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September 16, 1996

EA 96-289

Floyd D. Loop, M.D.
Chairman of the Board of Governors
Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195

SUBJECT: NRC INSPECTION REPORT NO. 030-02649/96001 (DNMS)
AND INVESTIGATION REPORT NO. 3-96-025

Dear Dr. Loop:

This refers to the inspection conducted on March 19-22, 1996, with continuing NRC review through August 6, 1996, at the Cleveland Clinic Foundation facility, Cleveland, Ohio. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with those members of your staff identified in the enclosed report.

Areas examined during the inspection are identified in the report. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observation of activities in progress.

This also refers to an investigation conducted by the NRC Office of Investigations (OI) to determine if your Director of Quality Management and Director of Radiation Safety deliberately violated NRC requirements pertaining to annual refresher training and annual senior management audits. A synopsis of the results of the investigation is enclosed.

Based on the results of the inspection and investigation, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (60 FR 34381; June 30, 1995). Two apparent violations pertain to the failure to implement annual refresher training for radiation workers from 1993 to 1996, and to perform an annual senior management audit in 1995. These apparent violations are of significant concern because they were apparently caused by two of your management officials who were knowledgeable of Cleveland Clinic Foundation's NRC-licensed requirements regarding refresher training and audit programs and who deliberately violated those requirements. The third apparent violation pertains to failure to secure from unauthorized removal or limit access to licensed materials that were stored in unrestricted areas.

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Three additional violations were also identified during this inspection but are not being considered for escalated enforcement at this time.

The apparent violations are described in the enclosed report and will be discussed with your staff in a transcribed predecisional enforcement conference. Consequently, a Notice of Violation is not presently being issued for these inspection findings. The number and characterization of the apparent violations may change as a result of further NRC review.

The transcribed predecisional enforcement conference has been scheduled for October 8, 1996, at 1:00 p.m. in the Region III office, 801 Warrenville Road, Lisle, IL. The decision to hold an enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. The purposes of this conference are to discuss the apparent violations, their causes and safety significance; to provide you the opportunity to point out any errors in our inspection report; and to provide an opportunity for your staff to present your proposed corrective actions. In particular, we expect you to address specific action to ensure licensed activities are conducted in full compliance with all NRC requirements and license commitments. In addition, this is an opportunity for you to provide any information concerning your perspectives on: (1) the severity of the violations, (2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and (3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In addition to the NRC findings identified in the March 1996 inspection, we would like to discuss during the predecisional enforcement conference the violations identified and your subsequent corrective actions regarding an iodine-131 contamination incident which occurred on August 27, 1996. The incident resulted in the uptake of iodine-131 to three Cleveland Clinic Foundation employees and off-site contamination at several locations. Consequently, you will be receiving an inspection report for your review describing NRC's findings prior to the October 8, 1996 conference.

To assist you in preparing for the predecisional enforcement conference, we are enclosing a copy of the NRC Enforcement Policy and an Information Notice which provides guidance on the development and implementation of corrective actions.

Please contact Mr. Michael LaFranzo at telephone number (630) 829-9865 if you have any questions.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and enclosures 1 and 2 will be placed in the NRC Public Document Room.

Sincerely,

Original signed by Cynthia D. Pederson

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

License No. 34-00466-01
Docket No. 030-02649

Enclosures: 1. Inspection Report
No. 030-02649/96001 (DNMS)
2. OI Synopsis
3. Enforcement Policy (NUREG-1600)
4. Information Notice 96-28

cc w/encls: Judy McKenna, RSO
Dr. Thomas Key, Director
of Quality Management

bcc w/encls 1 and 2: Office of Enforcement
D. Cool, NMSS
J. Goldberg, OGC
C. Weil, RIII

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