NOV 1 1989

In Reply Refer To:
License: 35-07018-02
Docket: 30-10044/89-01

Mercy Health Center
ATTN: David Landquist
Vice President
4300 West Memorial Road
Oklahoma City, Oklahoma 73120-8362

Gentlemen:

This acknowledges receipt of your letter dated October 10, 1989, in response to our letter and attached Notice of Violation dated September 21, 1989. We have reviewed your reply and find that additional information is needed.

During our review, we noted that you have not fully responded to those items specified on Page 2 of the Notice of Violation. Specifically, your reply does not indicate that you have initiated policies or procedures that would ensure that your corrective actions remain effective and that the violations do not recur. Consequently, you are required to identify those actions taken to prevent future recurrence for each of the violations.

Additionally, we would like to clarify our position regarding violations 1(b) and the requirement to check survey instrument operability using a dedicated check source on each day of use. Although the Notice of Violation referenced the requirement in 10 CFR 35.51, you should be aware that in your license application dated April 28, 1986, you have specified that you will use the Model Procedure shown in Appendix D, Section 1 of Regulatory Guide 10.8 (Revision 1, 1980), for survey instrument calibration. Appendix D of the aforementioned document requires that: (1) survey instruments be checked against a dedicated reference source before each use and also after each survey to ensure that the instrument was operational during the survey, (2) after each maintenance or battery change, and (3) at least quarterly.

It was observed during the inspection that you had performed the reference check at quarterly intervals during this inspection period. However, the provision for quarterly checks is intended for those survey instruments that are not routinely used in the department and is not meant to exempt you from performing the check on each day of use. Your review of this procedure should clarify any misunderstanding regarding conflict between your license conditions and the regulations.

We also note that your response to Violation 2(b) addresses the requirement to perform surveys of areas where radiopharmaceuticals are used, but does not mention records of these surveys. Your procedure should include documentation of such surveys as described in Item 17 of your license application dated April 28, 1986.

RIV:NMIS[illegible]C	C:NMIS[illegible]C	D:DRSS
LLKasner:ch	CLCain	ABBeach
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REG4 LIC30
35-07018-02 PNU

IE-07
1/1

You should provide your response to this office within 10 days of the receipt of this letter. Should you have any questions concerning this matter please call Linda Kasner at (817) 860-8100.

Sincerely,
Original Signed By:
LAWRENCE A. YANDELL

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

cc:
Oklahoma Radiation Control Program Director

bcc w/copy of licensee letter:
DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
LShea, RM/ALF (AR-2015)
CLCain
RJEverett
LLKasner
NMSB
MIS System
RIV Files (2)
RSTS Operator

NUCLEAR REGULATORY COMMISSION

INSPECTOR'S REPORT
Office of Inspection and Enforcement

PRINCIPAL INSPECTOR (Name and first and middle initials): KASNER, LINDA L

REVIEWER: CL CAIN

INSPECTORS:

LICENSEE/VENDOR	TRANSACTION TYPE	DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)	REPORT NO.	REPORT SEQ.	NEXT INSPEC. DATE MO	NEXT INSPEC. DATE YR
MERCY HEALTH CENTER	X I - INSERT M - MODIFY D - DELETE R - REPLACE	030T0044	8901	- A B C D	09	92

PERIOD OF INVESTIGATION/INSPECTION FROM MO	DAY	YR	TO MO	DAY	YR	INSPECTION PERFORMED BY	ORGANIZATION CODE OF REGION/HQ CONDUCTING ACTIVITY REGION	DIVISION	BRANCH
09	16	89	09	25	89	X 1 - REGIONAL OFFICE STAFF 2 - RESIDENT INSPECTOR 3 - PERFORMANCE APPRAISAL TEAM OTHER	4	3	4

REGIONAL ACTION (Check one box only)	TYPE OF ACTIVITY CONDUCTED (Check one box only)			
1 - NRC FORM 591 2 - REGIONAL OFFICE LETTER	X 02 - SAFETY 03 - INCIDENT 04 - ENFORCEMENT 05 - MGMT AUDIT	06 - MGMT VISIT 07 - SPECIAL 08 - VENDOR 09 - MAT ACCT	10 - PLANT SEC. 11 - INVENT VER 12 - SHIPMENT/EXPORT 13 - IMPORT	14 - INQUIRY 15 - INVESTIGATION

INSPECTION/INVESTIGATION FINDINGS (Check one box only) B C D	TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS A B C D	ENFORCEMENT CONFERENCE HELD A B C D	REPORT CONTAIN 2.790 INFORMATION A B C D	LETTER OF REPORT TRANSMITTAL DATE NRC FORM 591 OR REG LETTER IS SUED MO DAY YR	REPORT SENT TO HQ FOR ACTION MO DAY YR
1 - CLEAR 2 - VIOLATION 3 - DEVIATION 4 - VIOLATION & DEVIATION		1 - YES	1 - YES		

