June 19, 1997

Catherine E. Zamparelli
Hazardous Materials Coordinator
United States Department of Transportation
Federal Aviation Administration
1 Harborside Drive, Room 203-N
East Boston, Massachusetts 02128-2916

SUBJECT: LAHEY HITCHCOCK MEDICAL CENTER, BURLINGTON, MASSACHUSETTS

Dear Ms. Zamparelli:

We have been advised by Mr. Rick Boyle of the Department of Transportation's (DOT's) Research and Special Programs Administration, that your office is prepared to proceed with enforcement action against Lahey Hitchcock Medical Center for violations of DOT regulations identified by your staff following a March 14, 1997 incident. NRC also conducted a review of this incident and we were prepared to take enforcement action for the apparent violations of DOT requirements that we identified; however, because of your office's expressed interest in this matter and consistent with the Memorandum of Understanding between the NRC and DOT, we have decided to postpone our enforcement action indefinitely pending the outcome of your action. Please provide us with a copy of any enforcement action taken by your office against Lahey Hitchcock Medical Center for violations associated with the March 14, 1997 incident so that we may determine if additional actions on our part are appropriate at that time and assure that Lahey Hitchcock Medical Center is not subject to duplicate enforcement action for the same substantive violation.

Enclosed for your information is a copy of our April 24, 1997 inspection report which describes the apparent violations identified by NRC. Please contact Mohamed Shanbaky of my staff if you have questions regarding this matter. Dr. Shanbaky can be reached at (610) 337-5209.

Thank you for your cooperation in this matter.

Sincerely,

ORIGINAL SIGNED BY:
A. RANDOLPH BLOUGH

A. Randolph Blough, Director
Division of Nuclear Materials Safety

Enclosure:
Inspection Report dated April 24, 1997

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IE:07

cc (w/ enclosure):
Mr. Rick Boyle
United States Department of Transportation
Research and Special Programs Administration (DHM-22)
400 7th Street, SW
Washington, D.C. 20590-0001

Robert M. Hallisey, Director
Radiation Control Program
Massachusetts Department of Public Health
305 South Street, 7th Floor
Jamaica Plain, Massachusetts 02130

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OFFICE	DNMS/RI		RC/RI		ORA/RI		DNMS/RI			
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DATE	06/18/97		06/19/97		06/18/97		06/17/97		06/ /97	

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 24, 1997

Docket No. 030-01879
EA No. 97-170

License No. 20-05766-02

Herbert Mower, Sc.D.
Radiation Safety Officer
Lahey Clinic Foundation
41 Mall Road
Burlington, Massachusetts 01805

SUBJECT: INSPECTION NO. 030-01879/97-001

Dear Dr. Mower:

This refers to the inspection conducted on March 19 and 21, 1997, at your Burlington, Massachusetts facility, CIS-US, Inc., North Andover, Massachusetts, and at Frank Barker Associates, Inc., Towaco, New Jersey. The inspection was limited to a review of a shipment from your facility on March 14, 1997, of a package containing a GammaMed Source Changer containing a 5 curie iridium 192 sealed source that arrived at CIS-US, Inc. on March 17, 1997, with a dose rate of approximately 380 millirem per hour on contact with the top of the package. The enclosed report presents the results of this inspection. The findings of the inspection were discussed with you via telephone on March 31, 1997.

