

NOTICE OF VIOLATION

Memorial Hospital
South Bend, Indiana

Licenses No. 13-18881-01
13-18881-02
Dockets No. 030-17335
030-19173

During an NRC inspection conducted on May 4-5 and 10, 1994 and on June 24, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C the violations are listed below:

- A. 10 CFR 35.21(b)(1) requires, in part, that the licensee's radiation safety officer investigate accidents, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary.

10 CFR 35.22(b)(5) requires, in part, that the licensee's radiation safety committee review quarterly all incidents involving byproduct material with respect to cause and subsequent actions taken.

Contrary to the above, as of May 5, 1994, the licensee's radiation safety officer and radiation safety committee did not adequately investigate an incident which occurred on April 13, 1992 with respect to cause and subsequent actions taken. Specifically, the licensee's radiation safety officer and radiation safety committee did not evaluate possible radiation doses to unintended treatment sites as a result of a displaced 46 millicurie (1700 MBq) cesium-137 brachytherapy source from a temporary brachytherapy implant, which resulted in a misadministration.

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

- B. 10 CFR 35.33(a)(4) requires that, if the patient was notified of the misadministration, the licensee furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either: (i) a copy of the report that was submitted to the NRC pursuant to 10 CFR 35.33(a)(2); or (ii) a brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC pursuant to 10 CFR 35.33(a)(2) can be obtained from the licensee.

Contrary to the above, as of June 24, 1994, the licensee had not furnished a written report to the patient following the discovery of a misadministration on May 5, 1994, and notification of the patient of the misadministration on May 6, 1994.

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

- C. 10 CFR 71.5(a) requires, in part, that a licensee who delivers licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.475(i) requires that before each shipment of any radioactive materials package, the shipper ensure by examination or appropriate tests that external radiation and contamination levels are within the allowable limits specified in 49 CFR Parts 171 - 177.

Contrary to the above, as of May 5, 1994, the licensee delivered to a carrier for transport packages of radioactive materials, consisting of millicurie quantities of technetium-99m, and the licensee did not measure the contamination levels prior to offering the packages for shipment.

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

Pursuant to the provisions of 10 CFR 2.201, Memorial Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois, 60532-4351, 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 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.

Dated at Lisle, Illinois
this 15th day of July 1994