

APPENDIX A
NOTICE OF VIOLATION

Yale-New Haven Hospital
New Haven, Connecticut

Docket No. 030-01244
License No. 06-00819-03

During an NRC review of documents related to the therapeutic misadministration that occurred on July 5, 1991, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

10 CFR 35.33(a)(3) requires, in part, that the licensee also notify the patient or a responsible relative (or guardian) of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee that, based on medical judgement, telling the patient or the patient's responsible relative would be harmful.

Contrary to the above, on January 30, 1992, the Licensee discovered that a misadministration had occurred at its facility on July 5, 1991, and as of December 1, 1994, the Licensee had not notified the patient's responsible relative (or guardian) of the misadministration and the referring physician had not determined that, based on medical judgement, telling the patient's responsible relative would be harmful to patient's responsible relative (or guardian).

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

Pursuant to the provisions of 10 CFR 2.201, Yale-New Haven Hospital, New Haven, CT, 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 I, 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. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause 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.

OFFICIAL RECORD COPY - S:\PENDING\YALE-NH2.NOV - 12/01/94

9501100036 941214
PDR ADOCK 03001244
C PDR

RETURN ORIGINAL TO
REGION I

1817