

DCD/DCB

DEC 01 1993

St. Margaret Mercy Healthcare
Centers, Inc.
ATTN: Ms. Anne Miller, Manager
of Imaging Services
U.S. Highway 30
Dyer, IN 46311

License No. 13-12914-01
Docket No. 030-01666

Dear Ms. Miller:

This refers to the routine safety inspection conducted by Mr. James Mullauer and Mr. Kevin Null of this office on June 28, 1993 with continuing NRC review through October 29, 1993, of activities authorized by NRC Byproduct Material License No. 13-12914-01, and to the discussion of our findings with you and other members of your staff at the conclusion of the inspection.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

During this inspection, certain of your activities were found to be in violation of NRC requirements, as specified in the enclosed Notice. A written response is required.

In addition to the violations, we are concerned that your Quality Management Program (QMP) states that an authorized user or medical director may sign and date a written directive. Please note that in accordance with 10 CFR 35.2, a written directive means an order in writing for a specific patient, dated and signed by an authorized user. Although the inspection did not reveal any written directive that was not signed by an authorized user, your written QMP will need to be revised to reflect the requirement in 10 CFR Part 35.

We are also concerned with the effectiveness of your audits of the QMP. Specifically, failure of the audit program to detect six (6) written directives which were not dated by the authorized user is indicative of a failure to conduct an adequate audit. In your response, please describe the changes that you will make to increase the effectiveness of your audit program.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room.

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The response directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

B. J. Holt, Chief
Nuclear Materials Inspection
Section 1

Enclosure: Notice
of Violation

bcc w/enclosure:
R. DeFayette, EICS
PUBLIC

RIII
(41) Null/jaw
11/19/93

yes
RIII
Mullauer
12/1/93

(yes)
RIII
Holt
12/1/93