U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-15269/92001(DRSS)

Docket No. 030-15269

License No. 12-10057-04 Category G Priority 2

Licensee: V. A. Medical Center
North Chicago
3001 N. Green Bay Road
North Chicago, IL 60064

Inspection Conducted: November 12, 1992

Inspector: Evelyn R Matson 11-23-92
Evelyn R. Matson Date
Radiation Specialist

Reviewed By: Gary L. Shear 12/2/92
Gary L. Shear, Chief, Date
Nuclear Materials Inspection
Section 2

Approved By: Roy Caniano for 12/4/92
John A. Grobe, Chief, Date
Nuclear Materials Safety
Branch

Inspection Summary

Inspection on November 12, 1992 (Report No. 030-15269/92001(DRSS))
Areas Inspected: This was a special, unannounced safety inspection of the licensee's activities to evaluate compliance with Commission rules, regulations, and license conditions. The inspection included a review of concerns pertaining to the radiation safety program.
Results: Of the areas inspected, five violations of NRC requirements were identified:

1. Failure to test the xenon-133 gas trap each month of use, 10 CFR 35.205(e), (Section 5);

2. Failure to perform weekly removable contamination wipe tests in all areas where radiopharmaceuticals are routinely prepared for use, administered and stored, 10 CFR 35.70(e), (Section 6);

3. Failure to conduct a quarterly physical inventory to account for all sealed sources possessed, 10 CFR 35.59(g) (Section 8);

4. Failure to check each survey instrument for proper operation with the dedicated check source each day of use, 10 CFR 35.51(c), (Section 7); and

5. Failure to keep records of surveys prior to disposal of contaminated needles and syringes, 10 CFR 35.92(b), (Section 9).

In addition to the apparent violations, the inspector identified a concern that the Nuclear Medicine Service experienced a staffing shortage which could have potentially degraded radiation safety in that department (Section 4).

DETAILS

1. Persons Contacted

*Medical Center Director- Al Pate
+Chief of Staff- Carter E. Mecher, M.D.
*Acting Chief of Staff- Charles Barsano, M.D.
*Chief of Nuclear Medicine Service- Gregory A. Gergans, M.D.
Asst. Chief of Nuclear Medicine Service-T. Balachandra, M.D.
+Radiation Safety Officer- Sanda Loga, Ph.D.
*Acting Radiation Safety Officer- Gordon Pullen, Ph.D.
*Acting Director, Clinical Operations- George Patterson
*Assistant Medical Center Director- Earl Falast
*Executive Assistant to the Director- Michael Tyllas, Ph.D.
*Health System Specialist, Trainee- Kevin Gormley
*Illinois Nursing Assoc. President- Kathy Kelger-Norris
*Chief, Audiology/Speech Pathology- Katherine Dong
Acting Chief Nuclear Medicine Technologist- Timothy Ross
Nuclear Medicine Technologist- Candace Watkins-Thomas
Nuclear Medicine Technologist- Kailas Shah
Nuclear Medicine Secretary- Stacy Timmons
Housekeeper- Debbie Young

+ Interviewed by telephone.
* Indicates those present at the exit meeting held on November 12, 1992.

2. Inspection History

The last inspection was a special inspection conducted on April 16, 1991, to review a concern that a misadministration was not reported to the NRC. As a result of the inspection, one violation was identified against 10 CFR 35.33(c) for failure to report a misadministration to the NRC within 15 days after it occurred on September 27, 1989. A notice of violation was issued. Corrective actions were achieved and a similar incident has not recurred during this inspection period.

The second to last inspection was conducted on December 21, 1990, and one violation for failure to post xenon-133 emergency procedures was identified. This violation was corrected and is considered closed.

3. Licensed Program

The V. A. Medical Center at North Chicago uses NRC licensed radioactive materials in a nuclear medicine program and in laboratories for medical research and development.

The Nuclear Medicine Service performs routine, diagnostic nuclear medicine scans, bone mineral analysis, ultrasound imaging, and in-vitro diagnostic radioimmunoassay (RIA) tests. Therapeutic use of radionuclides is authorized but no patients have been treated for several years. The licensee currently receives prepared unit doses from a radiopharmacy.

Currently, there are approximately five authorized users performing research activities with radioactive material. Research use involves usually not more than 1 millicurie of mostly P-32, I-125, H-3, and C-14.

The organization is structured such that the Chief of Nuclear Medicine Service reports to the Chief of Staff who reports to the Medical Center Director.

The Radiation Safety Officer (RSO) reports to the Chief of Continuous Quality Improvement, who reports to the Medical Center Director. Refer to Attachment A for a chart of the organization. The RSO was available only by telephone during the inspection.

The quantities, kinds and use of radioactive material are as authorized on the license.

No violations of NRC requirements were identified.

