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In Reply Refer To: 521/115

J. Phillip Stohr, Director Division of Radiation Safety and Safeguards United States Nuclear Regulatory Commission, Region II 101 Marietta Street, N.W. Atlanta, Georgia 30323

03001204

Gentlemen:

SUBJECT:

Notice of Violation

(NRC Inspection Report No. 01-00643-02/89-01)

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.

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

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program was conducted that meeting such as or records and consultation not reflected. In the reflected in the minut will incorporate into the Radiation Safety of the radiation 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. Moreover, the Radiation Safety Officer 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.
- Review the efforts of all applicants to maintain exposure ALARA.
- 4) Delegation of authority to the Radiation Safety Officer to the enforcement of an ALARA program.
- Review current procedures 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.
- C. 10 CFR 35.59(b) (2) requires that sealed sources be tested for leakage at intervals not to exceed six months.

A checklist will be acquired by the Radiation Safety Officer to indicate compliance with 10 CFR 35.59(b) (2). This checklist will be reviewed and initialed by the Radiation Safety Committee at each quarterly meeting for compliance. The Radiation Safety Officer will perform leak tests twice annually and present his records to the Radiation Safety Committee for review.

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 Radiation Safety Committee for compliance. The Radiation Safety Officer will conduct a quarterly physical inventory of all sealed sources and present his records to the Radiation Safety Committee for review.

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> E. 10 CFR 35.70(e) requires that surveys be performed by 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 Radiation Safety Officer and the Radiation Safety Committee for compliance. The Radiation Safety Officer will be responsible for the performance of this regulation and will require, the technologist assigned this duty to present his/her records to the Radiation Safety Officer weekly for evaluation.

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 Radiation Safety Officer will also attach a correction chart or graph if the dedicated exposure rate differs from the calculated exposure rate.

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 Radiation Safety Officer will review weekly records of this regulation and prepare a quarterly summary report for the Radiation Safety Committee.

H. 10 CFR 35.30(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.

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

Robert

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Director

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Johnny W. Scott, M.D., Ph.D.

Chairman, Radiation Safety Committee