

THE CLEVELAND CLINIC
FOUNDATION



75 Years of World-Class Care

BY MESSENGER

January 16, 1997

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555

Re: Reply to December 20, 1996 Notice of Violation
Docket No. 030-02649
License No. 34-00466-01

Dear Sir:

As requested by the Nuclear Regulatory Commission and in accordance with 10 C.F.R. Section 2.201, The Cleveland Clinic Foundation (The Foundation) is submitting this letter in response to the Notice of Violation and Proposed Imposition of Civil Penalty issued by the NRC on December 20, 1996. The Foundation's response follows the format used and suggested by the NRC in the December 20, 1996 Notice.

I. Violations Assessed as a Civil Penalty Associated with Conduct of Training and Audits

A. Annual Training of Laboratory Workers - Item 8 of May 12, 1992 Letter

1. The Foundation admits that research laboratory workers did not receive annual refresher training in the form of lecture, discussion and demonstration, as set forth in Item 8 of the May 12, 1992 Letter, although they did receive refresher training in the form of quarterly memoranda distributed by the Radiation Safety Officer (RSO) detailing new requirements and in the form of day-to-day communications with and suggestions from the RSO based on first-hand observation of practices and procedures. The delayed training did not negatively impact patient care.

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2. The Foundation's Radiation Safety Department (RS) was focusing its efforts on these other training vehicles -- quarterly update memoranda and day-to-day communications with laboratory workers -- as well as other issues in The Foundation's licensed program.
3. Beginning in April, 1996 through October, 1996, RS provided several refresher training sessions to Authorized Users and their Safety contacts. Authorized Users and their Safety contacts were provided outlines and instructed to retrain those research laboratory workers whom they supervise.

The 1997 annual refresher training sessions for all research laboratory workers have been scheduled for April, May and June, 1997. Additional sessions will be scheduled if necessary.

4. RS has developed specific Policies which outline requirements and procedures to complete the annual training. The policies regarding this subject were approved by the Director of Clinical Effectiveness, Chairman of the Radioisotope and Radiation Safety Committee, and the Radiation Safety Officer. Through these Policies, The Foundation Senior Management will be kept apprised of the status of compliance matters and will assure future compliance.

In addition, RS has implemented a regulatory compliance calendar to track requirements, deadlines and compliance with the refresher training, as well as other compliance matters.

Also, through The Foundation's Corporate Compliance Program, the Office of General Counsel will monitor licensee requirements, provide reminders for deadlines, and implement systems designed to detect potential compliance issues.

5. The 1996 refresher training sessions described above were completed on or before October 31, 1996. For the future, full compliance will be obtained during each calendar year.

B. Annual Management Tour/Audit - Item 7.1 of May 12, 1992 Letter

1. The Foundation admits that for 1995 it did not conduct the annual management tour/audit, as set forth in Item 7.1 of the May 12, 1992 Letter, although it did plan a tour/audit conducted by an independent expert, Dr. Richard Vetter (the RSO of the Mayo Clinic), and that audit concluded there were no problems of any significance. Based on other audits during 1995 and other information known to the RSO, the RSO correctly concluded that no safety concerns resulted from the delay in the 1995 management tour/audit. There was no negative impact on patient care.
2. Upon evaluation of The Foundation's audit program -- including the management audit and the various other existing periodic audits and evaluations of its licensed program conducted by The Foundation internally -- it was determined that, to achieve continuous quality improvement for the existing audit program, an independent evaluation of The Foundation's licensed program was appropriate and would result in a fresh perspective because the traditional audit/tour was largely duplicative of other assessments by management during 1995. To this end, The Foundation decided to hire an outside consultant to conduct the next management audit.

Furthermore, the RSO submitted a request for amendment to the current license in order to modify the annual management tour/audit requirement to reflect this new approach. This request was submitted to the NRC on June 11, 1996 (the lapse of time was due to unanticipated delays in a separate project for which The Foundation was also seeking a license amendment).

3. To achieve its goal of continuous quality improvement and to obtain a fresh perspective, The Foundation hired Dr. Richard Vetter of the Mayo Clinic who conducted an audit on July 2 and 3, 1996. Dr. Vetter's resulting report and recommendations were reported to the Radioisotope and Radiation Safety Committee (RRSC) on July 30, 1996.

