Medical Center

700 South 19th Street
Birmingham AL 35233

Veterans Administration

DEC 12 1989

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

In Reply Refer To: 521/115

SUBJECT: Reply to Notice of violation
(Report No. 01-00643-02/89-01

1. Pursuant to the provision of 10 CFR 2.201, the following information is submitted:

A. 10 CFR 35.22(a) (2) required the licensee's Radiation Safety Committee to meet at least quarterly.

Due to a change in secretarial support the meeting scheduled for the third quarter of calendar year 1988 was five days late. We have had four meetings during calendar year 1989, two the first quarter, one in the second quarter, one in the third quarter and a fifth meeting scheduled for November 15, 1989. There will be a meeting during each quarter of the calendar year and additional meetings whenever needed. Notification of all meetings will appear in the Hospital Newsletter, at least one month prior to the announcement. In addition, minutes of the last meeting and the agenda of the forthcoming meeting will be sent to each member of the Radiation Safety Committee. A telephone call will be made to each member by the secretary to confirm date, time and place of scheduled meeting. Since the Administrative Officer to the Chief of Staff is a member of the Radiation Safety Committee, he will be responsible for announcing to management when and where the meetings are to be held. Full compliance to this violation was achieved during the first quarter 1989.

B. Licensee Condition 13 requires that the licensee's program be conducted in accordance with the statements and representations contained in the application dated June 19, 1987. Attachment 10.2 of the application states that the licensee will establish and implement the model ALARA program in Appendix G to Regulatory Guide 10.8, Revision 2. The model ALARA program requires the Licensee's management to perform a formal annual review of the radiation safety program including reviews of operating procedures and past dose records, inspections and consultation with the radiation safety staff or outside consultants.

In accordance with the above, a formal annual review of the safety program was conducted for calendar year 1988. The specifics of that meeting such as operating procedures, inspections, dose records and consultation with the radiation safety staff were not reflected. In the future a more detailed account will be reflected in the minutes.

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Moreover, the Radiation Safety will incorporate into the agenda the model ALARA program. Annually the Radiation Safety Committee will perform the following elements of the radiation safety program and ALARA considerations:

1) Management Commitment.
2) Review of proposed users and uses of radioactive materials.
3) Review of efforts of all applicants to maintain exposure ALARA.
4) Delegation of authority to the Radiation Safety Officer to the enforcement of an ALARA program.
5) Review current procedure and develop new procedures as appropriate to implement the ALARA concept.
6) Assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

In addition, the Radiation Safety Officer will report on the following items:

1) Annual review of the Radiation Safety Program for adherence to ALARA Concepts.
2) Review of occupational exposures.
3) Review of records of radiation level surveys.
4) Review of education responsibilities for ALARA program.
5) Review instances of deviation from good ALARA practices.

Full compliance to violation B will be achieved during Radiation Safety Committee meeting for November 15, 1989 and first quarter RSC meeting in calendar year 1990.

C. 10 CFR 25.59(b) (2) requires that sealed sources be tested for leakage at intervals not to exceed six months.

A checklist will be acquired by the RSO to indicate compliance with CFR 35.59(b) (2). This checklist will be reviewed and initialed by the RSC at each quarterly meeting for compliance. The RSO will perform leak tests twice annually and present his records to the Radiation Safety Committee for review. Compliance to violation C commenced October 23, 1989 which was the beginning of the fourth quarter for calendar year 1989.

D. 10 CFR 35.59(g) requires a licensee in possession of a sealed source to conduct a quarterly physical inventory of all such sources.

A checklist will be acquired by the Radiation Safety Officer to indicate compliance with 10 CFR 35.59(g). This checklist will be reviewed by the RSC for compliance. The RSO will conduct a quarterly physical inventory of all sealed sources and present his records to the RSC for review. Compliance to violation D commenced October 10, 1989.

E. 10 CFR 35.70(e) requires that surveys be performed for removable contamination once each week in all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.

The performance of this regulation will also be checked by the RSO and the RSC for compliance. The RSO will be responsible for the performance of this regulation and will require the technologist assigned this duty to present his/her records to the RSO weekly for evaluation. Compliance to violation E commenced June 9, 1989.

F. 10 CFR 35.51 requires that survey instruments be calibrated and that the apparent exposure rate from a dedicated check source determined at the time of calibration be conspicuously noted on the instrument. Also, the licensee shall attach a correction chart or graph to the instrument if the indicated exposure rate differs from the calculated exposure rate.

