

DEPARTMENT OF HEALTH SERVICES

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May 5, 1997

Mr. Richard L. Bangart, Director
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

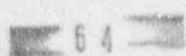
Dear Mr. Bangart:

Thank you for your letter of March 11, 1997, and the Draft Report on the Integrated Materials Performance Evaluation Program (IMPEP) review of California's Agreement State program which was conducted October 21-25, 1996. I have been informed by the staff involved in the review that it was conducted in a very professional manner and that the IMPEP review process itself is a great improvement over the process previously used by the U. S. Nuclear Regulatory Commission (NRC). Especially important was the perspective and balance brought to the review team and its conclusions by the inclusion on the review team of a representative from another Agreement State.

The draft report has been reviewed and found to be accurate in its factual findings.

The draft report identifies two areas of concern, the timely adoption of regulations and the quality of sealed source and device (SS&D) evaluations. The Department of Health Services is trying to make improvements in both of these areas, and I believe that the draft report bears out the fact that improvements have been made in both areas since the time of the last review.

Over the long term, the solution is getting more people to work in these activities. Toward that goal, the Radiologic Health Branch (RHB) has conducted a baseline study of its mandates, responsibilities, and activities and the resources, both people and funding, necessary to meet these. As a result of that baseline study, RHB developed and presented a Budget Change Proposal (BCP) which if approved would significantly increase both the staff and funding of RHB. This BCP was supported by this Department, the Health and Welfare Agency, the Department of Finance, and is included in the Governor's Budget for the next fiscal year beginning July 1, 1997. Presently the BCP is awaiting budget committee hearings in both the Assembly and the Senate. We are optimistic that the BCP will be successful. If approved, there would be an additional \$3,123,000 and 38.5 full time equivalents added to the present budget and staff of RHB.



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Additional staff would include two health physicists for regulation development and adoption work and an attorney for efforts related to regulation development and adoption and other activities of RHB requiring legal advice and assistance such as enforcement efforts. Included in the BCP are three additional health physicists and support staff for the unit that performs SS&D evaluations. Also included in the BCP is a request for \$180,000 to pay for technical training of the staff of RHB to replace training previously provided by NRC. We still feel that NRC is remiss in not providing training to the staffs of Agreement States, especially in view of the amount of money paid to NRC by licensees in Agreement States and the overall savings in federal costs that the Agreement States provide. I sincerely hope and request that the Commissioners of NRC will reconsider this decision.

With regard to the present status of regulations that were found to be overdue for adoption, the following information is provided:

1. "Definition of Land Disposal and Waste Site QA Program" -- There has been no change in the status of this regulation since the time of the review, and it is still scheduled for adoption by October 1, 1997.
2. "Notification of Incidents" -- This regulation involves a notification requirement that was inadvertently deleted by NRC when it adopted a complete revision of 10 CFR Part 20, and therefore had to be subsequently readopted by NRC. RHB, in adopting 10 CFR Part 20 by reference, also deleted this previously required notification. Proposed regulations to add this provision into the California regulations were submitted to the Office of Regulations (OR) on February 5, 1997, and are currently set for public hearing on June 9, 1997. From the time a proposed regulation is presented to OR, it is a minimum of 274 days before the regulation can become effective unless it is submitted as an emergency regulation, which this one was not. From a practical standpoint, California licensees are already complying with the notification requirements of this regulation because they were used to the old regulation which was rescinded. For example, earlier this year ICN had a fire at its facility that did not meet any of the notification or reporting requirements in the current California regulations; nonetheless RHB was notified immediately of the fire and the resultant damage.
3. "Quality Management Program and Misadministrations" -- California regulations presently contain a more stringent misadministration reporting requirement than do those of NRC. We do not intend to lessen those requirements to be identical to those of the NRC. No action is planned on the quality management program portion of the NRC regulation until the Commissioners of the NRC reach final resolution on the recommendations of the National Academy of Sciences, Institute of Medicine study regarding NRC's role in the regulation of the medical use of radioactive materials and other sources of radiation.

4. "Licenses and Radiation Safety Requirements for Irradiators" -- RHB is currently preparing the regulation package to submit to begin the regulation adoption process. It is anticipated that this package will be submitted to OR by the end of June 1997. Historically, RHB has licensed five large irradiator facilities of the type covered by this regulation; in addition, several other machine irradiation facilities with similar hazards and radiation dose rates are regulated by RHB. The first license for a large irradiator using radioactive materials was issued by RHB on February 20, 1969. In the almost 30 years since, RHB has licensed four additional facilities and overseen the decontamination and decommissioning of two of these facilities. The three currently licensed facilities meet all the licensing requirements in 10 CFR Part 36 and are subject to all safety equipment and procedures of those regulations. During the review these substantive determinations were made by the review team. The absence of California regulations identical to those of NRC does not constitute a health and safety issue at any of the three large irradiators in California. All requirements of 10 CFR Part 36 have been met in the license application review process, license conditions, and other California regulations.

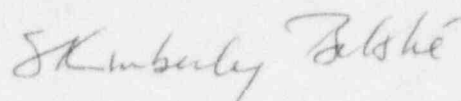
The other program area found to need improvement was the SS&D evaluation effort. RHB has already begun to address all the issues and recommendations noted in the Draft Report. Two staff members, David Wesley, Senior Health Physicist, and Thomas A. Schell, Associate Health Physicist, attended the "Workshop on Sealed Source and Device Evaluations" that was held at NRC Headquarters in Rockville, Maryland, on April 7-11, 1997. As other workshops and training courses become available, other RHB staff will attend to receive training in the new processes and procedures used in SS&D evaluation and documentation. It is anticipated that all issues raised by the Draft Report will be fully resolved by the time of the Management Review Board (MRB) meeting at which final determinations are made with regard to the adequacy and compatibility of the California Agreement State program.

In conclusion, we feel that the Agreement State program in California is not only adequate but is doing an excellent job of protecting the health and safety of radiation workers and other members of the public from the potentially deleterious effects of radiation from radioactive materials. It is our conclusion that the program is in all substantive matters compatible with the requirements, policies, and procedures of the NRC. We believe that MRB will also find the Agreement State program in California adequate to protect the public health and safety and compatible with the regulatory requirements and programs of the NRC.

Mr. Richard L. Bangart
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We look forward to meeting with MRB and our continued mutual effort to maintain and improve the radiologic health of the nation. If we can provide you with additional information or answer any questions, please contact me or Larry Barrett, D.V.M., M.S., Chief, Division of Food, Drug, and Radiation Safety, at (916) 324-3266.

Sincerely,

A handwritten signature in cursive script, reading "S. Kimberly Belshé".

S. Kimberly Belshé
Director

cc: Dr. Shirley Ann Jackson, Chairman
Mr. Nils Diaz, Commissioner
Ms. Greta Dicus, Commissioner
Mr. Edward McGaffigan, Commissioner
Mr. Kenneth Rogers, Commissioner
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001