MODULE INFORMATION

NUMBER	MODULE NUMBER INSP PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	REQ'D	PRIORITY	DIRECT INSPECTION TIME EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REQ FOLLOWUP PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL
1	5	30	703	B	A	001	100						
Management Meeting					B								
					C								
					D								
1	5	30	800	B	A								
~~Initial~~					B								
					C								
					D								
1	581	731	100	C	A	007	100		C				
Program Requirements					B								
					C								
					D								
1	583	822			A	001	100		C				
Radiation Protection					B								
					C								
					D								

CIRCLE SEQUENCE # OF VIOLATION OR DEVIATION

MODULE INFORMATION

NUMBER	MODULE NUMBER INSP PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	REQ'D	PRIORITY	DIRECT INSPECTION TIME EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REQ FOLLOWUP PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL
1	5	86	740		A	002	100		C				
Transportation					B								
					C								
					D								
1	5	92	702		A	001	100						
Noncompliance Followup					B								
					C								
					D								
1					A								
					B								
					C								
					D								
1					A								
					B								
					C								
					D								

NRC FORM 775 A

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

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)	RE NO	SEQ	MODULE NUMBER	
03010844	9901	A	5187101	6
		B	VIOLATION SEVERITY OR DEVIATION	SITE RELATED
		C	1 2 3 4 5 6 D:	A C B D
		D	X	

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 80 characters each.)

10 CFR 35.92(b) requires, in part, that records of each disposal of decayed waste permitted under paragraph (a) of that section must include the dose rate measured at the surface of each waste container.

Contrary to the above, the licensee had failed to include the surface dose rate of waste containers measured prior to disposal on the required record.

NRC FORM 766 A

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

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)	RL NO	SEQ	MODULE NUMBER	
030160244	8910	A	5871101	10
		B	VIOLATION SEVERITY OR DEVIATION	SITE RELATED
		C	1 2 3 4 5 6 D	A C
		D	X	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 80 characters each.)

10 CFR 35.51(a) requires that a licensee shall calibrate all survey instruments annually and following repair of the instrument. This shall include: (1) calibration of all scales with readings up to 1,000 millirem per hour with a radiation source; (2) two separate readings on each scale that must be calibrated; and (3) determination of the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the noting of the exposure rate and date of calibration on the survey instrument. 35.51(c) requires the licensee to check each survey meter for proper operation with the dedicated check source each day of use.

a. Contrary to the above, the licensee had failed to calibrate two Ludlum Model 5 survey instruments (Serial Nos. 27072 and 27093) at two points on each scale that required calibration.

b. Contrary to the above, the licensee had failed to determine and properly note on the instrument the apparent exposure reading for a dedicated cesium-137 sealed source that was used to check survey instrument operability.

c. Contrary to the above, the licensee had failed to perform an operability check on two Ludlum Model 5 survey instruments (Serial Nos. 27072 and 27093) as required for each day of use.

NRC FORM 766 A
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INSPECTOR'S REPORT
(Continuation)
Office of Inspection and Enforcement

DOCKET NO. (8 digits) OR LICENSE NO. (FOR PRODUCT) (12 digits)	REF NO.	SEQ	MODULE NUMBER
03001044	8901	A	5871010 6
		B	VIOLATION SEVERITY OF DEVIATION: 1 2 3 4 5 6 — X
		C	SITE RELATED: A C B D
		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 80 characters each.)

Condition 16 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated April 28, 1986.

Item 17 of the application specifies that waste storage, elution, preparation, and injection areas will be surveyed weekly. This survey will include measurement of ambient exposure rates with a survey meter and wipe tests to measure contamination levels.

Contrary to the above, during the period from the date when the license was amended to incorporate the above noted application in 1986, until the date of the inspection, the licensee had performed weekly wipe tests in the required areas but had failed to measure the ambient exposure rates.

NRC FORM 766 A

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

DOCKET NO. (50-[ ]) OR LICENSE NO. (BY PRODUCT) (3 digits)	RE	MODULE NUMBER
030 10044	NO 2201 / SEQ A	5871 00 / 16
	B	VIOLATION SEVERITY OF DEVIATION: 1 2 3 4 5 6 / D
	C	SITE RELATED: A C / B D
	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 80 characters each.)

Condition 16 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated April 28, 1986.

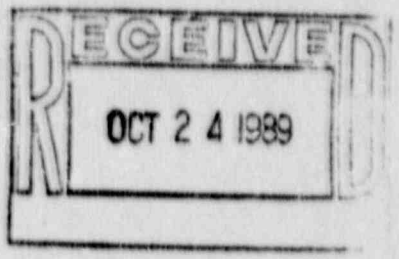
Item 14(4) of the application specifies that incoming unit dose radiopharmaceuticals received from a local radiopharmacy will be surveyed the day of receipt and prior to use. This survey will include a measurement of the surface exposure rate (expressed in mr/hr) and a wipe test of the outer package and source container (expressed in dpm), and records of such surveys will be maintained.