The exposure rate from a dedicated check is placed daily in a ledger. The present method will adhere to the requirements as indicated above in 10 CFR 35.51. The Radiation Safety Officer will calibrate survey meters once annually and the readings of a dedicated check source will be placed on each instrument. The RSO will also attach a correction chart or graph if the dedicated exposure rate differs from the calculated exposure rate. Full compliance to violation F will be achieved January, 1990.

G. 10 CFR 35.70(a) requires that surveys be performed with a radiation detection survey instrument at the end of each day of use in all areas where radiopharmaceuticals are routinely prepared for use or administered. 10 CFR 35.70(h) requires that records be maintained of surveys required by 10 CFR 35.70(a) and that the records include the date of the survey, a plan of each area surveyed, the trigger level of each area, the detected dose rate in each area, the instrument used to make the survey and the initials of the individual who performed the survey.

Three elements of the above regulation were omitted. This regulation 10 CFR 35.70(a) will be performed daily and the surveys will be reviewed for completion by the Radiation Safety Committee. The RSO will review weekly records of this regulation and prepare a quarterly summary report for the Radiation Safety Committee. Full compliance to violation G commenced November 8, 1989.

H. 10 CFR 35.50(e) requires that records be retained of various dose calibrator tests required by 10 CFR 35.50(b). Included in the information which must be entered on these records is the signature of the Radiation Safety Officer.

All specifics required in 10 CFR 35.50(e) will be completed, checked and reviewed periodically by the Radiation Safety Officer. Full

compliance to violation H achieved on August 11, 1989.

2. As requested by the U.S. Regulatory Commission, Region II, Atlanta, Georgia, the following statement is submitted:

There appears to be no specific management oversight in the Birmingham VA Medical Center Radiation Safety Program. However, the Radiation Safety Committee will review its administrative requirements and make recommendations, where necessary, to ensure that management oversight is not responsible for any violations that may be attributable to this program from future NRC inspections. All members of the Radiation Safety Committee are required to be familiar with rules and regulations in Title 10 CFR, with particular emphasis on Part 35, Human Uses of Byproduct Material. The RSO will periodically discuss sections from Title 10 CFR at RSC meetings in order to help keep the members abreast of the current rules and regulations. In addition, since all of the violations cited during the August 10, 1989 inspection by NRC were taken from Part 35, Human Uses of Byproduct Material, the Radiation Safety Officer will give periodic reviews on Part 35 to the RSC members, technologists, research workers, and any other group, concerned with human uses of byproduct material.

The level of knowledge of regulatory requirements of personnel involved in this program is without a doubt outstanding. The present RSO has served in this capacity for some 26 years. He has served as RSO at the BVAMC and The University of Alabama in Birmingham simultaneously. He established "Short-courses" in Radioisotopes in Biology and Medicine at the BVAMC and UAB. These courses were designed for medical doctors, technologists, research scientists, and other individuals interested in working with radionuclides. Regulatory requirements as submitted by NRC were constantly reviewed in these courses and course participants were given oral and written examinations on these requirements and procedures. Occasionally Radiation Safety Officers from other medical centers throughout the country converse with the BVAMC RSO, via telephone, seeking explanations, interpretations, and other pertinent information pertaining to regulatory requirements and procedures found in 10 CFR. The BVAMC RSO impresses upon other RSOs receiving this information that any inquiry concerning the accuracy of the received information, should be confirmed by their respective regulatory commission before utilization.

The Nuclear Medicine Division of this address of use has well-trained, experienced, and certified Nuclear Medicine Technologists who assist the RSO in maintaining a safe radiation environment. All of these technologists received their training at the School of Nuclear Medicine Technology, which was established by the BVAMC and UAB. Initially, the present RSO, because of his outstanding service in conducting the "Short-courses" in Radioisotopes Biology and Medicine, was given the task to set up the Nuclear Medicine Technology Training Program Curriculum. All of the current technologists working at the

BVAMC received their radiation safety training under the auspices of the present RSO. With a team consisting of two highly trained physicians who are Nuclear Medicine Specialists and who are chairpersons of their Nuclear Medicine Division (BVAMC and UAB), a radiation safety officer with 32 years experience, and experienced certified Nuclear Medicine Technologists should leave without a doubt that the level of knowledge of regulatory requirements of personnel involved in this radiation safety program is second to none.

Johnny W. Scott

Johnny W Scott, M.D., Ph.D.
Chairman, Radiation Safety Committee

Robert K. Davenport
Director

cc: U.S. Nuclear Regulatory Commission
Regional Administrator, Region II

VA Central Office
Director, Nuclear Medicine Service

Veterans Administration
Medical Center (115)
700 South 19th Street
Birmingham, Alabama 35233

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112