APPENDIX A

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 30-03255/89-01 License: 42-00084-06

Docket: 30-03255

Licensee: Veterans Administration Medical Center (VAMC)
2002 Holcombe Boulevard
Houston, Texas 77211

Inspection At: VAMC, Houston, Texas

Inspection Conducted: December 11-13, 1989, and January 8-10, 1990

Inspector: Linda Kasner 2/8/90
Linda L. Kasner, Health Physicist, Nuclear Materials Inspection Section — Date

Approved: Charles L. Cain 2/8/90
Charles L. Cain, Chief, Nuclear Materials Inspection Section — Date

Inspection Summary

Inspection Conducted December 11-13, 1989, and January 8-10, 1990 (Report 30-03255/89-01)

Areas Inspected: This was a routine, unannounced radiation safety inspection of a byproduct material program authorizing the use of materials for medical research with both human and animal subjects, clinical diagnostic procedures, and the use of radiopharmaceuticals or sealed sources in therapeutic procedures. The inspection included the review of facilities; equipment, instrumentation, and calibrations; byproduct material receipt, inventory control, and waste disposal; radiation surveys and evaluations; and management organization. This inspection also included review of activities conducted by the radiation safety committee (RSC) and radiation safety officer (RSO), as well as participation in a radioactive material use subcommittee (RUS) meeting.

Results: This inspection identified a number of apparent violations of both written commitments made in the license application and NRC regulations. Some of these apparent violations are significant independently in that they involved the failure to have evaluated the uses of large quantities of byproduct material, or to have identified specific safety concerns regarding

these activities. Collectively, the number and nature of the apparent violations identified are indicative of a lack of management oversight of the radiation safety program.

The inspector also observed several other problems, not noted as violations per se, which were recognized as contributing factors to the apparent violations identified during the inspection. These problems include the areas of communication, program review, and authority granted to both the RSO and the RSC.

Several of the apparent violations, relating to failure to conduct evaluations, were the result of a lack of communication regarding program activities between department directors or researchers and the RSC. This problem was accompanied by the failure of the RSC to adequately review program activities or research requests and to identify potential safety concerns and review them with staff members. In several cases, authorization had been given by the RSC for projects or procedures without regard to specific elements that may have required further evaluation or review. These project elements included locations where projects were conducted and specific ventilation requirements for the use of volatile radioactive material.

The inspector also observed that the authority delegated to the RSO was not commensurate with his incumbent responsibilities. Additionally, members of the RSC indicated that the committee had been ineffective in enforcing recommendations for some research practices. This system requires review and evaluation to reestablish priorities that will permit responsible individuals to fulfill obligations associated with their respective positions.

Within this inspection, the following apparent violations were identified:

Radiological Surveys and Evaluations

- Facility Ventilation and Exhaust Pathway Evaluations -
  - Failure to evaluate fume hood exhaust rates in areas using millicurie (1-100) quantities of volatile radioiodine and curie quantities of xenon-133 gas dispensed to syringes from multidose vials. (Section 3.a)
  - Failure to evaluate room ventilation and exhaust pathways for areas where weekly, curie quantities of xenon-133 were used and stored. (Section 3.a)
- Failure to conduct certain required radiation surveys and to fully evaluate others. (Section 7.b)
- Failure to implement a bioassay program for individuals handling millicurie (1-200) quantities of radioiodine in liquid form. (Section 7.a)

- Failure to provide dosimetry devices for personnel; improper exchange frequencies for some devices; and failure to evaluate occupational doses for individuals with damaged or missing devices. (Section 7.a)

Facilities and Equipment

- Storage of radioactive materials in areas not authorized by license. This was combined with a lack of security or surveillance in some areas. (Section 3.b)

- Failure to provide an adequate number and type of survey instruments; failure to calibrate those which were available; and failure to complete required operability checks prior to instrument use. (Section 4.b)

- Failure to perform dose calibrator constancy and linearity checks; failure to maintain records of linearity and accuracy checks that were performed. (Section 4.a)

Human Use of Medical Products

- Failure to record radiopharmaceutical doses administered to patients. (Section 6)

Records and Reports

- Failure to maintain records of occupational radiation exposures for staff personnel. (Section 7.a)

