Yale New Haven Hospital
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20 York Street, New Haven, CT 06504

January 26, 1994

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EA Nos. 92-241 & 93-016

James Lieberman, Director
Office of Enforcement
U.S. Nuclear Regulatory Commission
Attn. Document Control Desk
Washington, D.C. 20555

Re: Response to NRC Order Imposing Civil Monetary Penalties

Dear Mr. Lieberman:

In response to your order dated December 27, 1993, Yale-New Haven Hospital (YNHH) has elected to pay the civil penalty. Nonetheless, we wish to inform the Commission that in doing so we are not acknowledging the validity of the NRC's views stated in its December 27 Order. Rather, we have chosen to take this course because we believe that further appeals and legal challenges will serve only to diminish our program resources while offering little chance of altering the NRC's approach in its implementation of the Quality Management rule.

YNHH does not challenge the imposition of the Civil Penalty with respect to the issue regarding the lost source, nor does it dispute the facts related to the specific administrations involved here. Rather, it is the position of YNHH that the NRC has embarked upon a course in which it will find a violation of the Quality Management Program (QMP) requirements in any case in which a misadministration occurs. In so doing the NRC is imposing a <u>per se</u> rule upon licensees and exceeding its authority by infringing upon judgments which only licensed physicians can reasonably make.

In finding the procedures of YNHH's QMP insufficiently specific the NRC has acknowledged that our QMP did require verification of correct placement of the source. Moreover, in both cases involved here, steps were taken by the physicians to make such verifications. In the first case such verification was made by following certain specific procedures, and in the second, the physician used touch, determined the configuration of the applicator and inquired about the patient's comfort in order to

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verify the correct placement. Thus, we would maintain that the QMP's procedure provided the physicians in question with sufficient specificity to have completed the treatments appropriately. Unfortunately, despite this, errors went unrecognized. It is our belief that errors of this nature are unlikely to be prevented by even the most stringent and specific written procedures.

We would like to point out to the NRC in this case that our QMP had been submitted to the NRC in accordance with instructions over 10 months prior and YNHH was never informed of any inadequacies in its program. Moreover, the visual checks which the NRC has now suggested should be contained in the QMP are not required under 10 C.F.R. s. 35.32(a)(4). Instead, the NRC suggests with the benefit of hindsight that the lack of such checks in our program constitutes a violation.

The NRC's treatment of the Quality Management Rule as a per se rule is also inconsistent with the earlier removal of the word "ensure" from the regulatory objective in 10 C.F.R. s. 35.32(a)(4) which was done with the explicit intention of removing the connotation that all errors are to be prevented. (July 25, 1991).

Finally, we also object to the NRC's characterization of the YNHH program as inadequate and declining in performance. We believe that such a characterization contradicts abundant evidence to the contrary. First, the Hospital has demonstrated that it immediately identified and comprehensively corrected the problems involved. Second, an independent audit of our program by highly qualified individuals identified no significant problems in the Hospital's policies and procedures. Rather, the bulk of the recommendations made by this team were directed at the Hospital's diagnostic imaging program and not its radiation safety aspects. Finally, the NRC's latest licensure inspection which followed on the heels of these incidents was characterized in the exit interview as having been a "clean" inspection with no violations identified. A apparent Severity Level V violation was cited only after the fact.

In summary, we believe that the NRC has embarked upon a road outside of the scope of its authorized powers and strongly urge the NRC to reconsider the current direction of its policies in this regard.

Respectfully Submitted,

Yale-New Haven Hospital

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VP, Administration

Stuart G. Warner
Assistant Counsel