AUG 18 1989

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

Dr. Clayton Rich, Provost
The University of Oklahoma
Health Sciences Center
P.O. Box 26901
Oklahoma City, Oklahoma 73190

Dear Dr. Rich:

This refers to your letter and corresponding attachments dated August 11, 1989. We have reviewed your correspondence and appreciate your cooperation in providing copies of the revised nuclear pharmacy audit form and proposed duty assignments for the Assistant Radiation Safety Officer. As previously reviewed with you, enforcement action related to those inspection findings discussed at the enforcement conference is still under NRC staff review and will be forwarded to you by separate correspondence.

Your letter also included comments regarding the enforcement conference summary provided to you as an attachment to our letter dated July 13, 1989. The purpose of the conference summary was to summarize the facts presented by you and your staff during the enforcement conference.

Our decision regarding your request for changes to the conference summary also includes review of information obtained during a telephone conversation conducted on August 16, 1989, between Dr. B. Ahluwalia of your staff and Mr. C. L. Cain and Ms. L. Kasner of our office. Pursuant to this conversation, it is our understanding that the conference summary changes requested in your letter were suggested with the intent to document involvement of the Radiation Safety Officer (RSO) in the nuclear pharmacy program. We do not question involvement of the RSO in certain aspects of the nuclear pharmacy program. However, it was and still is our understanding, as presented during the enforcement conference, that the management of activities conducted within the nuclear pharmacy and related radiation safety program was left to the Pharmacy Director. Furthermore, based on our conversation with Dr. Ahluwalia, we understand that although the RSO may have visited the pharmacy area to review receipt, disposal, and certain quality control records during the semiannual audits, he did not routinely conduct an audit that included review of activities conducted within the pharmacy or the use and application of licensed material.

We wish to emphasize that whether records of material receipt and disposal were reviewed in the pharmacy is not an issue. The issues at hand are the labeling of radioiodine in fume hoods that were not properly installed and the

*RIV:NMIS	*C:NMIS	*C:NMSB	EO	D:DRSS
LLKasner/ch	CLCain	WLFisher	GFSanborn	ABBeach
/ /89	/ /89	/ /89	8/18/89	8/18/89

*Previously concurred

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IE-07

manufacturing with subsequent distribution of radioiodine capsules, which were not authorized under your NRC materials license. The fact that your RSO was unaware that such activities had been routinely conducted over an 18-month period raises concerns about the adequacy of the nuclear pharmacy audits. However, if we had believed that the RSO participated in an adequate audit program, we would have additional concerns that an individual who was knowledgeable of and responsible for your radiation safety program had not recognized the findings identified by this inspection during a routine audit of the nuclear pharmacy.

Following careful review of the above, we have concluded that the statements contained in the conference summary accurately represent the facts presented to the staff during the enforcement conference. Therefore, we find the facts as described in the conference summary to be appropriate, and not incorrect, and should not be revised as requested in your letter dated July 13, 1989.

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

cc:
Oklahoma Radiation Control Program Director

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

The University of Oklahoma
Oklahoma City Campus - Health Sciences Center

OFFICE OF THE PROVOST

August 11, 1989

Mr. A.B. Beach
Director
Division of Radiation Safety
and Safeguards
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76011

Dear Mr. Beach,

In response to you letter dated July 13, 1989, regarding the June 26 Enforcement Conference held at the Region IV Office, I describe below some corrective measures which we have taken in respect to Nuclear Pharmacy at the University of Oklahoma Health Sciences Center.

We have just completed a three-day detailed audit of the entire Radiation Safety Program. I asked our Radiation Safety Committee to suggest names of persons who were best qualified to conduct such a comprehensive audit, and have engaged their first choice, Mr. Thomas Pitchford of the University of Missouri. Mr. Pitchford will report his findings and recommendations in written form to me, and I will forward a copy of the external audit report to your office. In addition, to address the issue of labeling radiopharmaceuticals, the product labels for the dispensed products are being hand corrected until new printed labels become available.

I have reviewed the Enforcement Conference Summary and note there are two statements that should be corrected. It is stated in the fourth paragraph that "management of the nuclear pharmacy radiation safety had been left to the pharmacy director". This statement is not correct, and should be amended to read, "day to day management of the nuclear pharmacy radiation safety program had been left to the pharmacy director." Also, on page 2 the last sentence states "The RSO further stated he did not routinely visit the pharmacy during these audits". This statement should be corrected to read "The RSO stated that he did routinely visit the pharmacy during these audits." I would appreciate the insertion of these clarifications and corrections.

1000 Stanton L. Young Boulevard, Oklahoma City, Oklahoma 73190 (405) 271-2332

Dr. Ahluwalia has now developed an extensive list of items to be included in the monthly audit of the Nuclear Pharmacy program. In addition, we have developed a preliminary job description for the new position of Assistant Radiation Safety Officer. The audit list and the preliminary job description are attached.

If I may provide further information, please feel free to contact me.