In addition, Senior management conducted other tours/audits on September 10, 1996 and December 16, 1996. The summary of these other two management audit/tours was presented to the RRSC for review during the first 1997 quarterly RRSC meeting on January 13, 1997.

4. The RS has implemented a regulatory compliance calendar to track requirements, deadlines and compliance with the management tours/audits, as well as other compliance issues. Through procedures adopted in association with the compliance calendar, Senior Management will assure that the audit is performed in accordance with its license requirement.

Also, through The Foundation's Corporate Compliance Program, the Office of General Counsel will monitor licensee requirements, provide reminders for deadlines, and implement systems designed to detect potential compliance issues.

5. For 1996, full compliance was obtained on or before December 16, 1996. For future audits, full compliance will be obtained during each calendar year.

C. Penalty Payment For Above Violations

1. In accordance with 10 C.F.R. Section 2.205, The Foundation is submitting under separate cover full payment of the NRC's proposed \$5,000 civil penalty.

II. Violation Not Assessed a Civil Penalty Associated with Securing and Limiting Access to Licensed Material (10 C.F.R. Section 20.1801, et seq.)

- 1-2. Admitted. It occurred due to a temporary, very short-term and undiscovered malfunction in the key card security system in the FF Research Laboratory Building (FF Building) and because laboratory employees did not fully appreciate NRC requirements. There was no negative impact on patient care.
3. As noted in the NRC's December 20, 1996 letter, The Foundation has taken prompt and comprehensive responsive action with respect to the above. These actions included:
 - a. The key card system has been repaired and modified to restrict access to the FF Building.
 - b. Security for the FF Building has been heightened.
 - c. Research Laboratory Approved Users have been educated on the need to control access to their laboratories at all times and to be in attendance during experiments with licensed materials.

- d. RS has implemented quarterly review of security measures, which include after-hour inspections.
 - e. Security checks by The Foundation Police -- which have always been conducted on a frequent basis -- have been increased.
- 4. The Foundation is in the process of undertaking additional responsive actions. These actions include:
 - a. RS will continue quarterly security investigations for all buildings.
 - b. RS will continue to educate all radiation workers to increase their awareness of and attention to security precautions for licensed materials.
 - c. RS will revise the Radiation Safety Manual to instruct approved users on the appropriate measures to be used to attend and secure licensed materials.
 - d. The Foundation Police will perform additional surveillance and checks on the security systems for licensed materials.
- 5. Full compliance was achieved shortly after March 19, 1996.

III. Violations Not Assessed Civil Penalty Associated with Authorized Possession Limits, Ordering and Receiving Licensed Materials and Surveys

A. Authorized Possession Limits

- 1. The Foundation admits that on several occasions between December, 1994 and February, 1996, Research Laboratory Authorized Users exceeded total possession limits. Patient care was not impaired.
- 2. A written procedure had not been developed.
- 3. Effective on October 29, 1996, RS informed Authorized Users in research laboratories that any excess licensed material beyond the authorized possession limit must be either disposed of or transferred to RS, or that they must request an amendment to their pre-existing possession limits to the RRSC. Currently, all licensed materials are quantified and reported to RS on a quarterly basis.

4. The Foundation has also taken additional responsive actions to insure against future violations. RS has developed a policy to control the licensed material inventory, including audits of laboratory inventory records. The Policy was approved by the Director of Clinical Effectiveness, Chairman of Radioisotope and Radiation Safety Committee, and the Radiation Safety Officer.
5. Action was taken as of October 29, 1996 and full compliance was achieved on or before December 31, 1996.

B. Chemical Forms

1. The Foundation admits that prior to March 19, 1996, RS did not establish and maintain a comprehensive system for identifying chemical forms used in research laboratories. There was no negative impact on patient care.
2. A written procedure had not been developed.
3. On November 1, 1996, RS established the following:

Specific chemical forms on the purchase request prepared by the Authorized User are verified by RS before approval. Any request for a chemical form that has not been previously approved by the RRSC is denied. Any Authorized User who wishes to add a new chemical form must submit an amendment to the RRSC for approval before it is ordered. Once the licensed material is received, the chemical form is again verified by RS.
4. RS will monitor the effectiveness of these procedures.
5. Responsive actions were fully initiated on November 1, 1996, and full compliance was achieved on or before December 31, 1996.