4. Radiation Safety Program Concerns
AMS No. RIII-92-A-0127

Concern A: Staffing of the Nuclear Medicine Service has decreased from seven technologists to one or two creating an increase in the potential for patient misadministrations and needlestick injuries for the staff.

Information provided by the Nuclear Medicine Service personnel show that this service sees approximately 2000 nuclear medicine patients annually (167 per month), 1200 ultrasound patients annually and 7100 patients (40,000 individual tests) for RIA tests annually. The work load has been stable for the last several years.

The official staffing level approved for the Nuclear Medicine Service includes two physicians, one secretary and six technologists. An organizational chart for the Nuclear Medicine Service is enclosed as Attachment B to this report.

Prior to April 3, 1992, six technologists staffed the Nuclear Medicine Service and were actively employed in the department. However, as of April 3, 1992, when one technologist resigned, the department has not had a full staff of six working technologists. The person who resigned on April 3, 1992 was not replaced until August 24, 1992. In addition, on June 1, 1992, another technologist left the department to accept a scholarship to enter full time education as a physician's assistant. This technologist has not been replaced. On August 24, 1992, a third technologist began extended sick leave and is not expected to return. However, a new technologist started on this day. On September 16, 1992, a technologist began maternity leave and is not expected to return until December 1992. From October 19 through 26, 1992, a fourth technologist took leave to get married. At this point two technologists remained. At the time of this inspection, three technologists were working.

In summary, during three weeks beginning September 21 through October 13, 1992, the department was staffed by two physicians, and three technologists (one who was relatively inexperienced). The secretary and three technologists were absent. In addition, from October 19 through 27, 1992, the department was staffed by two physicians, one new secretary and two technologists. Four technologists were absent.

Personnel stated and a review of records confirmed that at least two technologists and one physician were on duty at all times except during lunch hours which they alternated. Staff shortages have been accommodated. One physician performs the ultrasound tests and one technologist has worked approximately 15 hours a week on overtime performing the RIA tests.

Licensee personnel interviewed stated that no misadministrations or recordable events as defined by 10 CFR 35.2 have occurred. The hospital obtains prepared, precalibrated, labeled unit doses from a radiopharmacy which reduces the risk of technologists' errors in dose preparation and labelling. In addition, the technologists stated that they are trained to check each patient's identification bracelet and name prior to administering radiopharmaceuticals.

The inspector reviewed the records for required daily radiation safety related activities and determined that these activities appear to have been completed as required even during times of low staffing levels. In addition, a complete radiation safety inspection was conducted. Several minor violations were identified as described in this report but appear to be caused by a lack of knowledge of specific requirements on the part of the radiation safety officer and the technologists rather than due to the staff shortage.

The technologists agree that they are short staffed and at times this has been a strain. Several technologists stated that they came to work when they were sick or injured because there was no one available to fill in for them. They did not want to leave only one technologist alone in the department.

The concern that staffing has decreased from seven technologists to one or two was substantiated in that staffing levels decreased from six technologists to two for a period of several weeks. Furthermore, the shortage potentially could have decreased safety within the department both for workers and patients.

No violations of NRC requirements were identified.

Concern B: Hospital personnel were informed of a dangerous shortage of technologists on multiple occasions and no assistance was offered.

The Chief of Nuclear Medicine Service stated that he discussed the staffing shortage during in-service meetings with the technologists and that those meeting minutes were reviewed and signed by the Chief of Staff. In addition, he filed a request during a Resource Committee

meeting on July 2, 1992 to recruit one nuclear medicine technologist. The new recruit was to replace a technologist who left the service in June 1992 to accept a scholarship. This request to recruit was disapproved by the Director pending a justification for need of the position. The justification was provided by the Chief of Nuclear Medicine Services on October 15, 1992. The memorandum containing the justification expressed urgency and requested approval for immediate recruitment due to work loads. However, there was no mention of a dangerous situation.

During an annual management briefing held on August 10, 1992, the Chief of Nuclear Medicine Service documented an issue regarding his perceived need to add two additional staff members, apparently in addition to the nine positions already approved for the service. Documentation of the briefing did not include discussion of an existing staffing shortage.

The RSO stated that she was aware of a shortage of technologists in the Nuclear Medicine Service. She stated that she was concerned but did not perceive that a dangerous situation existed. She stated that the Chief of Nuclear Medicine Service, in accordance with his responsibility, was pursuing approval to recruit a replacement technologist. She stated that she felt the three technologists were capable of working safely until a fourth technologist returned from maternity leave in December 1992. She stated that during the staff shortage, she has spent additional time in the Nuclear Medicine Service to provide radiation safety support.

The Director and the Chief of Staff were aware that the Chief of Nuclear Medicine Service had requested authorization to hire additional staff. They were not informed of a concern that a dangerous situation may exist until October 29, 1992.