- Failure to adequately document radiation surveys including ambient radiation area surveys; failure to establish threshold levels for decontamination surveys; and failure to identify in survey records the instruments used. (Section 7.b)

DETAILS

1. Individuals Contacted

*J. Sheehan, Hospital Director
*G. Rodman, Associate Director
*N. Kutka, M.D., Director, Nuclear Medicine and Chairman of the Radiation Safety Committee (RSC)
*M. Shaffer, Radiation Safety Officer (RSO)
*L. Berkeley, Assistant Hospital Director
*K. F. Martel, Ph.D., Associate Director, CBF Laboratory
*H. V. Lindstrom, Chief, Engineering Services
*M. Drahozal, Assistant Chief, Engineering Services
*R. Lyon, Safety Manager, Engineering Services
*E. Young, M.D., Chief of Staff
*G. Cunningham, M.D., Assistant Chief of Staff, Research
*R. D. Rossen, M.D., Chief, Allergy/Immunology Research
*J. Pittman, Supervisor, Nuclear Medicine
*A. E. Worden, Nuclear Medicine Scientist
*D. Bellezza, Medical Physicist, Consultant to VAMC
*J. H. Liem, M.D., Chief, Radiation Therapy Service
*E. Guity, Administrative Officer, Radiation Therapy Service
*W. Grant, Ph.D., Medical Physics Consultant to VAMC
*N. Prasad, Director, Radiology Research
*F. Konicki, Administrative Officer, Research
*H. Black, Ph.D., Research Service
*L. T. Kosnick, Ph.D., Medical Physics Consultant to VAMC
*S. C. Bushong, Ph.D., Medical Physics Consultant to VAMC
*J. S. Meyer, M.D., Chief, Cerebrovascular Research Laboratories
R. Simpson, Engineering
Dr. McShan, Research
A. Laughter, Research
G. Schulmeier, Research Assistant
A. Hernandez, Research Assistant/Technical Staff, CBF Laboratories
Dr. Shafer, Research
J. Sheppard, Technical Service Representative for RADX Technology

*Indicates those present during exit interviews.

2. Program Overview

This byproduct material program includes the use of medical products for both diagnostic and therapeutic clinical procedures, as well as research activities conducted under the specific approval of the RSC.

Routine diagnostic and therapeutic procedures have been performed in the nuclear medicine (NM) department, which services an 1100 bed medical facility. The licensee has performed 600-700 procedures per month, under the supervision of a single authorized user. This department also has performed approximately 20,000 radioimmunoassay procedures per year.

Brachytherapy procedures have been conducted in the radiation therapy (RT) department, under the supervision of the radiation oncologist, who also has been the single authorized user for these activities.

Research primarily has been conducted in a separate building designated for such activities. Although the technical staff involved with these activities have been employees of the VAMC, several members of the research staff have been associated with Baylor College of Medicine, Houston, Texas. The majority of the projects conducted during the previous 2 years involved the labeling of cells or proteins, with very little animal work. There was one project, originally approved in 1977, which involved the use of xenon-133 gas to perform cerebral bloodflow studies. This was the only research project involving human subjects. Although this has long been recognized as an approved diagnostic procedure by the Food and Drug Administration (FDA), the licensee has classified this as a research project with respect to the analysis of the information obtained from the procedure. The licensee has not conducted research on human subjects with any material that has not been approved by the FDA for human use.

The disposal of radioactive waste or the decay-in-storage of contaminated items have been supervised by the RSO. The licensee has specifically designated an area for waste storage. All laboratories and clinical facilities have been responsible for notification and delivery of such materials to the RSO.

3. Facilities

a. Ventilation and Exhaust Pathway Evaluation

This inspection identified several areas where xenon-133 and volatile radioiodine had been used and stored. Some of these areas had been identified and evaluated by the licensee at the time of the most recent license application in 1985, while others had not. The license application identifies three areas in the NM department for use and storage of xenon-133. An additional area, the cerebral bloodflow (CBF) laboratory, is also identified for use of xenon-133. The license application does not identify areas that were used for storage or handling of volatile radioiodine.

On December 11-13, 1989, the inspector reviewed three rooms in the NM department involved in the storage and use of xenon-133. These rooms were identified as 747A, 722, and 749, and matched those specified in the license application.

