Medical Center
2002 Holcombe Boulevard
Houston TX 77030

Veterans Administration

In Reply Refer To: 580/138

MAR 1 1990

Mr. A. Bill Beach
Director, Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission/Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Dear Mr. Beach:

As per our discussion, this letter is to provide you with a summary of corrective actions which were discussed during the enforcement conference held February 22, 1990. This information is a brief summary of corrective actions we have taken thus far and is not intended to be a formal written response to specific violations. The latter will be provided upon request.

As discussed during the conference, I have made a specific commitment to permanently correct the number and type of violations noted during the recent NRC inspection. Therefore, a great deal of administrative effort and engineering controls have been put into corrective actions.

One of the most significant changes to the Radiation Safety Program is the assignment of the Radiation Safety Officer (RSO) position to the medical center Director. In addition, the Resource Management Committee has approved the immediate recruitment of a Health Physics Assistant to assist the RSO with his radiation safety responsibilities.

The following pages will outline the specific corrective actions which have been implemented since January 1990.

Please feel free to contact me at any time concerning this matter.

Sincerely,

John Sheehan

JOHN SHEEHAN
Director

Enclosure

DMB 1/11
IE-07

IC-90-075

CORRECTIVE ACTION SUMMARY
BROAD LICENSE

Radiological Surveys and Evaluations:

1. Facility Ventilation and Exhaust Pathway Evaluations

a. Engineering Service has made the necessary modifications to Dr. Meyer's lab (Bldg. 26D) to insure compliance (calculations are provided for review). These measurements will be verified at the required intervals to insure continued compliance. Additionally, glass vials are now being used to dispense Xe-133, rather than plastic syringes. Vials left over from the day's activities will be stored in Nuclear Medicine fume hoods until the following working day.

b. Hoods in Nuclear Medicine have been calibrated and exhaust rates verified. Rooms are at negative pressure. These measurements will be checked at the required intervals to insure continued compliance.

c. We have calculated the spilled gas clearance times according to the procedure that was published in Appendix 0.4 to Regulatory Guide 10.8, Revision 2. These calculations have been posted within the respective rooms.

d. Research facility: with the exception of Bldg. 211, Rm. 207B, all fume hoods have been shut down until modifications are completed to insure proper flow rates. Outside vendor has been contracted to modify ductwork, and to install charcoal filters to be utilized by the Radiation Safety Officer (RSO) for air sampling of those hoods which will be utilized for iodinations. License will be amended immediately to indicate which rooms will be utilized for use and storage of radioactive iodine. Subsequent checks will be conducted at required intervals to insure continued compliance.

2. Failure to conduct certain required surveys and to fully evaluate others:

Training has been conducted to inform staff members of the proper frequency and methods to be used in conducting surveys. This included the proper intervals, type of instrument to be used, a reference map identifying areas surveyed, conversion of cpm to dpm, threshold level for decontamination, and documentation of results. Surveys have been conducted, and the RSO will conduct routine audits of these lab surveys as well as performing monthly surveys of these labs himself.

3. Failure to implement a bioassay program:

A contract with Baylor College of Medicine has been secured to provide interim basis bioassays for those individuals requiring such surveys. These individuals have already started the program. Nuclear Medicine personnel will have bioassays conducted within their department with equipment that is already available. Bioassay instrumentation has been authorized by Washington, D.C. for purchase by VA Medical Center in Houston and a purchase order has been placed to acquire this equipment. The bioassay program will be evaluated by the Radiation Safety Committee (RSC) on a quarterly basis as part of the ALARA report to this committee.

4. Failure to provide dosimetry devices for personnel; improper exchange rates; failure to evaluate occupational doses for individuals with damaged or missing devices:

a. Previous dosimetry vendor (Tech/OPs Landauer, Inc.) has been requested to provide duplicate records for those badge reports which are missing; subsequently any remaining badges which were damaged or lost will be evaluated so that a proper exposure can be assigned to these badges.

b. Additionally, a different system of exchanging film badges has been implemented. Each major service (i.e., Medicine, Surgery, Radiology, Research, etc.) has assigned a "Film Badge Coordinator" who will communicate directly with the RSO for the proper distribution of personnel dosimeters.

Facilities and Equipment:

1. Storage of radioactive materials in areas not authorized by license; also lack of security in storage areas:

a. Those rooms where charcoal traps containing Xe-133 are being temporarily stored (Rm. B-19, B-20B) have been posted with appropriate signage, and a weekly RSO survey of these rooms is conducted. Although these rooms are indeed a portion of the CBF lab, a license amendment will be submitted to indicate the room numbers and location.

b. The research personnel, Bldg. 211, have been individually instructed by the RSO as to the security requirements for those rooms where radioactive materials are used and/or stored. These rooms will be locked during any period when lab personnel are not in the area to provide surveillance.

c. The brachytherapy source storage area, located in the radiotherapy department has had the lock on the door changed to a dead-bolt type lock. Limited staff personnel have access to the key to this lock. Vendor will not be given the access to this lock.

2. Failure to provide an adequate number and type of survey instruments; failure to calibrate instruments; failure to complete required operability checks prior to use:

Although a recent inventory of survey instruments on station revealed more survey meters than was discovered during the walk-through with NRC (six (6) in Research, two (2) in Nuclear Medicine, two (2) in RSO office, and two (2) in Radiotherapy), three (3) additional meters have been ordered for the RSO, and additional meters are being purchased for the research facility. All survey meters presently on site have been calibrated by an outside vendor (Suntrak) since the NRC visit. Check sources were also attached to meters for daily operational checks. Staff have been instructed by the RSO as to the need for operability checks prior to use of the instruments.