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.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600. The apparent violation consists of three parts: 1) a package of radioactive material was offered for transportation and was not prepared for shipment so that under conditions normally incident to transportation, the radiation level does not exceed 2 millisievert per hour (200 millirem per hour) at any point on the external surface of the package (Section 4); 2) the licensee did not ensure by examination or appropriate tests that each special instruction for preparation of the packaging had been followed, prior to offering the package for shipment (Section 4); and 3) the licensee did not ensure that each hazmat employee was trained and tested, and that no hazmat employee performed any function subject to the requirements of 49 CFR Parts 171 - 177 unless trained (Section 6). NRC was informed on March 17, 1997, by John J. Munro, III, RSO of CIS-US, Inc., that the package in question arrived at their facility measuring 380 millirem per hour on contact with the surface of the package. The circumstances surrounding these apparent violations,

the significance of the issues, and the need for lasting and effective corrective action were discussed with you at the inspection exit meeting on March 31, 1997. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision. However, a Notice of Violation is not presently being issued for these inspection findings. Before the NRC makes its enforcement decision, we are providing you an opportunity, within 30 days of the date of this letter, to either (1) respond to the apparent violations addressed in this inspection report or (2) request a predecisional enforcement conference.

Your response should be clearly marked as a "Response to An Apparent Violation in Inspection Report No. 030-01879/97-001" and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response should be submitted under oath or affirmation and may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

If you choose not to provide a response and would prefer participating in a predecisional enforcement conference, please contact Eric H. Reber at (610) 337-5276 as soon as possible.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response (if you choose to provide one) will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

The responses to the apparent violations described in the enclosed inspection report are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Your cooperation in this matter is appreciated.

Sincerely,

A. Randolph Blough, Director
Division of Nuclear Materials Safety

Docket No.: 030-01879
License No.: 20-05766-02
EA No.: 97-170

Enclosures:
1. Inspection Report No. 030-01879/97-001
2. NUREG 1600 (Enforcement Policy)

cc w/enclosure (1):
Commonwealth of Massachusetts
State of New Jersey

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-01879/97-001 Program Code 2230

Docket No. 030-01879

License No. 20-05766-02 Priority 1 Category G2

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

Facility Name: Lahey Clinic Foundation

Inspection At: Lahey Clinic Foundation
41 Mall Road
Burlington, MA 01805

CIS-US, Inc.
35 Flagship Drive
North Andover, Massachusetts

Frank Barker Associates, Inc.
33 Jacksonville Road
Towaco, New Jersey

Inspection Conducted: March 19 and 21, 1997

Inspectors: _____ 4-22-97
Michelle R. Beardsley date
Health Physicist

_____ 4/22/97
Eric H. Reber date
Health Physicist

Approved By: _____ 4/22/97
Mohamed M. Shanbaky, Chief date
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

9705020134 4pp.

Inspection Summary: Special announced limited safety inspection conducted on March 19 and 21, 1997 (Report No. 030-01879/97-001) (Inspection Report No. 030-01879/97-001)

Areas inspected: Circumstances surrounding the shipment from Lahey Clinic on March 14, 1997 of a package containing a GammaMed Source Changer that arrived at CIS-US, Inc. on March 17, 1997 with a dose rate of 380 millirem per hour on contact with the top of the package including: Package Receipt, Package Preparation, Package Transport, and Hazmat Training

Results: One apparent violation was identified (Sections 4 and 6)

DETAILS

1. Persons Contacted

Herbert Mower, Sc.D., Radiation Safety Officer (RSO), Lahey Clinic
John J. Munro, III, RSO, CIS-US, Inc.
Robert Kirby, Radiation Technician, CIS-US, Inc.
Roy Parker, Consultant Health Physicist, Federal Express
Gary Nixon, RSO, Frank Barker Associates, Inc.

2. Scope of Licensed Activities

Lahey Clinic Foundation is a medical licensee authorized to perform nuclear medicine imaging studies, radiopharmaceutical therapy, and brachytherapy including high dose rate remote afterloading brachytherapy (HDR).

CIS-US, Inc. manufactures and distributes iridium 192 sources used in HDR machines.

Frank Barker Associates, Inc. provides services including installation, maintenance, repair and source exchange to users of Isotopen-Technik Dr. Sauerwein GMBH GammaMed HDR machines.

