U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-01879/93-001 Docket No. 030-01879

License No. 20-05766-02 Priority 3 Category G

Licensee: Lahey Clinic Foundation
41 Mall Road
Burlington, Massachusetts 01805

Facility Name: Lahey Clinic Hospital

Enforcement Conference Conducted At: King of Prussia, Pennsylvania

Enforcement Conference Conducted On: January 21, 1993

Prepared By: Sattar Lodhi 2-4-93
Sattar Lodhi, Ph.D., Health Physicist Date

Approved By: 2/4/93
Mohamed Shanbaky, Ph.D., Chief Date
Medical Inspection Section

Conference Summary: An Enforcement Conference was held at the NRC Region I Office in King of Prussia, Pennsylvania on January 21, 1993 to discuss the reported therapeutic misadministration and the violations identified during a routine inspection conducted on December 3, 23 and 29, 1992. The corrective actions taken and planned by the licensee since the inspection were also discussed. Enforcement options available to the Commission were explained.

DETAILS

1.0 Attendees

Lahey Clinic Foundation:

D. Harding, Vice President, Administration
D. Cameron-Hall, Vice President, Legal Affairs
T. Lo, M.D., Authorized User & Oncologist
H. Mower, Physicist and Radiation Safety Officer

NRC:

R. Cooper, Director, Division of Radiation Safety and Safeguards
R. Bellamy, Chief, Nuclear Materials Safety Branch, DRSS
D. Holody, Enforcement Officer, RI
K. Smith, Regional Counsel, RI
M. Banerjee, Enforcement Specialist, RI
S. Lodhi, Health Physicist

2.0 Summary

Representatives of Lahey Clinic Foundation met with NRC representatives on January 21, 1993 in the Region I Office at King of Prussia, Pennsylvania. The meeting was open to members of the public for observation, however, no member of the public attended the meeting. In his opening remarks, Mr. Richard Cooper stated NRC's policy to open some of these meetings to public observation. He also explained the purpose of the conference. The Enforcement Officer explained to the licensee the NRC's Enforcement Policy.

Mr. Cooper asked the licensee if there were any omissions of facts or corrections that they noted in the NRC Inspection Report sent to them on January 12, 1993. The licensee stated that they are submitting a written response to the report (Enclosure 2). Mr. Douglas Harding in his opening remarks stated licensee's continued commitment to comply with all regulatory requirements and cited the licensee's previous inspection history.

The Oncologist stated the sequence of events that led to the therapeutic misadministration. He stated that he has always prescribed the offset distances in centimeters in his written prescriptions although the HDR's computer system requires that these distances be entered in millimeters at the time of treatment. He also stated

that the staff physicists who enter these parameters at the time of patient treatment are aware of this and have always entered correct parameters except in one case on October 14, 1992 when the misadministration occurred. He stated that the system requires several distances to be entered at the time of the treatment and that all of these distances are required to be entered in centimeters except two that are required to be entered in millimeters. He also stated that the manufacturer of the system or users can not make any changes in the software of the system without getting approval from the Food & Drug Administration.

The RSO then presented licensee's response to the Inspection Report and the apparent violations contained in the report. He stated that their procedure called for one physicist to call out the parameters that he entered into the console at the time of treatment and the second physicist or the authorized user compared these parameters with those in the prescription and that the inspection report had this sequence in a reversed order. He stated that the licensee disagrees with the characterization of first violation as stated in the summary on page 2 of the inspection report but admitted that their Quality Management Program did not meet the objective that each administration is in accordance with the written procedure. The licensee also admitted that the geometry test of the dose calibrator was not performed in a timely manner but the accuracy, constancy and linearity tests were performed on September 14, 1992 and submitted records of accuracy, constancy, and linearity tests of the dose calibrator (Enclosure 3). The licensee admitted the other violations and elaborated on the circumstances that led to these violations and the corrective actions that have been taken and are planned to prevent a recurrence of similar violations. The details of licensee's response are included in Enclosure 2 that was submitted at the conference. The licensee stated that negotiations to provide radiation safety training to code team members are in progress with the agency that provides the licensee with the members of the code team. The licensee also stated that the required annual audit of their program was in progress. The licensee agreed to send to the NRC the record of telephone calls made to the Region I Office to notify the NRC of the misadministration, the final report of the program audit and the results of negotiations with the agency that provides the members of the code team to the licensee.

