OCT 18 1989

In Reply Refer To:
License: 05-01401-02
Docket: 30-01234/89-01

Veterans Administration Medical Center
ATTN: Fred Salas
Medical Center Director
1055 Clermont Street
Denver, Colorado 80220

Gentlemen:

Thank you for your letter of October 5, 1989, in response to our letter and attached Notice of Violation both dated September 5, 1989. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. We appreciate your detailed response to the identified violations, and 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:
A. B. BEACH

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

cc:
Colorado Radiation Control Program Director

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

*C:NMIS	D:DRSS
CLCain	ABBeach
/ /89	10/18/89

*Previously concurred

1/1
IE-07

Medical Center

1055 Clermont Street
Denver CO 80220

Department of Veterans Affairs

October 5, 1989

In Reply Refer to:

RE: License #05-01401-02
Docket # 30-01234/89-01

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

Dear Mr. Fisher:

This letter is in response to the Notice of Violation and cover letter from your office dated 09/05/89 which were the result of the routine unannounced inspection conducted by Messrs. Van Scovill, Howard Rose, and Scott Grace on August 2-3, 1989. Our letter of May 20, 1988 following inspection in January, 1988, indicated that we had contracted with the Radiological Sciences Division, Department of Radiology, University of Colorado, to provide radiation safety assistance and appointed a Nuclear Medicine Technician as Radiation Safety Technologist. Our intent was that this would be a short term arrangement. Unfortunately, due to the shortage of experienced Health Physicists it took us much longer to recruit than anticipated. Additionally, during this time our Nuclear Medicine Technician staff declined from four to one. The foregoing is intended to be a general explanation of the reason for the violations. While it does not excuse us, especially from the two repeat violations, I hope it will be considered as mitigating somewhat our lapses.

We are confident that our successful recruitment of a Radiation Safety Officer in August will markedly improve the management control of our licensed activities. A letter requesting an amendment to our license to list our new Radiation Safety Officer as such has just gone to your Licensing Branch following approval of his appointment by the Radiation Safety Committee.

The Radiation Safety Officer is in the process of preparing written procedures documenting NRC requirements, to insure that if staffing problems arise in the future, the requirements of the radiation safety program will be clearly outlined and lapses will not occur. Specific responses to each violation follow.

a. Violation 1 - This violation was the result of a very heavy workload for the sole Nuclear Medicine Technician and the lack of a full time Radiation Safety Officer. When the Technician got backlogged with the patient load, package surveys were one of the things he did not keep up with. The lack of a full time Radiation Safety Officer allowed this condition to persist rather than be corrected as it should have been, even at the expense of not handling all the patients in need of treatment.

IC-89-651 ~~8910180324~~ 3pp.

IE07

Corrective action has included recruitment of a full time Radiation Safety Officer and instruction to the Technician regarding the importance of license conditions/agreements. The surveys are being done as required. In addition, to prevent a recurrence the Radiation Safety Officer is preparing a written procedure. The procedure will be implemented not later than October 31, 1989, on an interim basis pending approval by the Radiation Safety Committee at its next meeting, scheduled for November 30, 1989.

b. Violation 2 - In conducting its research activities, this Medical Center has historically relied on its principal investigators or users to instruct their lab personnel. The reason for this has been two-fold - the burden was placed on the researcher who was using the material; and it was felt the researcher was best acquainted with his own lab activities and so was best able to instruct in lab specific precautions. The Radiation Safety Officer also provided supplementary in-service training sessions as requested. This approach is the same that many Broad Scope Licensees have taken, but has resulted in inadequate documentation of training held.

To correct this violation the Radiation Safety Officer will assume responsibility for instruction under Section 19.12. In-service training covering the requirements of 19.12 will be held not later than October 31, 1989 with Research Service personnel. Additional in-service training sessions will be scheduled to provide instruction to personnel who work in or frequent other restricted areas not later than December 31, 1989.

To prevent recurrence, the RSO will also prepare an information sheet for distribution at orientation informing all new employees of general guidelines required under 10 CFR 19.12, and informing them that they will receive further training should they be assigned to a restricted area. Additionally, the information sheet will be sent to all Service Chiefs with a cover memorandum explaining the requirements. Instruction of personnel newly assigned to restricted areas will initially be done by supervisors, but will be supplemented by additional training given by the Radiation Safety Officer.

c. Violation 3 - This violation was the result of our contract Health Physicist's failure to comply with the survey requirement. We had reason to believe that he understood the requirements of 10 CFR 20 and assumed he was complying with those requirements. We fully understand, however, that the responsibility is and was ours. That this was a repeat violation is particularly troubling to us. The Radiation Safety Officer is conducting all such surveys now. The Radiation Safety Officer will additionally prepare a written procedure for decay-in-storage waste disposal and surveys, to prevent recurrence. The procedure will be submitted to the Radiation Safety Committee for review and approval at its next meeting, and will be implemented not later than November 30, 1989.

d. Violation 4 - This violation was caused by the Nuclear Medicine Technician's haste to prepare a camera for a study. In his haste he failed to attach a label to some containers. The Technician has been given instruction with respect to the labeling of radiopharmaceuticals, and is nov labeling all containers which ma; be left unsecured and unattended (but in a restricted area).