Room 747A was the NM "hot lab" and contained two fume hoods which were used to store curie quantities of xenon-133. The gas has been dispensed, within the hoods, from multidose vials to syringes for use. The licensee has used approximately 6 curies of xenon-133 per month. These hoods also have been used to store and administer doses of volatile iodine-131 in quantities of 5-200 millicuries. The

liquid iodine-131 has been received in "open" screw-top vials rather than "closed" vials with rubber septum tops.

Rooms 722 and 749 have been used for administration of xenon-133 during diagnostic procedures. The licensee has used a closed administration and charcoal trapping system and has introduced xenon-133 to the system by means of a syringe. The trap systems used provide exhaust monitoring to detect release of xenon-133 and trap saturation. The licensee had also used room air monitors in these areas.

The CBF laboratory has involved large volume usage of xenon-133 of approximately 1 curie per week. A similar xenon delivery system also has been used for these procedures, and a room air monitor has been available.

During the review of evaluations related to the use of radioactive gas, the inspector identified several apparent violations. The license application specified that certain exhaust volumes would be maintained in each of the areas described above, as well as for each fume hood. Additionally, the licensee was required to reevaluate these rooms and hoods at 6-month intervals to verify that the required exhaust volume had been maintained. The inspector determined, during interviews conducted with the engineering staff and those individuals responsible for these areas, that although the evaluations had been done originally for the NM area, they may not have been completed for the CBF laboratory. Additionally, the licensee had failed to check these areas as required at 6-month intervals. Individuals working in the CBF laboratory could not verify that this room had ever been evaluated. Although some evaluations had been performed for the two fume hoods in NM, these had been conducted by a variety of individuals. The evaluations performed between August 1987 and December 1989 were not conducted at 6-month frequencies and did not include evaluation of total exhaust volume. These problems were identified as an apparent conflict with the procedures and standards submitted in the license application dated May 22, 1985, regarding facilities and use of radioactive gas.

This was reviewed with the engineering staff, the RSO, and the authorized users. The inspector recommended that these evaluations be done expeditiously to determine if these areas were under a negative air pressure as required by 10 CFR 35.205(b). The licensee's subsequent evaluation during this inspection demonstrated that Rooms 747A, 722, and 749 did have a negative pressure relative to surrounding areas, but the exhaust volumes for both the rooms and fume hoods did not meet the specifications submitted in the license application. It was determined that the CBF laboratory did not meet the negative pressure requirement. This evaluation also revealed that the only exhaust path for this room was a recirculated air vent. The licensee agreed to suspend the use of xenon-133 in this area until they are able to correct this problem.

The inspector also observed that the licensee had failed to determine the time required after a release to reduce air concentrations to occupational limits described in 10 CFR Part 20, or to post procedures to be followed should a release occur.

The failure (1) to evaluate ventilation rates at the required 6-month intervals; (2) to calculate released gas clearance times; (3) to establish and post emergency release procedures; and (4) to use radioactive gas in an area that was at negative pressure relative to surrounding areas were identified as apparent violations of 10 CFR 35.205.

Additionally, the licensee had dispensed xenon-133 to syringes for use in the CBF laboratory. The syringes were capped and transported to the CBF laboratory, and the staff stated that they usually had 1-5 syringes "stored" in the laboratory. This practice involved storage of syringes over 24-hour periods. The syringes had not been placed in a fume hood but were stored in a box located in the room. This was identified as an apparent violation of License Condition 18, which references procedures in the license application dated May 22, 1985, that specify that xenon-133 gas will be appropriately stored in fume hoods located in Room 747A.

During the inspection segment conducted on December 11-13, 1989, the inspector also reviewed areas in the research building where volatile iodine-131 and iodine-125 had been used and stored. During this review and subsequent discussions with the RSC chairman and RSO, she determined that this activity had not been evaluated with regard to ventilation requirements by either the RSC or RSO. Neither had been aware of the nature of this activity or the quantities of volatile radioiodine involved. One area was identified as the location of a project being conducted at the time of the inspection. Other areas were identified as having been used for storage of volatile radioiodine, but the staff was uncertain if material had been used in these hoods. The hood that was in use during the inspection was located in Room 207B, and the project involved iodination of proteins using sodium iodide (I-125 and I-131) supplied in open vials in quantities of 1-10 millicuries. Some of the procedures required the use of 10 millicuries, while others required users to pipette smaller quantities. The licensee had also used this hood for receipt and storage of the radioiodine. The inspector reviewed the quantities inventoried during this period and determined that the licensee had 1-100 millicuries, in use or storage, in this hood since this project was initiated in 1989. The failure to have evaluated air concentrations or exhaust volumes needed to maintain compliance with standards described in 10 CFR 20.103 was identified as an apparent violation of 10 CFR 20.201.