Mr. Cooper thanked the licensee's representatives for their forthrightness. The meeting was adjourned.

sponse to letter from Richard W. Cooper, II, Director, NRC
ion I, dated January 12, 1993

Encl. 2

. Failure to have a quality management program to meet the regulatory requirements:

We deny this point based on the following:

During his inspection of our facilities on December 3, 1992, Dr. Lodhi asked about our quality management program and asked to see our first annual audit. I explained that the program started in January of 1992. Audits are to be performed in January of each year on the activities of the program during the previous calendar year.

Fall, 1991: preparation of program according to the rules of 10 CFR 35.32 and the guidelines of Regulatory Guide 8.33.

12/12/91: program approved by our Radiation Safety Committee by a unanimous vote.

12/17/91: program forwarded to the NRC, Region I office

1/1/92: program implemented.

November, 1992: forms and materials prepared for the first annual review of the program.

11/25/92: agenda for Radiation Safety Committee of December 10, 1992 distributed. This included, as item 16, an agenda item reminding the authorized users that an annual audit of their quality manamgement program must be performed in January, 1993. The results to be reviewed at the first regular Radiation Safety Committee meeting in 1993.

12/10/92: Radiation Safety Committee meeting. Item 16 was covered.

January, 1993: program audit for 1992 is in progress.

CORRECTION to page 8 of the NRC letter of January 12, 1993. "The licensee's unwritten policy was to have one physicist call out the treatment parameters which the second physicist would enter into the HDR computer at the time of the actual treatment." Due to the nature of the HDR system, the procedure is more elaborate. At that time the procedure, picking-up at the appropriate point, followed this format:

a. Using the prescription from the authorized user, the treatment was planned using the HDR treatment planning system. (This is done by a member of the physics staff.)

b. A second member of the physics staff independently verifies the plan on the department's treatment planning computer

(CMS).

c. The physics staff and the authorized user compare the two plans and verify agreement. Agreement is required for the treatment to take place.

d. The treatment plan is transferred (internally) from the HDR planning program to the HDR treatment program.

e. The operator (a member of the physics staff) verifies the transfer and enters the treatment specific data as: treatment number and first stop position offset (starting point of the treatment in the applicator). The operator compares the data to the prescription. He then verbally communicates this information to another member of the physics staff or an authorized user for comparison with the prescription and confirmation.

f. Following confirmation, the treatment is initiated.

COMMENT: It was our belief that step "e" was similar to the procedures often followed at power plants and other licensed facilities.

CORRECTIVE ACTION: As a result of the misadministration of October 14, 1992, step "e" was modified on October 19, 1992, specifically:

e. The operator (a member of the physics staff) verifies the transfer and enters the treatment specific data as: treatment number and offset (starting point of the treatment in the applicator). The operator compares the data to the prescription. A second member of the physics staff or an authorized user independently compares the prescription to the HDR planned treatment for confirmation of the intended treatment.

IMPLEMENTATION: The revised procedure was personnally comunicated by the qualified physicist to each member of the physics staff and the authorized users on October 19 and 20, 1992. It was also incorporated into the inservice program and repeated as a part of that program on November 19 and 27, 1992.

One of the purposes of the quality management program is to provide a mechanism for review and improvement in our program. We feel that this was accomplished here and that the program worked as intended.

2. Failure to make timely notification to the NRC:

We admit that the Operations Center was not notified until 5 days later.

The following is a CORRECTED chronology of the events relative to the misadministration of October 14, 1992:

10/7/92 first treatment OK

10/14/92 second treatment OK

10/14/92 referring physician notified OK

10/15/92 RSO notified OK

* 10/15/92 @ 3:09 PM. Dr. Lo called NRC at 215-337-5000 and asked for the person to notify re the misadministration. NRC forwarded the call to the voice mail of (?) Mrs. Hanson at 215-337-5304.

10/19/92 NRC Operations Center OK

10/22/92 Third treatment OK

* 10/22/92 Penny Nessen of the NRC (215-337-5169) called for Dr. Mower. At 3:42 PM Dr. Mower returned her call. Ms. Nessen was not available, did not return Dr. Mower's call.

* 10/23/92 Dr. Mower again called Ms. Nessen, who was not available. Call again not returned.

* 10/26/92 @ 4:52 PM. Jenny Johanson (NRC: 215-337-5304) returned Dr. Lo's call. Dr. Lo apparantly had misunderstood "Johansen" as "Hanson."

COMMENT: Although we did not notify the NRC Operations Center the next day, we did contact the Region I Office for direction on whom to contact to report the misadministration.

COMMENT: upon his return on 10/19/92, the RSO contacted the Operations Cember. He also explained to attempts by Dr. Lo to contact the NRC to the person at the Operations Cemter.

