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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

October 6, 1997

Philip J. W. Lee, M.D.
A. Y. Wong Building
1507 South King Street, Suite 101
Honolulu, Hawaii 96826

SUBJECT: NRC INSPECTION 030-03545/97-01

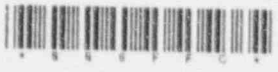
Dear Dr. Lee:

On August 27-28, 1997, the NRC conducted an inspection at your facility in Honolulu, Hawaii. The inspection findings were subsequently discussed with you during a telephonic exit briefing on September 16, 1997.

The inspection included a review of corrective actions taken in response to violations identified during the last inspection completed by NRC on February 3, 1997, involving your quality management program (QMP) and misadministrations associated with your use of a strontium-90 (Sr-90) ophthalmic applicator. The misadministrations had been caused in part, by the lack of accurate information regarding the actual output of the applicator source, by your failure to accurately correct the source dose rate for radioactive decay, and the absence of a written procedure or guidance for performing the calculations. Our recent inspection determined that the QMP had been implemented in accordance with the corrective actions described in your letters to NRC dated March 25, 1997, May 5, 1997, and June 27, 1997, and that within the program areas reviewed, no violations of NRC requirements were identified.

Our inspection confirmed that in January 1996, the National Institute of Standards and Technology (NIST) re-calibrated your Sr-90 applicator, and the NIST calibration report sent to you on January 22, 1996, specified an absorbed-dose rate to water output of 0.18 Gy/sec (18 rad/sec) at the source surface. This dose rate, decay-corrected using a 28.5 year half-life, was subsequently used by you for calculating exposure times for several patient treatments. However, on February 10, 1997, your consultant medical physicist computed decay-corrected dose rates for the applicator which were based on the original manufacturer's (Tracerlab) calibration data (47 rads/sec on April 4, 1961). Beginning on April 1, 1997, a Tracerlab decay-corrected dose rate of 19.5 rad/sec, computed by your consultant, was used in calculating treatment times for several additional patients.

Comparison of the calibrated dose rates between Tracerlab and NIST data, as noted above, indicates a difference of 11-12 percent, and a corresponding difference in the calculated times you had used for patient treatments since April 1, 1997. Information provided by Tracerlab with your applicator in 1961 indicated that the manufacturer's assigned dose rate was considered tentative and could change in the future as a result of improvements



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in the calibration technique. We believe that the current NIST calibration data is the most accurate since it is based on improved calibration methodology, and it should therefore be used as a basis for all of your patient treatment time calculations. This was discussed with you during the telephonic exit briefing. Based on your conversation with Region IV staff during the briefing, it is our understanding that you have agreed to use the NIST calibration data and to recalculate future treatment times based on the NIST data. Consequently, we request that, within 30 days from the date of this letter, you: 1) provide a written reply to NRC stating that you will utilize NIST calibration data for calculating all future patient treatment times and 2) revise and provide to NRC a copy of the decay-corrected dose rates for the Sr-90 applicator of the type prepared by your consultant which are based on NIST calibration data. Should your understanding differ from that presented above, you should notify us in writing.

During our inspection, we also identified a deficiency in your QMP involving written directives. Although all of your written directives for patient treatments completed since the last inspection had correctly included treatment site, exposure time, and total dose, as defined in 10 CFR 35.2, they had omitted the Sr-90 source strength used for each treatment. Therefore, in your written reply, please confirm that you will revise future written directives to also include the source strength. Since such a change constitutes a revision to your QMP, you are reminded to submit a copy of the revised written directive and QMP to NRC within 30 days of the change, as required by 10 CFR 35.32(e).

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room (PDR).

Should you have any questions concerning this inspection, please contact Mr. David D. Skov at (510) 975-0253 or Mr. Frank Wenslawski at (510) 975-0219.

Sincerely,

Linda Howell for

Ross A. Scarano, Director
Division of Nuclear Materials Safety

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