3. Package Receipt

Lahey Clinic uses a GammaMed HDR device for brachytherapy treatments. The GammaMed Source Changer is used to transport iridium 192 sources to and from these machines. Iridium 192 sources of the type transported in this type of changer are approximately 1 mm in diameter and 1 cm long. They are welded on the end of a wire approximately 1 m long. On March 17, 1997, John J. Munro, III, RSO of CIS-US, Inc. informed Region I that a package shipped from Lahey Clinic arrived at their facility in North Andover, Massachusetts measuring approximately 380 millirem per hour on contact with the surface of the package. On March 19, 1997, John J. Munro, III, RSO and Bob Kirby, Radiation Technician, were interviewed by the inspectors at CIS-US, Inc. The RSO stated that on March 17, 1997, at approximately 3:30 p.m., a GammaMed Source Changer containing 5 curies of iridium-192 was received at the CIS-US, Inc. facility. Mr. Kirby stated that the measured radiation level in one small area on the top surface of the package was 380 millirem per hour. He then contacted the RSO after discovering the elevated reading. The RSO determined that the iridium 192 source was in a partially unshielded position withing the source changer. He then moved the source into the fully shielded position. The source changer has a collet with four jaws that is used to hold the source in place. The collet has a set screw that is used to prevent the collet from moving once a source has been secured. The RSO then attempted to tighten the collet of the source changer. The collet could not be tightened because the set screw prevented its motion. The RSO then backed off the set screw and tightened the collet successfully (approximately 1 1/2 to 2

turns). The licensee then contacted the NRC because a package had arrived in excess of the 200 millirem per hour transportation limit.

The inspectors identified no safety concerns in this area.

4. Package Preparation

The GammaMed Source Changer was prepared for shipment at the Lahey Clinic Foundation on the afternoon of March 13, 1996 by Gary Nixon of Frank Barker Associates, Inc. On March 21, 1997 an inspector interviewed Gary Nixon, RSO, of Frank Barker Associates, Inc. Mr. Nixon stated that he has performed 2 to 3 source changes per month since September 1993 and that he follows the GammaMed Source Exchange Procedure when performing source changes. Mr. Nixon stated that he performed a source change at the Lahey Clinic on March 13, 1997. Mr. Nixon stated that first he attached a guide tube from the HDR device to the source changer. He exited the "Simulator Room" where the HDR is located and programmed the machine to expel the 5-curie iridium 192 source into the source changer. After the source was expelled, he then reentered the room, surveyed the HDR, guide tube, and the source changer. This survey indicated that the source was in its fully shielded position within the source changer. Next, he tightened the collet of the source changer. He then disconnected the guide tube from the HDR causing the HDR to automatically disconnect and expel the portion of the source wire inside the HDR. He stated that he then tugged on the portion of the source wire sticking out of the guide tube to make sure that the source was secured in the changer and that it did not move. Then he disconnected the guide tube from the source changer. After this, he tugged on the wire sticking out of the source changer and again it did not move. Then he coiled the wire and placed it inside the source changer and continued with the rest of his procedure. After the new source was installed, he conducted a survey of the top and sides of the package with the 5 curie "old" source. This survey indicated 0.04 millirem per hour at 1 meter from the front of the package and 2.0 millirem or less on contact with the top and sides of the package. At the end of the afternoon, the package was taken by hospital personnel to the "Cesium Room". When asked why the source changer arrived at CIS-US, Inc. with the source in a partially unshielded position, Mr. Nixon stated that he believes that the set screw was partially extended and that this permitted him to only partially secure the source with the collet. He also stated that during transport, the collet must have loosened and allowed the wire to move.