Contrary to the above, during the period from the date when the license was amended to incorporate the above noted application in 1986, until the day of the inspection, the licensee had failed to perform the required incoming package surveys for those radiopharmaceuticals routinely received from the radiopharmacy. The licensee had relied on and maintained records of surveys performed by the radiopharmacy prior to transportation and receipt of the material.

MERCY CANCER CENTER
4300 W. MEMORIAL ROAD
OKLAHOMA CITY, OKLAHOMA
73120-8362
405-752-3381

MERCY
CANCER CENTER
RADIATION ONCOLOGY

October 10, 1989



William L. Fisher, Chief
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76011

RE: License: 35-07018-02
Docket: 30-10044189-01

Dear Mr. Fisher:

This is in response to your Notice of Violations dated September 21st, 1989, resulting from the unannounced radiation safety inspection conducted by Ms. L. Kramer on September 6th and 8th, 1989.

1.a) The two Ludlum Model 5 (Serial Nos. 27072 and 27093) survey instruments are calibrated according to 10CFR 35.51 (a.) at 2 points on 4 scales ranging from X 0.1 to X 100 mR/hr. The X 1000 mR/hr scale has a range up to 2 R/hr. This scale is calibrated at one point, 500 mR/hr. Calibrating a second point at approximately 1.5 R/hr according to our NRC approved procedure is deemed a potential hazard under our ALARA personnel exposure levels. Any use of this instrument at this exposure rate level would be by remote control, for which this instrument is not suited. In order to be in compliance with 10CFR 35.51 (a), both instruments will be calibrated in the future by the manufacturer in order to obtain the one high exposure rate calibration point missing from our records. Full compliance will be achieved upon return of both instruments from the manufacturer for its annual calibration.

b) An exposure reading from a dedicated cesium-137 sealed source is made and recorded at the time of annual calibration and quarterly. This is in compliance with the terms of our current license conditions. Recent regulatory changes state that this reading also be conspicuously displayed on the instrument. We have corrected this situation to comply with your interpretation of the conflict between our current license conditions and more recent regulatory changes. The exposure rate readings with the check source in specific geometry relative to the detector has been posted on both Ludlum Model 5 (Serial nos. 27072 and 27093) survey instruments. Full compliance has been achieved.

c) An operational check of both Ludlum Model 5 (Serial Nos. 27072 and 27093) survey instruments with the dedicated check source will be performed each day of use. This is a visual operational check only and no records will be kept of these readings. Full compliance has been achieved.

2. a) Item 14 (4) of our current license application specifies that unit dose vials received from a local radiopharmacy will be surveyed the day of receipt and before use, and that records of such surveys will

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MERCY CANCER CENTER
4300 W. MEMORIAL ROAD
OKLAHOMA CITY, OKLAHOMA
73120-8362
405-752-3381

MERCY
CANCER CENTER
RADIATION ONCOLOGY

be maintained. Our intent in using this specific wording was to satisfy this condition with surveys performed by the local radiopharmacy on the day of receipt and before use of each unit dose vial. Records of these surveys are in our files as required. Since this was not a NRC recommended procedure, but one where we proposed our own unique wording for a license condition, we felt secure that NRC approval ensured compliance with 10CFR 20.205. Since the NRC interpretation of Item 14 (4) is different than the author, we will make the appropriate adjustments to ensure compliance. We will perform the required surveys on incoming packages containing unit dose vials on the day of receipt and before use, and maintain records of these surveys. Full compliance has been achieved.

b) Weekly ambient exposure rate measurements with a survey meter of waste storage, elution, preparation and injection areas have been added to our weekly wipe tests of these same areas. Full compliance has been achieved.

3 Surface exposure rate measurements of each waste container of decayed waste permitted under 10CFR 35.92 will be recorded on our disposal form. In the past, these measurements had been made to justify disposal, but they had not been recorded. This has been corrected and full compliance has been achieved.

If you have any other questions, please let me know. It was a pleasure working with Ms. Kasner on this inspection. We appreciate her professional approach and her thorough review. We feel her suggestions will help us continue to improve our quality control efforts in our byproduct material program. Your unannounced redundant review of our program is appreciated.