The inspector reviewed this requirement with the RSO, who scheduled an evaluation for this hood that will include exhaust volume measurements as well as air concentration evaluations to ensure that

occupational concentration limits are met. She also reviewed alternative methods of dispensing xenon-133, other than to open syringes. The RSO and research users agreed that they would evaluate the use of closed evacuated vials with a commercial xenon "gun".

Three apparent violations were identified.

b. Storage and Security

During the inspection segment conducted on December 11-13, 1989, the inspector reviewed those locations in the NM department, RT department, waste storage, and research areas used to store radioactive materials. Generally, she observed that materials were stored in appropriate areas identified in the license, and that an adequate level of security had been provided. However, two problems were identified.

The license was amended in May 1988, to permit storage of items held for decay-in-storage in a designated area in the basement of Building 202. This amendment also permitted temporary storage of saturated charcoal traps in the CBF laboratory. The inspector observed that Rooms B-19 and 20B in Building 26D had been used for a number of years (possibly 10 years) for storage of charcoal traps containing xenon-133. The rooms were secured against unauthorized entry or removal, but they had not been posted or surveyed weekly as required. This was identified as an apparent violation of License Condition 18, which references a letter dated May 26, 1988, describing the licensee's storage provisions.

The inspector also reviewed security of areas used to store radioactive materials in Building 211, the research area. She observed, on several occasions during the December 11-13, 1989, inspection, that most areas had adequate security provided. Although the building and respective rooms remained unlocked during normal working hours, there were sufficient staff members in the area to provide surveillance. However, as the inspector and the RSO observed, there was one corridor with few individuals working in the area. During normal working hours, the inspector observed several occasions where rooms containing licensed material were left unlocked. Additionally, there were no staff members in the area to provide surveillance. This was also examined after normal working hours, and she found the building to remain unlocked with several of these rooms also unlocked. The RSO had accompanied the inspector and agreed that the level of security afforded by this practice was inadequate.

During the review of the licensee's brachytherapy source storage area, the inspector observed that this room, located in the RT department, was locked. However, during discussions with members of the technical and physics staff, the inspector was informed that the couriers, employees of the licensee's brachytherapy source vendor,

routinely located the key to this room and used it for delivery. This occurred without specific notification or approval from staff members. This practice was recognized as a change from their previous procedure which required that only VAMC staff members have access to this area.

These problems were identified as an apparent violation of 10 CFR 20.207.

Two apparent violations were identified.

4. Equipment, Instrumentation, and Calibrations

Instruments used to conduct radiation surveys, and analysis and measurement of patient doses were the focus of this review. Several problems were identified during the inspection segment conducted on December 11-13, 1989.

a. Dose Calibrators

The licensee maintains two dose calibrators, a RADX Mark V (Serial No. 4155-72) and a RADX 425 Assayer I (Serial No. 537). The license application specified that procedures described in Appendix D of Regulatory Guide 10.8 (RG 10.8), Revision 1, would be used to perform dose calibrator constancy, linearity, and accuracy tests. The licensee had used cobalt-57, barium-133, and cesium-137 sources to conduct daily constancy checks, and although the RSO had conducted one linearity test (data was not available), they had used the manufacturer's service center to provide quarterly linearity and annual accuracy tests. Information available for these tests was reviewed during the inspection and the following problems were identified:

(1) The staff had performed the required constancy checks, although they had not been completed on both instruments for each day of use. This was due partly to the fact that the NM staff members preferred to use the Assayer I. However, the staff from the CBF laboratory used whichever instrument was not in use by NM. This resulted in the use of instruments that had not been tested as required. Additionally, the licensee's procedure required that test results be evaluated to determine a 5 percent error and that test data be graphed. The staff had decay tables for their specific sources available, but they had failed to perform these evaluations or to graph test data.

