



KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

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



EDMUND G. BROWN JR.
Governor

December 18, 2015

Mr. Christian E. Einberg, Chief
Agreement State Programs Branch
Division of Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Einberg:

Thank you for the opportunity to review and comment on the U.S. Nuclear Regulatory Commission's (NRC) Integrated Materials Performance Evaluation Program (IMPEP) draft report that was issued after concluding a review of the California Agreement State Program (Program) during the week of October 5, 2015. The California Department of Public Health (Department) is pleased to learn that the review team's proposed recommendations are that the Department's Program be found adequate to protect public health and safety, and compatible with the NRC's program.

We have reviewed the draft report along with the three NRC recommendations for improvement in the sealed source and device evaluation program. Our comments are as follows:

1. The Department would like to bring to your attention that the second recommendation of the Summary on page 15 is in conflict with the detailed evaluation language found on page 14. Specifically, the page 14 detailed evaluation language states, "The review team recommends that the Program implement a process to ensure that radioactive material incidents involving sealed sources and devices registered by California are periodically and independently assessed by the State for generic issues and that any potential generic issues are communicated to licensees and fellow regulators in a timely manner." In contrast to that, the Summary on page 15 states, "The review team recommends that the Program implement a process to ensure that radioactive material incidents involving sealed sources and devices registered by other jurisdictions are periodically and independently assessed by the State for generic issues and that any potential generic issues are communicated to licensees and fellow regulators in a timely manner."



Mr. Christian E. Einberg
Page 2

The Department's view is that the page 14 language is correct, since California has no regulatory authority over other jurisdictions' registries. Furthermore, the Department is concerned that the recommendation does not recognize a formal process that it has had in place for a number of years for identifying sealed source and device (SS&D) issues based on event reports that the Program receives via its 5010 investigation form. The Department believes that the Program's process for evaluating SS&D incidents to detect possible manufacturing defects and the root causes of these incidents has been adequate and consistent with NRC processes, including evaluation of incidents to determine if other products may be affected by similar problems, and notifications to NRC, Agreement States, and others as appropriate.

Accordingly, the Department requests that recommendation number two be removed from the IMPEP report. Should the NRC disagree, the Department asks that specific NRC guidance be provided on what constitutes an adequate "formal process" for identifying potential generic issues associated with sealed sources and devices registered by California.

2. The Department does not have any comments concerning recommendations one and three.

The Department appreciates the NRC's offer to provide invitational travel to the Management Review Board meeting in January 2016. We would prefer to use video conferencing for this meeting.

Again, thank you for the opportunity to review and comment on the NRC's IMPEP draft report of the California Agreement State Program. I can assure you the Department is committed to maintaining its satisfactory standing and looks forward to working with the NRC on improvements that will strengthen its protection to public health in California.

Sincerely,



Karen L. Smith, MD, MPH
Director and State Public Health Officer