

OCT 10 1989

In Reply Refer To:
License: 35-18282-01
Docket: 30-14781/89-01

Oral Roberts University
ATTN: Larry Edwards
Vice President
for Health Affairs
7777 South Lewis Avenue
Tulsa, Oklahoma 74171

Gentlemen:

Thank you for your letter of September 25, 1989, in response to our letter and attached Notice of Violation both dated August 18, 1989. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. We will review the implementation of your corrective actions during a future inspection to determine whether full compliance has been achieved and will be maintained.

Sincerely,
Original Signed By:
William L. Fisher

William L. Fisher, Chief
Nuclear Materials Safety Branch

cc:
Oklahoma Radiation Control Program Director

bcc w/copy of licensee letter:

DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
WLFisher
LShea, RM/ALF (AR-2015)
CLCain
RJEverett
SRajendran
NMSB
MIS System
RIV Files (2)
RSTS Operator

RIV:MMIS
SRajendran:ch
10/3/89

C:NMIS
CLCain
10/9/89

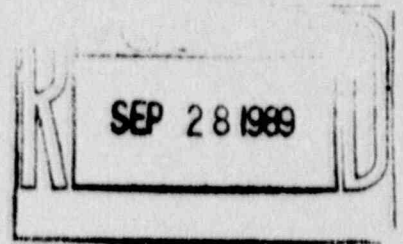
C:NMSB
WLFisher
10/10/89

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35-18282-01 PDC

IE-07
/

ORAL ROBERTS UNIVERSITY SCHOOL OF MEDICINE
CITY OF FAITH MEDICAL AND RESEARCH CENTER
8181 South Lewis, Tulsa, OK 74137
(918) 493-8959

September 25, 1989



William L. Fisher, Chief
Nuclear Materials Safety Branch
United States Nuclear Regulatory Commission
Region VI
611 Ryan Plaza Drive
Suite 1000
Arlington, TX 76011

RE: License: 35-18282-01
Docket: 030-14781/89-01

Dear Mr. Fisher:

In reference to your letter and NOV dated 18 August 1989, we offer the following response:

A1. Low specific activity of Cobalt 57 calibration source.

Due to an oversight, the Cobalt 57 source was allowed to decay beyond the range for calibration of accuracy check.

Immediate corrective steps taken include the ordering and subsequent receiving of an appropriate Cobalt Source. It is now being used as an accuracy check.

Further corrective steps taken include calculating and recording in the calibrator book the date at which the new source became non-compliant. A special note draws it to the attention of the calibrator.

Full compliance was accomplished 7 August 1989.

A2. Calculated constancy of dose calibrator.

This violation is a result of relying on visual checks rather than actual plots of data to ascertain the +5%. The plots were done after the fact; however, no procedure was started without the visual check indicating the accuracy was within limits.

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JPP

IC-89-636

IE07

Immediate corrective steps taken include plotting by readings daily before the fact. A poster is now in place in the hot lab, reminding all who are involved of the need to plot the readings daily.

Full compliance was achieved 7 August 1989.

B. Lack of wipe tests from 14-31 July 1989.

These violations occurred during the Chief Nuclear Technologist's vacation, due to lack of familiarity of the back-up person with all the procedures.

Immediate corrective steps taken include the posting of a reminder of wipe test requirements for those people left in charge of the nuclear lab during vacation and absences. Since posting the weekly list, no violations have occurred.

Full compliance was accomplished 7 August 1989.

C. Lack of Quarterly Laboratory Surveys since 29 May 1987.

The laboratories had last been inspected during the first quarter of 1988 rather than 29 May 1987 as shown on the NOV. They were not in the proper folder. The laboratories have not been systematically inspected since mid-April of 1988, although they were surveyed from time to time.

Prior to August of 1988, the clinical and non-clinical isotope users records were kept in separate offices. They were moved and merged together at the beginning of the new fiscal year. During the merger, the laboratory surveys were not filed appropriately, although they had been performed.

