

Fiscal Year 2016 California IMPEP
Comment Resolution for the December 18, 2015, letter from California
(ML15365A402)
regarding the November 13, 2015, draft IMPEP report

California Comment 1

Section 4.2.c and section 5.0:

California commented on the discrepancy in language for Recommendation #2 as it is described in Section 4.2.c and Section 5.0. In Section 4.2.c, “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 Section 5.0, the recommendation is summarized as “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.”

NRC Response

The recommendation is correctly stated in Section 4.2.c and not in Section 5.0. The discrepancy was the result of an editing error and inadvertently missed when the report was finalized. The team acknowledges that California does not have regulatory authority over other jurisdictions. As noted below, this recommendation was removed from the report.

California Comment 2

Recommendation #2

Recommendation #2 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.” California is concerned that the recommendation does not recognize a formal process that it has had in place for a number of years for sealed source and device (SS&D) issues based on event reports that California receives via its 5010 investigation form. California believes its process for evaluating SS&D incidents to detect possible manufacturing defects and the root cause 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.

NRC Response

The review team agrees to withdraw recommendation #2. As written, the recommendation implies that California does not have a process to evaluate sealed source and devices registered by California for generic issues. The team observed that California has a robust system for performing an investigation once California receives a report of an apparent generic issue. Thus, California's process meets the intent of the IMPEP evaluation criteria. California receives information on potential SS&D generic issues from the manufacturer/distributor, users, inspection staff, and the NRC and takes appropriate action.