Sincerely Yours,

Fred Salas
Medical Center Director

SEP - 5 1989

In Reply Refer To:
License: 05-01401-02
Docket: 30-01234/89-01

Veterans Administration Medical Center
ATTN: Fred Salas
Medical Center Director
1055 Clermont Street
Denver, Colorado 80220

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Messrs. Van Scovill, Howard Rose, and Scott Grace of this office on August 2-3, 1989, of the activities authorized by NRC Byproduct Material License No. 05-01401-02 and to the discussion of our findings held by the inspectors with Dr. Geoffrey Friefield 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 inspectors.

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 these matters 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.

The inspectors also reviewed the actions you had taken with respect to the violations observed during our previous inspection conducted on January 28-29, 1988. We have no further questions concerning Violations 2, 3, 4a, 4b, 4c and 4d; however, we have noted that Violations 1 and 4e have recurred since the previous inspection. These violations are identified as Violations 1 and 3 in the attached Notice.

After our previous inspection, which was conducted on January 28-29, 1988, we requested that you provide us with a written commitment to improve the management control of your licensed operations. In your response dated May 20, 1988, you described the measures you would take to ensure that the two violations indicated above would not recur. We are concerned that these violations have recurred and that additional violations were identified during the current inspection.

*URFO	*RIV:NMIS	*C:NMIS	C:NMSB
VScovill	ADGaines	CLCain	WLFisher
/ /89	/ /89	/ /89	9/5/89

*Previously Concurred

8909130213 2pp.

Therefore, in your response to the attached Notice, you should describe those specific actions planned or taken to improve the management control of your licensed activities. These actions should be in addition to those described in your letter dated May 20, 1988. You should be aware that further recurrence of these violations will result in escalated enforcement actions by this agency.

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:
Colorado Radiation Control Program Director

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

*W/766

IE-07

APPENDIX

NOTICE OF VIOLATION

Veterans Administration Medical Center
Denver, Colorado

Docket: 30-01234/89-01
License: 05-01401-02

During an NRC inspection conducted on August 2-3, 1989, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1989), the violations are listed below:

1. License Condition 19 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application dated January 4, 1980.

   Item 14, page 42, of the application requires, in part, that incoming packages containing radioactive materials be surveyed at the package surface and at 3 feet from the package surface.

   Contrary to the above, incoming packages containing radioactive material were not surveyed at the package surface and at 3 feet from the package surface for the period September 19, 1988, through the date of this inspection.

   This is a repeat violation.

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

2. 10 CFR 19.12 requires that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radiation and radioactive materials, and in the applicable provisions of the Commission's regulations and licenses.

   Contrary to the above, as of August 2, 1989, individuals who work in the research areas had not been instructed in the required subjects.

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

3. 10 CFR 20.401(b) requires, in part, that each licensee maintain records showing the results of surveys required by 10 CFR 20.201(b).

   Contrary to the above, for the period January 28, 1989, to the date of this inspection, records of surveys were not maintained of decay-in-storage radioactive waste (iodine-131) disposed of as normal waste to ensure compliance with 10 CFR 20.301, which describes authorized means of disposing of radioactive waste.

   This is a repeat violation.

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

~~8909130217~~ 2pp

4. 10 CFR 20.203(f) requires that each container of specified amounts of licensed material bear a durable, clearly visible label identifying the radioactive contents.

   Contrary to the above, on August 2, 1989, two lead containers, one containing approximately 7.7 millicuries and one containing approximately 1.6 millicuries of technetium-99m were identified during the inspection and no label had been applied.

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

Pursuant to the provisions of 10 CFR 2.201, Veterans Administration Medical 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 5th day of September 1989

NRC FORM 766 (11-81) NRC MC 0535

U.S. NUCLEAR REGULATORY COMMISSION

INSPECTOR'S REPORT
Office of Inspection and Enforcement

PRINCIPAL INSPECTOR (Name, last, first, and middle initial): Scavilli, Dan R

REVIEWER: Cain, Charles OMC

INSPECTORS: Dan Scavilli; Howard Rose; Scott Grace

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.
VA Medical Center 1055 Clermont Street Denver, Colorado 80220	X I – INSERT M – MODIFY D – DELETE R – REPLACE	0300 1234	8901	A	08	80

PERIOD OF INVESTIGATION/INSPECTION FROM	TO	INSPECTION PERFORMED BY	ORGANIZATION CODE OF REGION/HQ CONDUCTING ACTIVITY (See IEMC 0530 "Manpower Reporting – Weekly Manpower Reporting" for code)
MO. DAY YR.	MO. DAY YR.	X 1 – REGIONAL OFFICE STAFF 2 – RESIDENT INSPECTOR 3 – PERFORMANCE APPRAISAL TEAM OTHER	REGION: 4 DIVISION: 4 BRANCH: 2
08 02 89	08 03 89		