During the fall of 1988 and the spring of 1989, the Radiation Safety Office operated with a manpower shortage. Because: (1) a tight control of ordering and receiving isotopes was (is) in place, thus allowing us to know who had what on hand; (2) only minimal waste on hand, since a pick-up had occurred in mid-April of 1988; and (3) only minimal research activity was underway; it was felt that spot checks of laboratories would be adequate, thus allowing the personnel assigned to Radiation Safety to deal with critical issues.

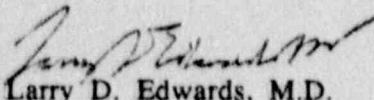
William L. Fisher
September 25, 1989
Page 3

Immediate corrective steps include the filing of the missing reports, the assigning of more personnel to the Radiation Safety Office and the reinstatement of the mandatory quarterly surveys of laboratories. The survey for the third quarter will be completed by 9 October 1989. Survey forms will be filed appropriately, at which time we will be fully compliant.

Further corrective steps will include a tickler file system to be utilized by the RSO as a reminder, to ensure compliance of our license.

We trust this response is sufficient and are proceeding accordingly.

Sincerely,



Larry D. Edwards, M.D.
Vice-President for Health Affairs
Oral Roberts University
School of Medicine

/llw

AUG 18 1989

In Reply Refer To:
License: 35-18282-01
Docket: 030-14781/89-01

Oral Roberts University
ATTN: Larry Edwards
Vice President for Health Affairs
7777 South Lewis Avenue
Tulsa, Oklahoma 74171

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Mr. Selvan Rajendran of this office on July 31 and August 1, 1989, of the activities authorized by NRC Byproduct Material License 35-18282-01 and to the discussion of our findings held by the inspector with members of your staff at the conclusion of the inspection.

The inspection was an examination of the activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations, and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements, and observations by the inspector.

During this inspection, certain of your activities were found not to be conducted in full compliance with NRC requirements. Consequently, you are required to respond to this matter, in writing, in accordance with the provisions of Section 2.201 of the NRC "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Your response should be based on the specifics contained in the Notice of Violation enclosed with this letter.

The response directed by this letter and accompanying Notice is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

RIV:NMIS
SRajendran/tw
8/17/89

C:NMIS *ew*
CLCain
8/17/89

C:NMSB *WLF*
WLFisher
8/17/89

89 08 290036 2 p. 1

IE-07

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

Sincerely,

**Original Signed By:
William L. Fisher**

William L. Fisher, Chief
Nuclear Materials Safety Branch

Enclosure:
Appendix - Notice of Violation

cc w/enclosure:
Oklahoma Radiation Control Program Director

bcc:
DMB - Original (IE-07)
RDMartin
ABBeach
REHall
WLFisher
LShea, RM/ALF (AR-2015)
*RIV Files (2)

*CLCain
*RJEverett
*SRajendran
*NMSB
*MIS System
*RSTS Operator

*w/766

APPENDIX
NOTICE OF VIOLATION

Oral Roberts University
Tulsa, Oklahoma

Docket: 030-14781/89-01
License: 35-18282-01

During an NRC inspection conducted on July 31 and August 1, 1989, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1988), the violations are listed below:

Condition 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated March 2, 1983.

A. Item No. 10 of this application requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8, Revision 1.

1. Item G of Appendix D, Section 2, requires that dose calibrators be checked for accuracy with a cobalt-57 source of 3-5 millicuries.

Contrary to the above, on March 20, 1989, the cobalt-57 source in use had decayed to 90 microcuries.

2. Item C.6 of Appendix D, Section 2, requires that dose calibrator constancy be within ± 5 percent of the calculated activity.

Contrary to the above, from June 22 to July 31, 1989, the dose calibrator constancy test results were not evaluated to determine if they were within ± 5 percent of the calculated activity.