(2) The former RSO had performed a linearity test for the instruments in January 1989, but this test data was not available. The remainder of the linearity tests conducted during this inspection period had been performed by a RADX representative. The only documentation provided to the licensee was a "certificate" stating that the instrument had been

calibrated. The document did not include a description of procedures used or test data. The licensee's representatives and RSC chairman stated that they had never inquired about test results or methods employed during these calibrations. The inspector interviewed the RADX representative during this inspection and determined that these "calibrations" did not meet linearity test requirements. The tests, performed during the period from August 1987 through December 1989, had been conducted using different sealed sources (cesium-137, cobalt-57, barium-133, and cobalt-60) ranging in activity from 8 microcuries to 13 millicuries. The licensee typically has used these instruments to measure doses from 0.1 to 200 millicuries.

(3) The inspector determined that the calibrations performed by RADX met the requirements for annual accuracy testing of the instruments. However, the licensee had not obtained records or reviewed the test results.

The failure (1) to adequately evaluate or perform dose calibrator daily constancy checks, (2) to perform linearity checks according to required procedures that included activity ranges equivalent to clinical use, and (3) to maintain records of test results as required were identified as apparent violations of License Condition 18, which references the license application dated May 22, 1985, where these procedures are described.

One apparent violation was identified.

b. Survey Instruments

The license application specified a number of survey instruments that were to be available for use. These instruments appeared to meet program requirements and would have satisfied requirements under 10 CFR Part 35. However, the inspector discovered that the licensee owned only three survey instruments. These included a Ludlum Model 14C, a Ludlum Model 12, and a Victoreen Model 491 (Serial Nos. 40896, 550, and 6630-5076 respectively). The Ludlum Model 14C was designated to the RSO and the other two instruments were located in the NM department. The Ludlum Model 12 was observed to have no dedicated check source and there was no record of its having been calibrated. The Victoreen 491 had last been calibrated in September 1989. There were two additional survey instruments located in the research area. These were Victoreen Models 491 and 493 (Serial Nos. 46512 and 38955) which are property of Baylor College of Medicine. There was no evidence that the instruments had ever been calibrated.

The inspector reviewed survey meter calibrations with the RSO, who was unable to locate records (completed by the former RSO) indicating that these instruments had been calibrated during this inspection

period. (Records were available for 1979 calibrations.) Additionally, with the exception of the two instruments calibrated by an authorized vendor in September 1989, staff members could not confirm that the instruments had been calibrated. They had been checked by the engineering staff, but these evaluations did not include determination of instrument accuracy in a radiation field. The licensee also did not have records available for those calibrations performed in September 1989. This was identified as an apparent violation of License Condition 18, which references procedures in the license application dated May 22, 1985, specifying that meter calibrations will be performed annually and describing the method to be used.

During interviews conducted with staff members, the inspector determined that survey instruments used in the NM department had not been checked for operability with a dedicated check source each day of use as required. This was identified as an apparent violation of 10 CFR 35.51.

These problems were reviewed with the RSO, who confirmed on December 13, 1989, that survey instruments would be sent for calibration by a local authorized vendor. However, the inspector noted, during the inspection conducted in January 1990, that the instruments had not been calibrated. These items were again the subject of discussion at the conclusion of the inspection. The inspector emphasized the need to calibrate those instruments available, as well as to provide a sufficient number and type of instruments to support program requirements. Specifically, there were areas in the research department requiring daily and weekly surveys that did not have calibrated instruments available to them.

Two apparent violations were identified.

5. Material Receipt, Inventory Control, and Waste Disposal

The inspector observed that, generally, procedures implemented with regard to receipt of radioactive materials were satisfactory. The NM department had received radiopharmaceuticals from a local radiopharmacy, and brachytherapy sources were received from a local vendor. Receipt of materials within the NM department appeared to meet license requirements.

The RSO had reviewed each request from the research department for byproduct material acquisition. The use of this procedure as an audit to identify the use of volatile materials was reviewed with the RSO. Apparently this had not been evaluated in the past. During discussions with the RSO, he indicated that procedures implemented for receipt of materials may have introduced unnecessary delays in their transfer to appropriate areas. This was reviewed with management and the inspector suggested that material receipt be given further review to ensure that adequate security would be maintained.

