JUL 13 1989

In Reply Refer To:
License: 35-03176-04MD
Docket: 30-12750/89-02
EA: 89-128

University of Oklahoma
Health Sciences Center
ATTN: Clayton Rich, M.D.
Provost and Vice President
for Health Sciences
P.O. Box 26901
Oklahoma City, Oklahoma 73190

Dear Dr. Rich:

This refers to the Enforcement Conference held at Region IV's request in the Region IV office on June 26, 1989. This meeting related to activities authorized by NRC License No. 35-03176-04MD.

The subjects discussed at the meeting are described in the enclosed Enforcement Conference Summary. I feel the Enforcement Conference to have been beneficial for both your staff as well as NRC and appreciate your attendance and candor during the conference discussion. As indicated in the Summary, we have yet to notify you of the enforcement action to be taken.

This letter also acknowledges receipt of your letters dated June 23 and 30, 1989. I have forwarded your response to the Notice of Violation issued on June 15, 1989, for technical review. You will receive separate correspondence regarding your response and proposed corrective actions. I am pleased to note that you are proceeding with an independent audit of your radiation safety program. Please be advised that your review of the audit might suggest significant program changes that may require license amendment. These should be appropriately submitted for NRC review prior to implementation.

In response to your comment regarding the inspection record of the University's other licensed programs, I wish to emphasize two points; first, the lack of significant findings during the inspection of your other programs does not change NRC's opinion that management of your radiation safety program deserves careful review. Secondly, NRC does not expect licensees to rely on inspector identification of items of noncompliance or safety issues. We expect and encourage our licensees to develop programs that will provide objective evaluation of potential problem areas and initiate prompt corrective action.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter will be placed in the NRC's Public Document Room.

*RIV:NMIS	*NMIS	*C:NMIS	*C:NMSB	*EO	*D:DRSS
LLKasner/ch	WLHolley	CLCain	WLFisher	GFSanborn	ABBeach
/ /89	/ /89	/ /89	/ /89	/ /89	/ /89

*Previously Concurred

IE07
111

Should you have any questions concerning this matter we will be pleased to discuss them with you.

Sincerely,

Original Signed By:
A. B. BEACH

A. B. Beach, Director
Division of Radiation Safety
and Safeguards

Enclosure:
Enforcement Conference Summary
w/Attachment

cc w/enclosure:
Oklahoma Radiation Control Program Director

bcc:
DMB - Original (IE-07)
DBHowe, NMSS
JDelMedico, CE
RDMartin
ABBeach
WLFisher
LShea, RM/ALF (AR-2015)
GFSanborn
CLCain
DAPowers
LLKasner
WLHolley
NMSB
RIV Files (2)
RSTS Operator

APPENDIX

ENFORCEMENT CONFERENCE SUMMARY

Licensee: University of Oklahoma
Health Sciences Center

License No.: 35-03176-04MD

Docket: 30-12750

SUBJECT: ENFORCEMENT CONFERENCE TO DISCUSS NRC FINDINGS

On June 26, 1989, representatives of the University of Oklahoma Health Sciences Center (UOHSC) met with NRC personnel in the Region IV office to discuss apparent violations of NRC requirements as observed during an inspection conducted at the UOHSC nuclear pharmacy. The discussion included review of those corrective actions proposed or taken by the licensee as a result of the inspection.

The NRC staff presentation focused on those violations related to the manufacture and distribution of capsules containing iodine-131 that were not approved for human use by medical licensees, the inappropriate labeling of radiopharmaceuticals dispensed from the nuclear pharmacy, the inoperability and lack of charcoal filters in fume hoods used to process volatile liquid iodine-131, and the Radiation Safety Officer's (RSO) and Radiation Safety Committee's (RSC) management of the licensee's program.

The licensee reviewed those corrective actions which have been implemented, including restructuring the reporting responsibilities of the RSO within the management organization, expanding the RSO's staff, and the use of leaded glass vial shields to prevent future errors that the licensee identified as the root cause of a mislabeling incident resulting in seven diagnostic misadministrations at customer hospitals. The licensee has terminated the manufacture of iodine-131 capsules and noted that they are working on an amendment request for this activity to be submitted for NRC review. The licensee reported that they had not taken action to correct a violation related to a distribution statement printed on labels of products dispensed from the pharmacy.

The licensee then reviewed the RSO's management of the radiation safety program as related to the nuclear pharmacy. The RSO stated that, due to the variety of activities conducted under the University's broad license and the number of individuals involved in the program, management of the nuclear pharmacy radiation safety program had been left to the pharmacy director. The RSO explained that, although internal audits were performed at weekly or semiannual intervals, the audit did not include an evaluation of activities conducted within the pharmacy. The audits focused on monitoring byproduct material receipt and disposal without attention to its use or application. The RSO

further stated that he did not routinely visit the pharmacy during these audits and that he had been unaware of the use of two fume hoods to store, label, and compound radioiodine. The licensee plans to add an additional full-time employee to the RSO's staff but could not confirm how the additional staff member would impact the nuclear pharmacy's radiation safety program. The NRC staff expressed their concern that management functions of the RSC and RSO had been inappropriately delegated to other individuals and that significant areas of the nuclear pharmacy program were not being properly evaluated. The NRC staff emphasized the need for the licensee to review the conditions of the license and to adequately evaluate the activities conducted in their programs to ensure that all are authorized under the license. During the conference the Provost expressed his concern regarding the significance of these deficiencies and proposed conducting an independent audit of the program by outside consultant.

The NRC staff explained that a decision would be made as to the appropriate enforcement action and that the licensee would be notified.

Linda L. Kasner
Health Physicist

Attachment:
Attendance List

ATTACHMENT

Enforcement Conference Attendance List

University of Oklahoma Health Sciences Center

Arlington, Texas

June 26, 1989

University of Oklahoma Health Sciences Center

Clayton Rich, M.D., Provost and Vice President, Health Sciences
Tom Godkins, Assistant to the Provost for Administrative Affairs
Victor Yanchick, Ph.D., Dean, College of Pharmacy
Stanley Mills, Ph.D., Director, Nuclear Pharmacy
Bhagwat Ahluwalia, Ph.D., Radiation Safety Officer

Nuclear Regulatory Commission, Washington, D.C.

D. B. Howe, Nuclear Materials Safety and Safeguards
J. R. DelMedico, Office of Enforcement

Nuclear Regulatory Commission, Arlington, Texas

A. B. Beach, Director, Division of Radiation Safety and Safeguards
W. L. Fisher, Chief, Nuclear Materials Safety Branch
C. L. Cain, Chief, Nuclear Materials Inspection Section
D. A. Powers, Chief, Nuclear Materials Licensing Section
G. F. Sanborn, Enforcement Officer
W. L. Holley, Radiation Specialist
L. L. Kasner, Health Physicist