This is a Severity Level IV violation. (Supplement VI)

B. Item 17 of the application requires that surveys be performed in accordance with the "Area Survey Procedures" in Appendix I of Regulatory Guide 10.8, Revision 1.

Item 1 of Appendix I requires that all elution, preparation, and injection areas be surveyed daily. Item 4.b of this appendix requires that weekly surveys include wipe tests.

Contrary to the above, from July 14-31, 1989, no wipe tests were performed.

This is a Severity Level IV violation. (Supplement VI)

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- C. In the application, page 24, item 17, "Survey Procedures," requires radiation safety staff to inspect the laboratories and the investigators' records at least once per quarter.

Contrary to the above, the inspection of laboratories had not been performed since May 29, 1987.

This is a Severity Level IV violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Oral Roberts University is hereby required to submit to this office, within 30 days of the date of the letter transmitting this Notice, a written statement or explanation in reply, including for each violation: (1) the reason for the violation if admitted, (2) the corrective steps which have been taken and the results achieved, (3) the corrective steps which will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending the response time.

Dated at Arlington, Texas,
this 18th day of August 1989

RAJENDRAN, SELVAN

INSPECTOR'S REPORT

Office of Inspection and Enforcement

REVIEWER

CXA

REGIONS

LICENSEE/VENDOR: Oak Ridge University; TRANSACTION TYPE: X - INSERT; DOCKET NO: 03014781; REPORT NO: 8901; NEXT INSP DATE: 0890

PERIOD OF INVESTIGATION INSPECTION: FROM 07/31/89 TO 08/01/89; INSPECTION PERFORMED BY: REGIONAL OFFICE STAFF; ORGANIZATION CODE OF REGION/HQ CONDUCTING ACTIVITY: 4-3-4

REGIONAL ACTION: 1 - NRC FORM 801; TYPE OF ACTIVITY CONDUCTED: 02 - SAFETY; 06 - MGMT VISIT; 10 - PLANT SEC; 14 - INQUIRY

INSPECTION LEVEL/VIOLATION FINDINGS: 1 - CLEAR; TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS: 0; ENFORCEMENT CONFERENCE HELD: 1 - YES; LETTER OR REPORT TRANSMITTAL DATE: 08/18/89

MODULE INFORMATION table with columns for Module Number, InSP, Priority, Status, and Follow-up. Includes entries for Exit/Entrance Interview, Radiation Protection, Materials Programs, and Initial (100C Required).

CIRCLE SEQUENCE # VIOLATION OR DEVIATION

INSPECTOR'S REPORT
 (Continuation)
 Office of Inspection and Enforcement

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)		REPORT		MODULE NUMBER	
03014781		NO	SEC	8711001	
			A	VIOLATION SEVERITY OR DEVIATION	
			B	1	2 3 4 5 6
			C		
			D		

VIOLATION OR DEVIATION (Enter up to 240 characters for each item. If the text exceeds this number, it will be necessary to paraphrase. Limit lines to 50 characters each.)

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Contrary to the above, on March 20, 1989, the cobalt-57 source in use had decayed to 90 microcuries.

This is a severity level IV violation. (Supplement VI)

INSPECTOR'S REPORT
(Continuation)
Office of Inspection and Enforcement

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)		REPORT		MODULE NUMBER	
03014781		NO	SEQ	871001	
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		D			
				SITE RELATED	
				A C B D	

VIOLATION OR DEVIATION (Enter up to 2400 characters for each item. If the text exceeds this number, it will be necessary to paraphrase. Limit lines to 50 characters each.)

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INSPECTOR'S REPORT
 (Continuation)
 Office of Inspection and Enforcement

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NRC FORM 788 A <small>(11-81)</small> <small>18 MC 0635</small> INSPECTOR'S REPORT (Continuation) Office of Inspection and Enforcement	DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)		REPORT NO.		MODULE NUMBER		VIOLATION SEVERITY OR DEVIATION						SITE RELATED																																																	
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