NOTICE OF VIOLATION

Philip .I. W. Lee, M.D.
Honolulu, Hawaii

Docket No. 030-03545
License No. 53-04935-01
EA 97-038

During an NRC inspection completed February 3, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

A. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

Pursuant to 10 CFR 35.32(a)(3), the quality management program must include written policies and procedures to meet the specific objective that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with a written directive, which is defined in 10 CFR 35.2.

Contrary to the above, as of November 15, 1995, the licensee's quality management program did not include a written procedure to meet the objective that finals plans of treatment and related calculations for brachtherapy treatments were in accordance with the applicable written directive. Specifically, the licensee did not have a written procedure for performing decay correction calculations required to determine treatment times for treatments performed using a strontium-90 ophthalmic applicator. As a result, treatment times for 17 treatments were incorrectly calculated and the doses administered in 17 treatments exceeded the intended dose, as documented in the applicable written directives, by greater than 20 percent. (01013)

This is a Severity Level III violation (Supplement VI).

B. 10 CFR 35.33(a)(3) requires, in part, that the licensee notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgement, telling the individual would be harmful.

10 CFR 35.33(a)(4) requires, in part, that if the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either a copy of the report that was submitted to the NRC or a brief description of both the event and the consequences as they may affect the individual.

Contrary to the above, on February 6, 1996, the licensee was made aware of 17 misadministrations involving treatments performed using a strontium-90 ophthalmic

applicator and the individuals receiving the misadministrations were not notified of the misadministrations until March 21, 1996, a period in excess of 24 hours, and the referring physicians had not informed the licensee that they would inform the individuals or that based on their medical judgement, telling the individuals would have been harmful. In addition, letters sent by the licensee to inform the individuals, dated March 21, 1996, did not include a description of the consequences of the misadministrations. (02014)

This is a Severity Level IV violation (Supplement VI).

With respect to Violation A above, the NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 030-03545/95-01 and a letter from Dr. Lee dated March 25, 1997. Therefore, no response to this violation is required. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

With respect to Violation B above, and pursuant to the provisions of 10 CFR 2.201, Dr. Lee is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region IV, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response

that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated at Arlington, Texas
this 16th day of April 1997