



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

March 6, 1998

EA 98-023

James Meyer, President
MedCentral Health System
335 Glessner Avenue
Mansfield, OH 44903

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report 030-00407/98001(DNMS))

Dear Mr. Meyer:

This refers to the inspection conducted on January 5 through 21, 1998 at the MedCentral Health System located in Mansfield, Ohio. The purpose of the inspection was to review a reported teletherapy misadministration and to determine whether activities authorized by the license were conducted in accordance with NRC requirements. The subject inspection report documenting our findings was sent to you by a letter dated January 29, 1998. As indicated in our letter, apparent violations were identified which involved teletherapy operations and the reported misadministration. You were given the option of participating in a predecisional enforcement conference or submitting a written response to the apparent violations. You chose to submit a written response dated February 26, 1998.

Based on the information developed during the inspection and the information provided in your February 26 response to the inspection report, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in the subject inspection report. The violations involve failure to follow specific items of your quality management program (QMP), such as performance of second calculations by the technologists and second checks by the physicist to verify the correctness of the calculations. In addition, the violations include failure to perform reviews of modified written directives to ensure that all of the information is correct and on the record prior to administering the third patient treatment. As a result of these failures to fully implement the QMP, a misadministration occurred.

Although the misadministration did not appear to adversely effect the health of the patient and was properly reported to the NRC, the NRC is very concerned about the implementation of your QMP because these violations represent a breakdown in a program designed to reduce the probability of treatment errors. During the inspection, we learned that the QMP had been changed several times without appropriate NRC notification and apparently without conducting adequate personnel training. We believe that these factors contributed to the misadministration. The NRC expects each entity licensed by the NRC to use byproduct material responsibly by ensuring that the rules, regulations and license conditions are followed

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at all times. Failure to fully implement your QMP program and the resulting misadministration is a matter of significant regulatory concern to the NRC. Therefore, these violations are classified in the aggregate in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level III problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,750 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions within the last two years or last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective action is warranted because your actions were both prompt and comprehensive. These actions included, but were not limited to: (1) implementation of an improved check-off form used to document each step in the treatment series, (2) modifications were made to the QMP to clearly define the procedures for oral and written revisions to the written directive, and (3) appropriate staff is being or has been provided with training on the revised QMP procedures.

Therefore, to encourage prompt and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III problem constitutes escalated enforcement action, that may subject you to increased inspection effort.

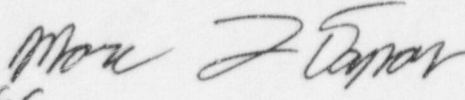
The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket in Inspection Report 030-00407/98001(DNMS) and the letter from the licensee dated February 26, 1998. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

J. Meyer

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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to respond, will be placed in the NRC Public Document Room.

Sincerely,


for

A. Bill Beach
Regional Administrator

Docket No. 030-00407
License No. 34-02007-02

Enclosure: Notice of Violation

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