CORRECTIVE ACTION: On the 19th of October and at the inservice on November 19 and 27, the proper method of handling a misadministration was reviewed. This included:

- what is a misadministration
- whom to contact, when, and how
- information that needs to be recorded
- that the information is in the HDR procedure book at the HDR console and in the department policies and procedures book, copies of which are in Dr. Lo's office and Dr. Mower's office.

3. Failure to provide radiation safety training to workers:

We admit that some members of the code team had not received prior training in radiation safety.

This is clarified on page 5 indicating that "some members of the code team were not trained in radiation safety procedures."

After talking with a nurse on the floor where brachytherapy patients are cared for, Dr. Lodhi commented on our effective training program for the nursing staff. In the past, we have not trained nospital personnel not expected to be invovled with radiation exposures that would equal or exceed those levels allowed for the general public. In 10 CFR 20.105, an unrestricted area is considered okay if any person in such an area can be shown to expect to receive less than 0.5 rem (500 mrem) in a year. The regulations in 10 CFR 19.12 require that "all individuals working in or frequenting any protion of a restricted area be instructed ..." We have not considered code team members to be included in this definition since they routinely do not work in or frequent a restricted area.

Should occassion arise whereby a code team respondes to a therapy patient, the procedures call for replacing the code team every 20 minutes. Making the following assumptions:

- same code team responds to every code involving a therapy patient
- 20 minutes exposure time per code
- 10 brachytherpay patients per year
- 5 mR whole body exposure per response

If every patient coded (have only had 1 code in my 2.5 years here - have never had a brachytherapy patient code before during 20 years experience) and if the same team always responded (not likely), the annual whole body exposure would be 50 mR per year For planning purposes, a response of once per year is more realistic. This translates to an anticipated maximum exposure of 5 mR per year, well below the 500 mR level for an unrestricted area.

ACTION: As a part of its continued evaluation of our radiation safety program, the admininstration appointed a new RSO in September of 1992. Part of his duties are to upgrade and improve our records, policies, procedures, and training. This process started in September.

CORRECTIVE ACTION: we will include radiation safety training as a part of the inservice program for those responding on a code team. The RSO and administration are now working on implementing this policy.

Dr. Mower will be addressing the Critical Care Committee on this issue at their next meeting.

4. Failure to perform the required tests of the dose calibrator:

We admit that one of the four tests, the geometrical variation was not performed in a timely manner. The other test in question, the linearity test, was performed on the 14th of September. A copy of this report has since been forwarded to the RSO.

This is clarified on page 5 of the letter dated January 12, 1993 to confirm that only one of the required tests was not performed.

CLARIFICATION: although the dose calibrator was returned on September 14, 1992, it was not returned to service until September 19, 1992.

Chronology:

9/14/92 CRC-7 returned to the department

9/14/92 accuracy test performed

9/14/92 linearity test performed

9/16/92 daily constance checks started

9/19/92 unit returned to service

Prior to returning the unit to service, the chief technologist checked with the diagnostic physicist to see if other tests were requaired. Noting the manufacturer's tests, he responded, "No." As a part of his inspection, Dr. Lodhi noted the missing geometrical varition test. This was subsequently performed.

CORRECTIVE ACTIONS:

- the geometrical variation test was performed following the NRC inspection to bring us in compliance.
- the RSO reviewed the regulations with the chief technologist and the diagnostic physicist on December 4th.
- in the future, the chief technologist will confer with the RSO as well as the diagnostic physicist on all questions
- the regulations were covered with the nuclear medicine technologists at an inservice on January 6, 1993.

COMMENTS: as a part of our revised radiation safety program, initiated in September, 1992, the following are being included:

- involvement of the chief nuclear medicine technologist and the diagnostic physicist in the review of all procedures as well as the writing of new procedures and the compilation of a comprehensive radiation safety manual.
- involvement of nuclear medicine technologists with the RSO in required activities as those involving the dose calibrator
- regular reviews on a more frequent basis of all licensed activities, procedures, and related records. Initially these will be on a monthly basis and will start in January of 1993.

5. Failure to perform radiation surveys:

We admit that ~~one~~ one day we did not perform the required survey.

Page 5 clarifies this by noting that, on a single day (Saturday, September 12, 1992), a survey was not performed at the end of the day. Surveys were performed on the other days reviewed, including other weekend days when procedures were carried out.

CORRECTIVE ACTION:
- all technologists were individually reminded that the surveys are required
- this was also reiterated at the inservice on January 6, 1993

COMMENT: we are investigating seeing if we can incorporate into the "unit dose manager" computer a method of having the computer request and verify that a survey has been performed as a part of the daily system log-off procedure. If possible, this will add an additional check on this procedure

6. Failure to maintain the prior exposure record of a new employee:

We admit that we did not receive the prior exposure record on a new employee, though we did request it. Since our highest quarterly personnel exposure in this Department is less than 15% or the MPD, we feel that we were below the requirement level of 25%.

