, that RHB's action plan for adoption of NRC regulations in accordance with NRC's current policy on adequacy and compatibility is not specific enough to transition the branch through the regulations development process in a timely manner. Therefore, since completion of the IMPEP, RHB has formed a regulation team, which includes health physicists from the Radioactive Materials Licensing Section and a redirected regulation expert from CDPH's Office of Regulations to ensure that regulations on adequacy and compatibility are adopted in a timely manner. A copy of the action plan provided to the IMPEP team is enclosed.

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RHB's review of the draft IMPEP report identified three areas where corrections are warranted:

1. In section 3.2, the number of overdue inspections noted in the third paragraph of this section is incorrect. There were 54 routine, priority 1-3 inspections conducted after they became overdue during the IMPEP review period, not 73. As noted in paragraphs three and four of this section, there were also nine inspections overdue at the time of the IMPEP review and 19 initial inspections were conducted after they became overdue, for a total of 82 overdue inspections out of 838 inspections performed (this yields an overdue percentage of 9.8 percent).

2. In section 3.2, RHB granted 204 reciprocity permits during the IMPEP review period, not 104, and 75 of these permits were candidate licensees, not 36. Of the 75 candidate licensees, 26 were inspected for an inspected percentage of 34.7 percent.

3. In section 3.4, page 7, fifth paragraph, RHB issues license renewals with ten-year intervals, not five years as stated in the document.

CDPH remains committed to conducting a quality Radiation Safety Program, which complies with all NRC requirements and is protective of the public health and safety. CDPH would like to thank the IMPEP team for the time and effort related to the evaluation of California's Radiation Safety Program, and for the constructive comments provided. If you need additional information, please contact Mr. Stephen A. Woods, Chief, Division of Food, Drug, and Radiation Safety, at (916) 440-7584.

Sincerely,

Kathleen Bellersley for Dr. Ron Chapman

Ron Chapman, MD, MPH
Director & State Health Officer

Enclosure

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TITLE: Radioactive Materials Regulation Amendments				Date: Nov. 2011	DPH-11-024
Step	**Action**	**Projected Due Date**	**Actual**	**Responsible Party**	**Notes/ Comments**
	Start Date of Project			**Program**	
1.	**Organize initial Rulemaking Project Team (RPT) (Program, OOR, OLS, Budgets, at minimum) meeting.**	**14**		**Program**	**These Steps combined.** **NOTE: Action plan shows basic steps. Additional steps occur if required to complete additional 15-day comment periods.**
1.1	Initial RPT meeting	15		Program Lead	
2.	**Develop regulation package (reg pkg).**	**255**		**RPT (Program Lead)**	
2.1	Prepare and distribute reg pkg for final pre-notice RPT meeting.	271		RPT (Program Lead)	
2.2	Final pre-notice RPT meeting. (Reconciliation of remaining issues.)	272		Program & OOR Co-Leads	
2.3	Finalize documents and obtain concurrence of RPT to proceed.)	281		Program & OOR Co-Leads	
3.	**Obtain Center Deputy approval.**			**Program Lead**	**9 days * (Concurrent)**
	Route Budget Analysis w/399.	**290**		**Budgets**	
4.	**Director's Office review of the reg pkg.**	**299**		**OOR**	**9 days***
5.	**Agency and DOF approval of reg pkg and STD 399 w/attachments.**				
5.1	Agency review of the reg pkg.	359		OOR	At minimum, 60 days *
5.2	DOF review of the reg pkg. (If applicable)	419		OOR	At minimum, 60 days *
6.	**Public Participation Process**				
6.1	Prepare Public Notice (PN) package for Director's signature.	422		OOR	3 days *
6.2	Route PN package for the Director's signature, via OLS, for submittal to	431		OOR	9 days *
6.3	OAL's review of the PN.	434		OOR	3 days
6.4	Duplication and Mailing.	464		OOR	30 days *
6.5	Post PN on CDPH Website. Publication of PN in Notice Register and begin Public Comment Period. (30th day) [Starts one-year clock.]	465			1 day
6.6	Last day to request a Public Hearing.	495		OOR	30 days (15 days before end of 45-day comment period.)
6.7	End of 45-day Public Comment period/Public Hearing	510		OOR	15 days (45 days from Step 6.5.)
6.8	Review and evaluate public comments and determine if any changes should be made to the regulations as noticed. If yes, use Action Plan - R15-day (Page 2).	525		Program Lead	15 days *
6.9	Prepare Updated Informative Digest, responses to all comments, regulation text, and FSOR.	570		Program (RPT Assist)	45 days *

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6.10	Review of Updated Informative Digest, All Responses to Comments, Regulation Text, and FSOR.	579		RPT (Program Lead)	9 days *
6.11	Finalize documents and obtain concurrence of RPT to proceed.	594		RPT (Program Lead)	15 days *
6.12	Obtain Center Deputy approval.	603			9 days *
7.	**Complete rulemaking file.**			**OOR**	**Concurrent with Step 8.**
8.	**Route package for Director's signature, complete rulemaking file. Submit package to OAL. (Must be on or before one year from Step 6.5.)**	**612**		**OOR**	**9 days ***
9.	**OAL review of package and if approved, filing with the SOS.**	**657**		**OOR**	**45 days (30 working days)**
10.	**Regulations become effective 30 days after filing with SOS or on an alternative designated date.**	**687**		**OOR**	**30 days**

* ***Actual review time frames will vary depending on the size and complexity of each regulation package.***

Program Lead maintains the official version of regulation documents through Center Approval (Step 3). OOR Lead maintains the official version from Step 4 through the end of the process. Co-leaders will ensure that each Lead has copies of the most current version at all steps through the process.