The inspector determined that inventory control of sealed sources had been inadequate. During the period from August 1987 through December 13, 1989, the required quarterly inventories for reference sources had not been performed. Also, during this period, inventories for brachytherapy sources had been conducted for patient use, but the licensee had not met the requirements for quarterly source inventories or the surveys required for areas used to store these sources. These problems were identified as an apparent violation of 10 CFR 35.59.

The inspector observed that inventories reflecting material receipt, use, and disposal in research areas were satisfactory and met license requirements.

The inspector noted that the licensee had not disposed of any radioactive waste during this inspection period. Those items with half lives of less than 65 days had been held for decay and subsequently disposed under the provisions granted in the license. The licensee had employed the services of a waste broker to categorize and package the radioactive waste currently in storage, although they did not have records available to identify package contents. This was reviewed with the RSO who stated that another vendor would be used for future disposal. The inspector informed the licensee that the vendor identified in their license application was no longer authorized for this activity. She also reviewed the requirements for categorization, labeling, and documentation regarding waste disposal with the RSO. The inspector determined that the licensee had complied with the requirements of 10 CFR 20.311 with regard to waste disposal.

One apparent violation was identified.

6. Human Use of Radiopharmaceuticals

Records related to human use of medical products were reviewed. The licensee had (correctly) not used any radiopharmaceuticals that were not the subject of an FDA new drug application (NDA). The inspector noted that the NM staff had identified and corrected one violation related to recording the millicurie quantity of radiopharmaceuticals administered to patients. Specifically, this involved the licensee's former practice of using the pharmacy's prescription label as a patient record without correcting the activity administered data to indicate the actual dose measurement.

The inspector observed one problem in the CBF laboratory. The laboratory staff indicated that when this project was initiated, they had made a record of patients receiving xenon-133 during these studies. However, they were never advised or audited on this requirement by the RSO, so they had terminated the practice approximately 5 years ago. Additionally, they destroyed the records that had been made up to that time. This project may have involved as many as 3,000 patients since that time, for which no dose records were available. This was identified as an apparent violation of 10 CFR 35.53.

During the inspection conducted on December 11-13, 1989, the inspector reviewed this problem with the RSO and researchers involved, and indicated that corrective action should be implemented immediately.

One apparent violation was identified.

7. Radiation Surveys and Evaluations

a. Personnel Monitoring, Bioassays, and Related Evaluations

The licensee has provided thermoluminescent dosimeters (TLD) for both whole body and extremity monitoring. Whole body monitoring devices are to be exchanged at monthly or quarterly intervals, and extremity devices, a mixture of wrist badges and ring badges, are to be exchanged at monthly intervals. The license application also specifies that bioassays will be required for any individual using unsealed forms of volatile radioiodine, within properly operating fume hoods, in quantities exceeding 1 millicurie.

During interviews conducted on December 13, 1989, and January 9, 1990, the inspector observed that some individuals were wearing personal monitoring devices from the previous calendar quarter. While interviewing staff members, the inspector was informed that on several occasions personnel monitoring devices had not been exchanged at appropriate intervals. This involved individuals required to have badges exchanged at both monthly and quarterly intervals. Staff members working in research and the NM and RT departments indicated that this had occurred during the first quarter of 1989, and also was a common problem for new employees. During further discussion with the RSO and staff members, the inspector determined that this problem had involved staff members in several areas. Additionally, the licensee's personnel exposure records did not indicate that all individuals working with licensed materials in research areas had been provided with monitoring devices prior to 1989. The current RSO could not confirm that monitoring devices had been supplied to all appropriate research staff during 1987 and 1988.

Additionally, the inspector observed that one research laboratory had obtained phosphorus-32 in 1- and 5-millicurie quantities. These were subsequently dispensed in smaller quantities to various users in research. During discussions regarding this practice, the inspector learned that individuals handling millicurie quantities of phosphorus-32 had not been provided ring badges as required in the licensee's procedures.

The failure to provide and to exchange personnel monitoring devices at appropriate intervals and for appropriate personnel was identified as an apparent violation of License Condition 18, which references the personnel monitoring program described in the license application dated May 22, 1985, and letter dated August 20, 1986.