3. Failure to perform dose calibrator constancy and linearity checks and failure to maintain records of those test procedures:

Linearity, Geometry, and Accuracy have been performed on both dose calibrators by the RSO. Personnel have been trained by the RSO as to the proper techniques for daily constancy check. Tables have been posted reflecting the decay values for check sources so as to insure +/- 5% compliance. This data will be kept on file with both the RSO office and the Nuclear Medicine Service.

Human Use of Medical Products:

1. Failure to record radiopharmaceutical doses administered to patients:

Proper documentation of patient records has been implemented within the CBF lab for patients receiving Xe-133. The RSO will periodically audit these records to ensure continued compliance.

Records and Reports:

1. Failure to maintain records of occupational radiation exposures for staff personnel:

Corrections have been made with regard to the appropriate frequency by which badges are exchanged. Finger badges have been issued to those individuals working with millicurie amounts of P-32. Additionally, the RSO is now on-line, via MODEM, with the dosimetry vendor so that any future modifications such as deletions, additions, quick reports, history updates, etc. can be made expeditiously. Bar coding system is also being evaluated to insure lost or damaged dosimeters are properly monitored and assigned a proper exposure rate in a timely manner.

2. Failure to adequately document radiation surveys including ambient dose rates & wipe tests; failure to establish threshold levels for decontamination surveys; failure to identify the instruments used to perform these surveys:

As stated above, staff has been instructed by the RSO for the proper techniques to be employed during wipe testing and ambient dose rate surveys. Proper documentation of the surveys will be checked by RSO to insure continued compliance.

Organization and Management:

1. Research project approval:

Both the Radiation Safety Committee and the Radioisotope Use Subcommittee will be re-evaluated as to its membership and their communication/interactions with each other. A summary checklist has been established for use by the Subcommittee to be utilized for review of each protocol involving radioactive material. This list includes such pertinent information as quantities, adequate ventilation rates, locations, instrumentation, etc.
Additionally, this Subcommittee will provide a thorough presentation to the Radiation Safety Committee of each protocol so that authorization is granted only to those projects which have addressed the appropriate elements of safety.

2. Functions of the RSO and RSC:

The RSO's chain of command has been changed so that he is now directly responsible to the medical center Director. This change in accountability will thereby delegate commensurate authority with his incumbent responsibilities.
Additionally, this change will also provide a direct line of communication for the Radiation Safety Committee, and thereby provide effective enforcement of their recommendations.

CORRECTIVE ACTION SUMMARY
TELETHERAPY LICENSE

Review and Designation of Authorized Users, RSO and Teletherapy Physicist:

1. Failure of the RSC to review credentials; failure to provide credentials to NRC for review and amendments to license -

Committee has reviewed credentials, and license amendment was submitted to reflect changes.

2. Failure to notify NRC regarding loss of RSO, authorized users and teletherapy physicist:

License amendment has been submitted reflecting changes in personnel.

Teletherapy Spot Checks and Annual Calibrations:

1. Failure of teletherapy physicist to review monthly spot checks performed by other individuals or to provide written reports as required:

Spot checks will only be performed by an authorized teletherapy physicist. If personnel other than physicist performs these check reports, the physicist will provide a written report of his review of these checks. Periodic audits of these records by the RSO will ensure continued compliance.

2. Performance of full calibrations by individuals other than the designated teletherapy physicist:

Under no circumstances will a full calibration be conducted by anyone other than the teletherapy physicists listed on this license. License will be amended to reflect any changes in teletherapy physicist staffing.

3. Failure to include evaluation of timer linearity and constancy during monthly spot checks; Full calibration of the teletherapy unit had not included evaluation of linearity and constancy over full range of clinical use:

These changes have been implemented by teletherapy physicist, and future documentation of these procedures will reflect these changes.

4. Failure to include an evaluation of radiation field uniformity with respect to beam orientation:

These changes have been implemented by teletherapy physicist, and future documentation of these procedures will reflect these changes.

5. Failure to conduct full calibration of teletherapy unit during 1989:

Full calibration of the teletherapy unit was completed during January 1990 by Dr. Kosnik, authorized teletherapy physicist for this license. Documentation of this calibration is on file for inspection.

Records and Reports:

1. Failure to maintain records of leak test results:

Leak test results will be maintained by the RSO as well as the radiotherapy department. Semi-annual inventory of sealed sources, and subsequent leak testing of these sources will be conducted by the RSO. Results of leak tests will be maintained on file for inspection as required by license condition 14.A.

2. Failure to maintain records of occupational radiation exposure for personnel:

Previous dosimetry vendor has been requested to forward duplicate records of those film badge reports that are missing. Subsequently, film badges which were lost or damaged will be evaluated so that appropriate radiation exposure can be assigned.

CLOSING SUMMARY

During the enforcement evaluation conference, VAMC Houston has demonstrated immediate corrective actions for violations and deficiencies which were cited during the NRC visit. This medical center has identified the corrective actions that have already been implemented, as well as outlining our plans for preventing any recurrence of these deficiencies. We understand the severity of the violations noted, and have taken immediate steps to correct these areas. Concurrently, we are correcting those areas which require equipment purchase and facility modifications. With regard to specific actions planned to improve the effectiveness of management's control of our licensed operations, we have (a) initiated re-evaluation of the RSC membership and its interaction with the Radioisotope Use Subcommittee, (b) changed the RSO's accountability to being directly responsible to the Director's Office, and have started work on new quality control plan for maintaining compliance. We are currently participating in a NRC pilot study, being conducted by Brookhaven Laboratories, to draft a quality control program which addresses the changes to CFR Part 35 requirements. We have taken positive steps toward improving our Radiation Safety Program, and maintaining full compliance with NRC.