For the employee in question, we did not receive her prior exposure record. This was requested from the school where she trained. She remembers receiving a copy of our request to her school for this information. Our exposure reports indicate that we did receive similar information on others starting employment at that time. The indication of this information for others was verified by Dr. Lodhi during his inspection. None of these were requested from the same school.

We are concerned about prior exposures to our employees just as we are concerned about maintaining occupational exposures ALARA. Historically and current data support the fact that our nuclear medicine technologists receive less than 180 mrem/calendar quarter (170 mrem max and 75 mrem average per calendar quarter for the last 5 years).

Thus we fall well below the regualtory level of "is likely to receive in any period of one calendar quarter an occupational dose in excess of 25 percent of the applicable standards: being 25 % of 1250 mrem or 310 mrem. For this reason, we do not feel that we are in violation of 10 CFR 20.102 (a).

COMMENT: effective with our badging period of October, 1992, we have divided our badges into series by area of employment to more easily track groups of employees involved in similar activities.

CORRECTIVE ACTION: Effective Jan 1, 1992, we now maintain a "hot" file with a copy of the request for previous exposures in order to follow-up on deliquent return of reports from previous employers.

Items not listed as apparent violations but referred to in the letter dated January 12, 1993:

1. RSO as chairman of the RSC (page 3)

As noted by Dr. Lodhi, there is nothing in the regulations which prohibits this. For the past several years the RSO has served as the chairman of our Radiation Safety Committee. The administration appreciates Dr. Lodhi's comments and is presently considering the implementation of an alternative policy.

2. Survey meter check prior to operation (page 6)

Dr. Lodhi asked a nuclear medicine technologist about this test. Granted, it was a hectic day in the department and, due to illness, the department was short staffed. However, this does not forgive the error.

HISTORY: on October 24, 1991, the proper procedure for performing this check was reviewed by the then RSO and forwarded to the chief nuclear medicine technologist. She then reviewed the policy with all the techs and gave each technologist a copy of the policy. A copy was (and still is) posted on the door of the cabinet where the meter is stored. Dr. Lodhi reviewed this during his inspection.

CORRECTIVE ACTION: this procedure was reviewed in an inservice conducted on January 6, 1993. All technologists took a turn at a "hands on" drill as a part of the inservice.

Encl. 3

** DOSE CALIBRATOR SERIAL # [illegible] / CRC-7 71532

* DATE OF CONSTANCY TEST 08/21/92

Co-57 Vial Reference Source [illegible] on 11/18/91 [illegible] on 08/21/92 [illegible]

DUPONT CER#[illegible]

Cs-137 Vial Reference Source [illegible] on 02/22/75 [illegible] [illegible]

DUPONT SEM#[illegible]

* DATE OF CONSTANCY TEST 09/15/92

Co-57 Vial Reference Source [illegible] on 11/18/91 [illegible] on 09/15/92 [illegible]

DUPONT SEM#[illegible]

Cs-137 Vial Reference Source [illegible] on 02/22/75 [illegible] on 09/15/92 [illegible]

In-Service

[illegible]

changed to Sept

th
Sept 19
back in perinatal
spot

DOSE CALIBRATOR ACTIVITY LINEARITY CHECK

Section of Nuclear Medicine
Lahey Clinic Medical Center

Date: 9/14/92

Calibrator: CRC-7 Performed by: DAK

Serial No.: _____ Reviewed by RSO: [signature] 4/3-93

All readings must be taken at the lowest range setting available and converted to mCi units

Tube Color	First	Second	Factor	Product
Black	35.9	35.1	1	35.5000
Black & Red	11.3	11.13	3.19	35.7759
Black & Orange	3.6	3.59	9.83	35.3389
Black & Yellow	1.04	1.03	34.3	35.5005
Black & Green	0.322	0.321	110	35.3650
Black & Blue	0.136	0.134	260	35.1000
Black & Purple	0.0435	0.0434	786	34.1517
Black & Purple/Red	0.01311	0.01309	2558	33.5098
Black & Purple/Orange	0.0043	0.00431	7213	31.0520
Black & Purple/Yellow			23778	
Black & Purple/Green			64200	
Black & Purple/Blue			160500	

Mean Product: 34.5882

Lower Limit (95 % Mean): 32.8588

Upper Limit (105% Mean): 36.3176