REGIONAL ACTION (Check one box only)	TYPE OF ACTIVITY CONDUCTED (Check one box only)			
1 – NRC FORM 591 X 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 – ENQUIRY 15 – INVESTIGATION

INSPECTION/INVESTIGATION FINDINGS (Check one box only)	TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS	ENFORCEMENT CONFERENCE HELD	REPORT CONTAIN 2.790 INFORMATION	LETTER OR REPORT TRANSMITTAL DATE: NRC FORM 591 OR REG. LETTER IS SUED	LETTER OR REPORT TRANSMITTAL DATE: REPORT SENT TO HQ FOR ACTION
A B C D 1 – CLEAR X 2 – VIOLATION 3 – DEVIATION 4 – VIOLATION & DEVIATION	A B C D: 0 4	A B C D: 1 – YES	A B C D: 1 – YES	MO. DAY YR.: 09 05 89	MO. DAY YR.

MODULE INFORMATION

REC ORD	TYPE	MODULE NUMBER INSP. PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	PRIORITY	DIRECT INSPECTION EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REQ. FOLLOWUP PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	Description
0	1	5 3 0	7 0	3		0 0 1	~~1 0 0~~							Management Entrance/Exit Interviews
0	1	5 8 8	0 0	5										~~Management Organization and Controls~~
0	1	5 9 2	7 0	2		0 0 3	1 0 0	C						Followup on Noncompliance
0	1	~~5 9 2~~	~~7 0~~	~~4~~		0 0 1	1 0 0							~~Independent Effort~~

MODULE INFORMATION

REC ORD	TYPE	MODULE NUMBER INSP. PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	PRIORITY	DIRECT INSPECTION EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REQ. FOLLOWUP PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	Description
0	1	5 8 8	0 2	5										~~Maintenance/ Surveillance Testing~~
0	1	5 8 3	8 2	2		0 0 2	1 0 0	C						Radiation Protection
0	1	5 8 7	1 0	1		0 0 1	1 0 0	C						Program Requirements
0	1	5 8 6	7 4	0		0 0 1	1 0 0	C						Transportation of Radioactive Materials

NRC FORM 766 A (11-81) IE MC 0535

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

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)	REPORT NO.	SEQ.	MODULE NUMBER	VIOLATION SEVERITY OR DEVIATION "D"	SITE RELATED
03001224	8901	A	58382	5 (X)	

Suppl

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.)

A. 10 CFR 20.401(b) requires, in part, that each licensee maintain records showing the results of surveys required by 10 CFR 20.201(b).

Contrary to the above, for the period January 28, 1989, to the date of this inspection, records of surveys were not maintained of decay-in-storage radioactive waste (iodine-131) disposed of as normal waste to ensure compliance with 10 CFR 20.301, which describes authorized means of disposing of radioactive waste.

~~This is a Severity Level V violation. (Supplement IV)~~

NRC FORM 766 A (11-81) IE MC 0535

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

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)	REPORT NO.	SEQ.	MODULE NUMBER	VIOLATION SEVERITY OR DEVIATION	"D"	SITE RELATED
030-01234	8901	A	58711 00	4 (X)	4	

Suppleme[illegible]

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.)

B. Condition 19 of License No. 05-01401-02 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in the application dated January 4, 1980.

Item 14, page 42, of the application requires, in part, that incoming packages containing radioactive materials be surveyed at 3 feet from the package surface and at the package surface and that the results be maintained.

Contrary to the above, incoming packages containing radioactive material were not surveyed at 3 feet from the package surface and at the package surface for the period September 19, 1988, through the date of this inspection.

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

Suppl.

NRC FORM 766 A
(11-81)
E MC 0535

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

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)	REPORT NO.	REPORT SEQ.	MODULE NUMBER
0 3 0 0 1 2 3 4	8 9	0 1	5 1 3 1 8 1 2 1 4

VIOLATION SEVERITY OR DEVIATION: 1 2 3 4 X 5 6 — "D" — 6

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 80 characters each.)

C. 10 CFR 19.12 requires that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radiation and radioactive materials, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of August 2, 1989, individuals who work in the research areas had not been instructed in the required subjects.

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

Supplement

NRC FORM 766 A
(11-81)
10 CFR 6535

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

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)	REPORT NO.	SEQ.	MODULE NUMBER
0 3 0 0 1 2 3 4	8 9 0 1	A	5 1 3 1 8 1 2 1

VIOLATION SEVERITY OR DEVIATION: 1 2 3 4 5 6 — "D" — 4

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 80 characters each.)

D. 10 CFR 20.203(f) requires that each container of specified amounts of licensed material bear a durable, clearly visible label identifying the radioactive contents.

Contrary to the above, on August 2, 1989, two lead containers, one containing approximately 7.7 millicuries and one containing approximately ~~1580 microcuries~~ 1.6 millicuries of Technetium-99m were identified during the inspection and no label had been applied.

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