

NOTICE OF VIOLATION

Jackson County Schneck
Memorial Hospital
Seymour, Indiana

License No. 13-05605-01
Docket No. 030-01622

During an NRC inspection conducted on September 24, 1996, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

10 CFR 35.32(a)(1) requires, in part, that the licensee establish and maintain a quality management program which must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation and containing certain information including for administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, the required dosage.

Contrary to the above, the licensee used iodine-131 for multiple medical treatments of thyroid disease that required a written directive from January 1, 1992 to September 24, 1996 and, as of September 24, 1996, the licensee did not prepare the written directives for the administrations. Specifically, the authorized users did not sign and date the written directives.

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

Pursuant to the provisions of 10 CFR 2.201, Jackson County Schneck Memorial Hospital 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 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. 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. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Dated at Lisle, Illinois
this 5th day of November 1996