

DCCD

November 5, 1996

EA 96-289

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

SUBJECT: PREDECISIONAL ENFORCEMENT CONFERENCE SUMMARY

Dear Dr. Loop:

On October 22, 1996, representatives of The Cleveland Clinic Foundation met with NRC personnel in the Region III office located in Lisle, Illinois, to discuss the apparent violations identified in the NRC Inspection Report Numbers 030-02649/96001(DNMS) and 030-02649/96002(DNMS). The conference was held at the request of Region III.

The licensee generally agreed with the facts detailed in the inspection reports and did not contest any of the apparent violations.

The licensee indicated that the two apparent violations pertaining to annual refresher training for laboratory workers and the annual audit of the radiation safety program by senior management were the result of devoting time and resources to other radiation safety-related activities which were of greater priority. The licensee also stated that other aspects of its radiation safety program adequately covered the two commitments which were not performed as required. In response to these violations and other regulatory time tables, the licensee committed to implement a Radiation Safety Compliance Calendar. This compliance calendar will be reviewed monthly by the Radiation Safety Officer (RSO). It will be a standing agenda item for the routine meetings between the RSO, Dr. Melinda Estes, Associate Chief of Staff, and the new Director of Environmental Health and Safety. In addition, the Radiation Safety Committee will review the compliance calendar during each quarterly meeting and the Office of Corporate Compliance will review the Foundation's overall corporate compliance. The licensee stated the senior management officials, who review the Compliance Calendar, have the authority to implement all necessary changes to the radiation safety program to insure compliance with all NRC regulations and licensee commitments.

The licensee stated that it was particularly concerned about the third apparent violation regarding security of licensed material. Its representatives stated that the security key card system for Building FF has been repaired and quarterly after hours security sweeps by the radiation safety office staff have been implemented to insure security procedures are implemented by laboratories which use and store licensed material. In addition, the licensee committed to placing the FF building on a 24 hour security key card system,

9611080114 961105
PDR ADOCK 03002649
C PDR

10
IE07

obtain a "mini-bar" type system which will be used to lock refrigerators, freezers and cabinets which contain licensed material and to review security key card access procedures.

Regarding the two apparent violations on establishing and maintaining a system for ordering and receiving radioactive material, and limiting authorized users' total possession of radioactive material to quantities approved by the Radioisotope and Radiation Safety Committee, the licensee stated that a computer software package has been purchased, known as CHAMPS, which will verify and track all required information regarding licensed material received and distributed to users by the licensee. The licensee stated the software package had been received, appropriate data had been entered into the program and verification testing to insure the system is functioning properly will be completed in the near future. The licensee stated the system will be implemented after the verification testing is complete.

In response to the apparent violation on the evaluation of the solubility of liquids containing licensed material discharged into the sanitary sewerage system, the licensee stated it had provided authorized users with NRC's Information Notice 94-07 and directed them to use the methods described therein. In addition, the licensee committed to evaluate sewerage discharges of liquids containing licensed material from January 1994 through approximately June 1996 to insure compliance with NRC regulations.

The NRC summarized the licensee's response and corrective actions to the iodine-131 contamination event described in Inspection Report No. 030-02649/96002(DNMS). The licensee agreed with the summary as presented.

The attendance list is attached to this summary.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this summary and its enclosure will be placed in the NRC Public Document Room.

Sincerely,
Original Signed by Roy J. Caniano
 Cynthia D. Pederson, Director
 Division of Nuclear Materials Safety

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

Enclosure: Attendance List

cc w/encl: Melinda Estes, M.D.
 Associate Chief of Staff

DOCUMENT NAME: R:\LTRS2LIC\MTLS\030\96302649.L05

To receive a copy of this document, indicate in the box: "C" = Copy without enclosure "E" = Copy with enclosure "N" = No copy

OFFICE	RIII	<input checked="" type="checkbox"/>	RIII	<input checked="" type="checkbox"/>	RIII	<input checked="" type="checkbox"/>	RIII	<input checked="" type="checkbox"/>
NAME	LAFRANZO:dp	<input checked="" type="checkbox"/>	HOLT	<input checked="" type="checkbox"/>	BURGESS	<input checked="" type="checkbox"/>	PEDERSON	<input checked="" type="checkbox"/>
DATE	11/1/96	<input checked="" type="checkbox"/>	11/1/96	<input checked="" type="checkbox"/>	11/1/96	<input checked="" type="checkbox"/>	11/5/96	<input checked="" type="checkbox"/>

OFFICIAL RECORD COPY

F. Loop

-3-

Distribution

bcc w/encl:

Office of Enforcement

J. Goldberg, OGC

D. Cool, NMSS

C. Weil, RIII

PUBLIC IE07

ATTACHMENT

Conference Attendees

Licensee

Dr. Melinda Estes, Associate Chief of Staff
Robert Coulton, Administrator, Office of Professional Staff Affairs
Dr. Thomas Keys, Director of Quality Management
Judy McKenna, Former Radiation Safety Officer
George M. Von Mehren, Attorney

Nuclear Regulatory Commission

Region III

Roy J. Caniano, Deputy Director, Division of Nuclear Materials Safety
Bruce Burgess, Enforcement Director
Toye Simmons, Enforcement Specialist
Bruce Berson, Regional Counsel
B. J. Holt, Chief, Nuclear Materials Licensing Branch
Michael LaFranzo, Radiation Specialist
Wayne Slawinski, Senior Radiation Specialist
Darrel Wiedeman, Senior Radiation Specialist
Robert Gattone, Radiation Specialist

Office of Nuclear Material Safety and Safeguards (Present Via Telephone)

Dennis Serig, Regional Coordination & Events Section
Cynthia Jones, Office of the Director