During review of personnel exposure histories, the inspector noted that in general occupational exposures were within the licensee's Level I limits defined in their ALARA program. However, she also noted that records for several monthly periods during 1988 and 1989 were not available. Additionally, those records available indicated that several individuals' whole body or extremity badges had been damaged or were not returned for processing on several occasions during 1988 and 1989. This was reviewed with the RSO and RSC chairman. These individuals indicated that the former designated and acting RSOs, also the RSC chairman, had failed to request duplicate records from the dosimetry vendor or to perform evaluations to determine exposures for those periods when TLD badges had been damaged. These problems were identified as an apparent violation of 10 CFR 20.401(a) and 20.201 in that there was no evaluation in regard to limits set in 20.101.

The inspector observed that several members of the NM department were involved in the routine administration of 10-millicurie doses of iodine-131 in volatile liquid form from open containers. Members of this staff were also involved in administration of therapeutic doses of iodine-131, on a less frequent basis, in quantities ranging from 30-200 millicuries. These doses were also a volatile liquid form administered from open containers. Additionally, there were members of the research staff who handled 1- and 10-millicurie quantities of volatile radioiodine in open containers daily. During discussions with the RSC chairman regarding the licensee's bioassay program, the inspector was informed that the former RSO had determined that this procedure was "no longer necessary" in 1987. After further discussion, the RSC chairman admitted that the RSC had not reviewed or been consulted in this decision, and that he was not familiar with the bioassay program submitted in the license application. Apparently, the licensee had performed whole body counting at another facility for a few individuals at some time in the past, but no records of these results had been maintained. The failure to provide bioassays for those individuals handling millicurie quantities of volatile radioiodine, in open containers, was identified as an apparent violation of License Condition 18 which references the bioassay program described in the license application dated May 22, 1985.

The inspector subsequently reviewed the RSC minutes and determined that the bioassay program had not been reviewed by this committee. This was discussed with committee members during the exit briefing.

Three apparent violations were identified.

b. Radiation Surveys

Several problems were observed in this area of the radiation safety program. These included the failure to have adequately recorded or evaluated some surveys which had been conducted, as well as the

failure to have conducted surveys in several areas of the research building and waste storage area. As previously noted, the absence of an adequate number of survey instruments may have contributed to the licensee's failure to conduct required radiation and decontamination surveys. Additionally, staff members had not been informed of the proper frequency and methods to be used in conducting such surveys.

The inspector observed that during the period from August 1987 through December 13, 1989, the licensee had failed to conduct or record radiation surveys to determine ambient radiation rates or removable contamination in the following circumstances:

- After each use of millicurie quantities of phophorus-32,
- Monthly in labs using less than 200-microcurie quantities of radioactive material,
- Weekly in labs using greater than 200-microcurie quantities of radioactive material,
- Weekly in the waste storage room and surrounding unrestricted areas, and
- Weekly and daily in areas involved in the use and administration of radiopharmaceuticals.

In some circumstances, this included the failure to have ever conducted surveys in specific areas of use. Additionally, the licensee's procedures required that wipe sample tests performed to determine levels of removable contamination be analyzed using methods sufficiently sensitive to detect 200 dpm per 100 square centimeters. Although some of the users had employed methods that may have met this requirement, others had failed to evaluate the method used to count these samples. Records of such surveys were not appropriately documented in units corresponding to dpm per unit area sampled, and counting efficiencies for the instruments used had not always been recorded or evaluated. The inspector also observed that records of radiation surveys conducted in the NM department did not provide adequate information to identify the specific areas surveyed, and on some occasions did not include the measured survey result. The licensee had also failed to record the instruments used to conduct some of these surveys.

These problems were identified as an apparent violation of License Condition 18 which references documents incorporated in the license describing survey procedures and record requirements. Some of these problems were identified as an apparent violation of 10 CFR 35.70 with regard to record content.

The inspector noted that the surveys related to the use of brachytherapy sources had been completed as required. These surveys had been conducted by the RSO and included surveys of areas used for source implantation, patient surveys, and those required to determine radiation levels surrounding patient rooms. Although the majority of the sources used at this facility are permanent implants, the licensee routinely requires that patients remain at the facility for a short duration following this procedure.

Two apparent violations with multiple examples were identified.