Sincerely,

Clayton Rich, M.D.
Provost

/sm

Attachments

cc: Thomas Godkins, M.P.H., Assistant to the Provost
Bhagwat Ahluwalia, Ph.D., Radiation Safety Officer

NUCLEAR PHARMACY AUDIT CHECKLIST

ACTIVITIES: IN COMPLIANCE: YES NO

HOOD VENTILATION

a) Rm 139C East
b) Rm 139C West
c) Rm 139D
d) Rm 139 HOT

HOOD OPERABLE LEVEL INDICATOR

a) Rm 139C East
b) Rm 139C West
c) Rm 139D
d) Rm 139 HOT

OUTSIDE RECEIVING
CONTAINER, LOCK

DISPENSING ACTIVITIES
a) SYRINGE SHIELD
b) GLOVES
c) LABCOATS
d) FOOD & DRINKS

GENERATOR ELUTION PROCEDURES

SURVEY METER CALIBRATION DATE
a) PACKAGE RECEIVING
b) OUTGOING PACKAGE SURVEY METER
c) OTHER SURVEY METERS
d) CHECK SOURCES
e)

OUTGOING PACKAGE CONTAINER CHECKLIST
a) CONTAINER LABELING (35.60).
b) CONTAINER SURVEY.
c) CONTAINER SHIPPING PAPERS.
d) SHIPPING PAPERS FOR RETURNED ITEMS.
e)

CAR TRUNK
BLOCKING, PACKING & BRACING

METAL BOXES WITH FOAM IN CAR TRUNK
"NOT IN PASSENGER COMPARTMENT"

SURVEY: OUTGOING PACKAGES

AT THE TIME OF DISPATCH
MARKING OF "TRANSPORT INDEX"

WORKERS WEAR BADGES AND RING BADGE

OFF HOURS RECEIVING PROCEDURES

WASTE CONTAINERS

REFRIGERATORS

COMMENTS:

APPROVED USER PRACTICES: IN COMPLIANCE: YES NO

USE OF UNAUTHORISED RM

USE OR STORAGE OF RM IN UNRESTRICTED AREA

RM PROVIDED TO UNAUTHORISED STAFF

PRESCENCE OF AUTHORISED USER

POSTING:

POSTING OF RADIOACTIVE MATERIAL SIGNS

NRC FORM 3

NOTICE TO EMPLOYEES (Reg. Part 19, 20 etc.)

RADIATION AREA SIGN

EMERGENCY PROCEDURES

RS MANUAL, NRC Part 10, PROCEDURES

TEST:

DOSE CALIBRATOR #1
- ACCURACY
- DAILY CONSTANCY

DOSE CALIBRATOR #2
- ACCURACY
- DAILY CONSTANCY

AREA SURVEY
- RECEIVING AREA
- WORK BENCH
- SINK
- DISPENSING HOOD
- DISTRIBUTION AREA
- GENERATOR AREA
- STORAGE AREA
- WASTE CONTAINERS
- OTHER AREA

COMMENTS:

RECORDS IN COMPLIANCE: YES NO

SEALED SOURCE WIPE RECORDS

DOSE CALIBRATOR #1
DAILY CONSTANCY
QUARTERLY LINEARITY
HIGH RANGE _____ LOW RANGE _____

DOSE CALIBRATOR #2
DAILY CONSTANCY
QUARTERLY LINEARITY
HIGH RANGE _____ LOW RANGE _____

RADIOACTIVE WASTE DISPOSAL RECORDS

DAILY RESULTS: Mo99

RECEIPT RECORDS

NUCLEAR PHARM RELATED MISADMINISTRATIONS

DISTRIBUTION RECORDS

ORDER APPROVAL RECORDS

DAILY ROOM SURVEY RECORDS
WEEKLY WIPE TEST RECORDS

PERSONNEL EXPOSURE RECORDS

PREVIOUS RSO INSPECTION REPORT

BIO ASSAY RECORDS

OFF HOURS RECEIVING RECORDS

STAFF TRAINING

ALL ITEMS IN COMPLIANCE? YES NO

DEFICIENCIES IN PREVIOUS AUDIT? YES NO
CORRECTED? YES NO

COMMENTS: _____

PERSON RECEIVING COPY OF REPORT: _____

AUDITOR: _____

RSO REVIEW AND COMMENTS: _____

The
University of Oklahoma
Oklahoma City Campus-Health Sciences Center

DEPARTMENT OF RADIOLOGICAL SCIENCES
College of Medicine

MEMORANDUM

TO: Eugene Patterson, Ph.D.
Chairman
Radiation Safety Committee

FROM: B. Wally Ahluwalia, Ph.D.
Director, Office of Radiation Safety

DATE: July 31, 1989

SUBJECT: OFFICE OF RADIATION SAFETY PERSONNEL AND TENTATIVE SCHEDULE ASSISGNMENT OF ASSISTANT TO RSO

The following lists the staff of the Office of Radiation Safety. This includes the proposed additional position of Assistant RSO.

Radiation Safety Officer
Assistant to the Radiation Safety Officer
Radiation Safety Assistant
Radiation Safety Secretary
Medical Physics Assistant (Student 0.5 FTE)
Medical Physics Assistant (Student 0.5 FTE)

The following is an outline of the job description for the new position of Assistant Radiation Safety Officer.

a. Semi annual audit of all OUHSC Minilicenses.
b. Monthly audit of Nuclear Pharmacy Medical Distribution license activities.
c. Receipt audits of Nuclear Pharmacy.
d. Monthly preparation of papers for RSC (with input from RSO).
e. To assist Campus RSO in audit of Nuclear Medicine at OMH, OCMH, Therapy, Clinical Lab and etc.
f. Final inspection and clearance of all areas released from radioactive material activity.
g. Patient room survey.
h. Assistance to RSO.
i. Ancillary staff teaching.
j. Overall responsibility of all OUHSC licenses in the absence of RSO from campus.

/db

Post Office Box 26901 Oklahoma Memorial Hospital, Room 35X Oklahoma City, Oklahoma 73190 AC (405) 271-5125

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

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.

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

Sincerely,

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

Enclosure:
Enforcement Conference Summary
w/Attachment

cc w/enclosure:
Oklahoma Radiation Control Program Director

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