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.

S Wight Signed Dy:

A: B. BEACH

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

cc: Colorado Radiation Control Program Director

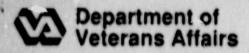
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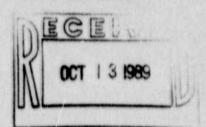
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1055 Clermont Street Denver CO 80220



October 5, 1985



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 vill 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.

Mr. William L. Fisher

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.

Mr. William L. Fisher

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 now labeling all containers which may be left unsecured and unattended (but in a restricted area).

Sincerely Yours,

Fred Salas

Medical Center Director

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 pravious 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.

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^{*}Previously Concurred

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

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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:

 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)

 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)

 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)

 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

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