8. Organization and Management

Several members of the RSC, the Radioactive Material Use Subcommittee (RUS), hospital management, and RSO were interviewed during this review. The inspector also attended an RUS meeting on December 13, 1989, to review activities conducted by this subcommittee. This review identified several concerns regarding the function of these organizational groups and their communication with top-level management.

a. Research Project Approval

The licensee had established a subcommittee, the RUS, which is composed of selected members of the RSC, the RSO, and selected section chiefs from research. This committee's primary purpose has been to review research requests, identify issues that may require further information prior to approval, and to recommend projects for review by the RSC. They have provided the initial review for research requests. Those requests approved by the RUS then have passed for approval by the RSC.

The licensee submitted procedures and guidelines to be used for research project approval as part of their license application and subsequent correspondence. These guidelines specify factors to be given consideration for project approval including: (1) experience of the applicant and ability to cope with hazards involved, (2) adequacy of equipment and facilities, and (3) thoroughness and attention given to safety precautions. These guidelines further specify that approval will only be granted for a period of 3 years or the life of the project, whichever is shorter. The applicant must then submit another application to continue the project.

During reviews of active projects, discussions with members of these committees and individual researchers, and participation in an RUS meeting, the inspector observed that review of such projects by both the RUS and RSC had been inadequate.

Three fundamental problems were identified. First, the RUS review was focused on broad descriptions of project activities. The inspector observed applications that sometimes contained very little information regarding details of activities. Some of the

applications did not identify the location where the project was to be performed, the number of individuals involved, or equipment requirements.

The failure of this subcommittee to identify specific elements requiring further review in regard to radiation safety such as ventilation for areas where volatile materials are to be used, provisions for personnel monitoring, and instrumentation requirements for surveys, was the subject of discussion with several committee members. Apparently, the licensee held individual researchers responsible to ensure that some of these concerns were addressed, while others remained unresolved. This problem was compounded by a second factor, the RSC's apparent "blanket" approval of such projects without independent review by the RSC.

A specific example was reviewed with members of both committees. A project had been approved in 1989 granting a researcher authorization to use millicurie quantities of radioiodine in volatile form to label proteins. Neither committee had given consideration to facility ventilation requirements or the need to conduct bioassays for the individuals involved. The individuals reviewing the application had not given attention to the fact that the material would be used in open containers.

The inspector also learned that most research applications did not require identification of the number of individuals involved in handling licensed materials as a part of the review process. Additionally, there were no provisions for the RSO to become involved with instruction provided to these individuals regarding specific safety concerns for individual projects. This was left to individual researchers. The inspector reviewed training with research staff members and observed that some individuals had been provided instruction while others had not.

A third problem identified was the failure of the RSC or RUS to require researchers to reapply for continuation of a project after a period of 3 years. A specific example of this omission was identified in the CBF lab. This application, for the use of xenon-133, was originally submitted in 1977, without subsequent review or resubmission. This was identified as an apparent violation of License Condition 18, which references a letter dated August 20, 1986, which documents research approval requirements.

These problems were reviewed with committee members and hospital management. The inspector expressed her concerns that the failure of these committees to identify specific elements requiring further review and their reliance on individual researchers, which in many cases were not active in the daily project activities, had compromised effective management of this aspect of the program. She

reminded committee members of their responsibility to review all approval criteria and clearly establish that all safety concerns had been addressed prior to granting approval for such projects.

One apparent violation was identified.

b. Functions of the RSC and RSO

The inspector observed that the RSO appeared to be submerged within several levels of management. He has reported to a safety manager, who in turn reported to second-level management in the engineering staff. During the inspection, several RSC members expressed concern regarding this organization. The inspector observed that this structure had resulted in a lack of authority for this position and apparent delays of RSO recommendations reaching top-level management. Additionally, members of the RSC indicated that this committee had been ineffective in enforcing certain recommendations.

The inspector also observed that on several occasions, individuals had made decisions regarding changes in procedures without the required review by the RSC. A specific example was the former RSO's decision to terminate the bioassay program in 1987. Additionally, prior to termination, he had implemented a procedure other than the one described in the license application. This was reviewed with the RSC chairman, who indicated that although he had been aware of this, it had not been brought to discussion before the RSC.

9. Exit Interview

This inspection included two exit interviews with staff members present as previously noted in Section 1. The inspector reviewed the specific findings as noted in this report and discussed her concerns regarding program management and communication among the staff, the RSC, and hospital administration. The discussion was focused on the need to review management controls and program audits with the goal of making them more effective, and to aggressively pursue corrective actions for the problems identified during this inspection.