On March 17, 1997, the inspectors interviewed Herb Mower, RSO, at Lahey Clinic. Dr. Mower stated that the package containing the source changer was prepared for shipment in the "Simulator Room" by Gary Nixon of Frank Barker Associates. It was then moved directly to Room 112, the "Cesium Room" late on the afternoon of March 13, 1996. On the morning of March 14, 1997, Dr. Mower made a confirmatory survey (confirming the measurements of Gary Nixon of Frank Barker who prepared the package) of the dose readings at contact and at 1 meter from the top and sides of the package. All readings agreed with the

measurements by Frank Barker. Lahey Clinic personnel took possession of the package with the security seal in place. The package was not opened and the licensee (Lahey Clinic) did not ensure by examination or appropriate tests that each special instruction for preparation of the packaging had been followed. On the afternoon of March 14, 1997, the package was offered for shipment by Lahey Clinic to Federal Express. Dr. Mower signed the shipper's certification on the shipping paper that accompanied the package, therefore, taking the responsibility as the shipper of record for compliance with the applicable DOT regulatory requirements. Dr. Mower stated that the only hospital personnel present when the package was in the "Simulator Room" and the "Cesium Room" were himself and another medical physicist. He also stated that the ceilings of these rooms are shielded with concrete and soil. In addition, dose rates decreased significantly with distance from the package surface (The CIS-US, Inc. RSO measured a dose rate of 3 millirem per hour at one meter from the top of the package). The inspectors concluded that due to the fact that the dose rates on the exterior of the package were collimated, decreased precipitously with distance and the limited presence of hospital personnel, any absorbed doses by hospital personnel were minimal.

10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.441(a) requires in part, with exceptions not applicable here, that each package of radioactive materials offered for transportation be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 millisievert per hour (200 millirem per hour) at any point on the external surface of the package.

The finding that, on March 14, 1997, the licensee delivered to a carrier for transport 5 curies of iridium 192 in a package that arrived at its destination with a measured radiation level of approximately 380 millirem per hour on the external surface of the package is an apparent violation of 49 CFR 173.441(a).

49 CFR 173.475 requires, in part, that before each shipment of any Class 7 (radioactive) materials package, the offeror must ensure by examination or appropriate tests, that: (1) the packaging is proper for the contents to be shipped; (2) the packaging is in unimpaired physical condition, except for superficial marks; and (3) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed.

The finding that, on March 14, 1997, the licensee offered to a carrier for transport a package containing 5 curies of iridium 192, and the licensee did not ensure by examination or appropriate tests that each special instruction for filling, closing

and preparation of the packaging for shipment had not been followed is an apparent violation of 49 CFR 173.475.

The licensee stated that their corrective action will be to have Frank Barker Associates, Inc. be the shipper of record for future shipments of HDR sealed sources.

5. Package Transport

On March 19, 1997, Roy Parker of Federal Express was contacted via telephone. He stated that potential doses to Federal Express employees would have been minimal from the package. Mr. Parker compared the potential for absorbed dose to Federal Express employees from the shipment of this package to that of shipping two normal packages, each measuring 200 millirem per hour on contact (the allowable limit) since the amount of time when personnel were directly involved in the movement of the package was minimal.

6. Hazmat Training

The inspectors discussed with the RSO at Lahey Clinic training given to personnel on Hazmat packaging and transportation. The RSO stated that no Lahey employees have attended hazmat employee training as required by Subpart H of 49 CFR Part 172 because he was unaware of this requirement.

49 CFR 172.702 requires that each hazmat employer shall ensure that each hazmat employee is trained and tested, and that no hazmat employee performs any function subject to the requirements of 49 CFR Parts 171-177 unless trained, in accordance with Subpart H of 49 CFR Part 172. The terms Hazmat Employer and Hazmat Employee are defined in 49 CFR 171.8.

Contrary to the above, as of March 19, 1997, the licensee had not provided training for its hazmat employees as required by Subpart H to 49 CFR Part 172, and the licensee otherwise meets the definition of hazmat employer in 49 CFR 171.8.

The licensee stated that their corrective action will be to have several employees attend hazmat training as specified in Subpart H to 49 CFR Part 172.

7. Exit Meeting

The inspection finding were discussed with the Lahey Clinic RSO via telephone on March 31, 1997.