Sincerely yours,

David Lundquist
Vice President

cc: David Rogers, M.D., RSO
A.P. Turner, Ph.D., Medical Physicist
Dee Tucker, R.T., Radiology Manager

SEP 21 1989

In Reply Refer To:
License: 35-07018-02
Docket: 30-10044/89-01

Mercy Health Center
ATTN: Gary Blan
President and C.E.O.
4300 West Memorial Road
Oklahoma City, Oklahoma 73120

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Ms. L. Kasner of this office on September 6 and 8, 1989, of the activities authorized by NRC Byproduct Material License 35-07018-02, 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 the inspection, the inspector also reviewed the organization of the nuclear medicine department and the effectiveness of the Radiation Safety Committee (RSC) and the Radiation Safety Officer (RSO) in managing the various aspects of your radiation safety program. The inspector observed that these individuals appeared to function well in their respective roles and gererally directed program audits that adequately identified and corrected potential safety problems. However, as reviewed with members of your staff during the inspection, the inspector observed that you have designated many of the RSO's duties to be performed by your consulting medical physicist. Although the performance of these tasks may be designated to another individual and subsequently reviewed by the RSO, it must be emphasized that the RSO is responsible for the overall effectiveness and compliance of the radiation safety program with the Commission's rules and regulations and the conditions of your license.

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's "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.

RIV:NMIS	C:NMIS	C:NMSB
LLKasner:jt	CLCain	WLFisher
9/20/89	9/20/89	9/22/89

IE-07

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During the inspector's discussion with your staff at the conclusion of the inspection, the inspector reviewed the provisions of the revised 10 CFR Part 35 (effective April 1987), including § 35.999. Specifically, the inspector reviewed with your staff members that the purpose of this regulation is to provide resolution to points of conflict between license conditions authorized prior to April 1987, when the revised Part 35 became effective, and the regulations. This regulation is not intended to exempt licensees from the requirements of the regulations, but is meant only to resolve specific areas of conflict. You should be advised that we have given careful consideration to those items noted in the enclosed Notice of Violation to assure that the noted violations of 10 CFR Part 35 (as revised in April 1987) do not conflict with the conditions of your NRC Materials License or commitments made in your license application.

The response directed by this letter and the 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.

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:
Oklahoma Radiation Control Program Director

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

*W/766

APPENDIX

NOTICE OF VIOLATION

Mercy Health Center
Oklahoma City, Oklahoma

Docket: 30-10044/89-01
License: 35-07018-02

During an NRC inspection conducted on September 6 and 8, 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 (1989) (Enforcement Policy), the violations are listed below:

1. 10 CFR 35.51(a) requires that a licensee shall calibrate all survey instruments annually and following repair of the instrument. This shall include: (1) calibration of all scales with readings up to 1000 millirem per hour with a radiation source; (2) two separate readings on each scale that must be calibrated; and (3) determination of the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the noting of the exposure rate and date of calibration on the survey instrument. 35.51(c) requires the licensee to check each survey meter for proper operation with the dedicated check source each day of use.

   a. Contrary to the above, the licensee had failed to calibrate two Ludlum Model 5 survey instruments (Serial Nos. 27072 and 27093) at two points on each scale that required calibration.

   b. Contrary to the above, the licensee had failed to determine and properly note on the instrument the apparent exposure reading for a dedicated cesium-137 sealed source that was used to check survey instrument operability.

   c. Contrary to the above, the licensee had failed to perform an operability check on two Ludlum Model 5 survey instruments (Serial Nos. 27072 and 27093) as required for each day of use.

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

2. Condition 16 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated April 28, 1986.

   a. Item 14(4) of the application specifies that incoming unit dose radiopharmaceuticals received from a local radiopharmacy will be surveyed the day of receipt and prior to use. This survey will include a measurement of the surface exposure rate (expressed in mR/hr) and a wipe test of the outer package and source container (expressed in dpm), and records of such surveys will be maintained.

   Contrary to the above, during the period from the date when the license was amended to incorporate the above noted application in 1986, until the day of the inspection, the licensee had failed to

2pp

perform the required incoming package surveys for those radiopharmaceuticals routinely received from the radiopharmacy. The licensee had relied on and maintained records of surveys performed by the radiopharmacy prior to transportation and receipt of the material.

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

b. Item 17 of the application specifies that waste storage, elution, preparation, and injection areas will be surveyed weekly. This survey will include measurement of ambient exposure rates with a survey meter and wipe tests to measure contamination levels.

Contrary to the above, during the period from the date when the license was amended to incorporate the above noted application in 1986, until the date of the inspection, the licensee had performed weekly wipe tests in the required areas but had failed to measure the ambient exposure rates.

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

3. 10 CFR 35.92(b) requires, in part, that records of each disposal of decayed waste permitted under paragraph (a) of that section must include the dose rate measured at the surface of each waste container.

Contrary to the above, the licensee had failed to include the surface dose rate of waste containers measured prior to disposal on the required record.

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

Pursuant to the provisions of 10 CFR 2.201, Mercy Health Center 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 21st day of September 1989