C. Solubility Survey

1. The Foundation admits that it did not make solubility surveys.
2. Research laboratory personnel did not fully understand the recent standards for evaluating solubility of licensed material.

3. On December 5, 1996, RS distributed information to all Authorized Users on how to evaluate solubility according to NRC information notice 94-07. The pertinent section in the Radiation Safety Manual has also been revised. Further, RS reemphasized to all Authorized Users that solubility must be evaluated prior to disposal.
4. RS will periodically audit compliance with solubility standards. Approved Users will be held accountable for providing RS with this information.
5. Full compliance was achieved on or before December 31, 1996. Periodic audits will be conducted in 1997 and thereafter.

IV. Additional Information Requested

Mr. Beach's letter of December 20, 1996 requests the following information:

A. Schedule For Implementing the Security Key Card System For the FF Building

1. The 24-hour security key card system for the FF Building has been purchased and installed.

B. Schedule For Installing the "Mini-Bar" System

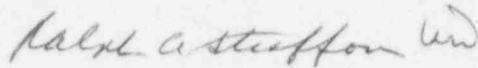
1. The Foundation has ordered 75 mini-bars and anticipates installation by April 30, 1997.
2. With respect to additional locations, The Foundation has not identified "mini-bars" which will accommodate different needs for locked freezer, refrigerator and/or room temperature space. The Foundation is investigating additional options, including specially designed units. The Foundation will provide you with a further status report on or before February 28, 1997.

We trust that the enclosed is fully responsive to your December 20, 1996, Notice of Violation. The Foundation is committed to a program of full compliance with NRC requirements and believes that the actions described in this letter will strengthen The Foundation's research programs. Patient care and safety issues were not implicated in the

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Notice of Violation. The Foundation remains committed to the highest standards of care and safety for its patients.

Sincerely,

Handwritten signature of Ralph A. Straffon in cursive, followed by a small "MD" monogram.

Ralph A. Straffon, M.D.
Chief of Staff

Handwritten signature of Melinda Estes in cursive, followed by a small "MD" monogram.

Melinda Estes, M.D.
Associate Chief of Staff
Director, Office of Clinical Effectiveness

cc: Regional Administrator,
U.S. Nuclear Regulatory Commission, Region III

Floyd Loop, M.D.

VERIFICATION

STATE OF OHIO)
) SS:
COUNTY OF CUYAHOGA)

Ralph A. Straffon, M.D., being first duly sworn under oath, states that I am Chief of Staff at The Cleveland Clinic Foundation and that the foregoing facts set forth in The Cleveland Clinic Foundation's Reply to December 20, 1996 Notice of Violation are true and correct to the best of my knowledge, information, and belief.

Ralph A. Straffon MD

Ralph A. Straffon, M.D.

SWORN TO AND SUBSCRIBED before me on this 16th day of January, 1997.

[Signature]

Notary Public

LESLIE A. GIETANO
Notary Public - State of Ohio
Cuyahoga County, Ohio
My Commission Expires On
February 26, 2001

VERIFICATION

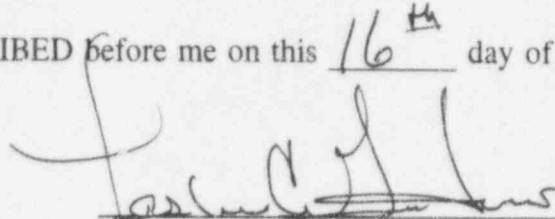
STATE OF OHIO)
) SS:
COUNTY OF CUYAHOGA)

Melinda Estes, M.D., being first duly sworn under oath, states that I am an Associate Chief of Staff at The Cleveland Clinic Foundation and that the foregoing facts set forth in The Cleveland Clinic Foundation's Reply to December 20, 1996 Notice of Violation are true and correct to the best of my knowledge, information, and belief.



Melinda Estes, M.D.

SWORN TO AND SUBSCRIBED before me on this 16th day of January, 1997.



Notary Public

LESLIE A. GIETANO
Notary Public - State of Ohio
Cuyahoga County, Ohio
My Commission Expires On
February 26, 2001