It appears that the Chief of Nuclear Medicine Service communicated his desire to hire additional staff to run his department on multiple occasions from July 1992 through October 1992. Management representatives were aware of the staffing situation in nuclear medicine but were not informed of a concern that a dangerous and unsafe situation existed in Nuclear Medicine Service until October 29, 1992. The Chief of Staff stated that his goal was to manage the Nuclear Medicine Service to provide quality care for patients and that he responded by initiating a study in June 1992 to determine the feasibility of transferring the RIA tests from the Nuclear Medicine Service to another service department. However, the Chief of Nuclear Medicine Service challenged the study, was not in favor of this solution, and continued to state that hiring additional staff was necessary.

After becoming aware that there was considerable concern for safety in the Nuclear Medicine Service, the acting Chief of Staff immediately transferred RIA testing service out of the Nuclear Medicine Service on November 9, 1992. However, on November 10, 1992, the Chief of Nuclear Medicine Service stated that an emergency situation did not exist, and requested the transfer be delayed until further discussion and proper

authorizations were obtained. His request was granted.

Therefore, the concern was not substantiated.

However, the NRC is concerned that a significant staffing shortage did occur in the Nuclear Medicine Service during several weeks in September and October 1992, which could have increased the potential for degradation of radiation safety. It appears that communications regarding this issue were not clear until October 29, 1992, and that there was a delay in addressing the shortage effectively prior to that time.

Staffing levels currently in existence were not considered by the inspector to be dangerously low, however, they do not appear to be ideal for the long term. No immediate radiation safety emergency was identified.

No violations of NRC requirements were identified.

5. Personnel Radiation Protection-Internal

10 CFR 35.205(e) requires, in part, that a licensee check each month the operation of reusable collection systems for radioactive gases. The inspector determined that as of November 12, 1992, the licensee used a reusable collection system for radioactive xenon-133 gas at least twice a month and did not check the operation of the collection system each month of operation. Failure to check the operation of reusable xenon-133 collection systems is a violation of 10 CFR 35.205(e).

Interviews with personnel and a review of survey records indicated that once a week a technologist surveyed the exterior of the xenon-133 unit with a G-M survey instrument. However, this survey is not an adequate check to assure that the charcoal collection system is actually operational in removing spent xenon-133 gas from the unit's exhaust.

The safety significance of this violation is decreased by the fact that xenon-133 is used only occasionally, that charcoal traps remain reasonably efficient for an extended period of time and that the room where the gas is used is tested every six months to assure it is under negative pressure with respect to surrounding areas. In addition, the charcoal trap was replaced on November 18, 1992.

The acting RSO stated that he will assure that the xenon-133 gas trap is tested for proper operation during the next patient study. He stated that the test will include collection of the unit's exhaust during the patient washout phase and the sample will be counted under a gamma camera. He stated that if the trap is not functioning, no xenon-133 procedures would be performed until the unit is repaired.

The technologists and the RSO stated that they were not aware of the correct procedure for testing the xenon-133 gas trap. They thought the weekly G-M surveys were sufficient.

One violation of NRC requirements was identified.

6. Area Surveys

10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored. The inspector interviewed personnel, reviewed survey records and determined that as of November 12, 1992, the licensee did not survey for removable contamination in all areas in the hot lab and in the room used to inject patients. These areas are used routinely to prepare or administer radiopharmaceuticals. Failure to perform weekly removable contamination surveys in all areas where radiopharmaceuticals are prepared or administered is a violation of 10 CFR 35.70(e).

The radiation safety significance is mitigated by the fact that the licensee does perform removable contamination surveys daily only on the hood apron located in the nuclear medicine hot lab. In addition, the RSO performs removable contamination wipe tests once per calendar quarter in all areas. A review of these survey results indicate that these areas were not contaminated in the past. In addition, the inspector performed independent surveys during the inspection with a G-M survey meter using a pancake detector and did not find any contamination.

Statements made by the technologists who perform the surveys and the RSO indicate that neither were aware of the requirement for weekly wipe tests. They thought the requirement was for a daily survey in the hood only. The acting RSO stated that as corrective action, he would instruct the technologists in the correct requirements, discuss the needed changes with the RSO and perform a review to assure that the tests were performed weekly in all use and preparation areas.

One violation of NRC requirements was identified.

7. Facilities and Equipment

10 CFR 35.51(c) requires, in part, that a licensee check each survey instrument for proper operation with the dedicated check source each day of use. The inspector observed that on the day of the inspection, November 12, 1992, the licensee did not check a stationary Texas Nuclear survey meter with a dedicated check source. Failure to check each survey instrument for proper operation is a violation of 10 CFR 35.51(c).

On November 12, 1992, a licensee representative used a Texas Nuclear stationary monitor to survey a package containing radioactive material and the inspector observed that the instrument was not functioning. In addition, this meter is used daily by technologists to survey their hands prior to leaving at the end of the day. The meter was calibrated by a contractor on July 16, 1992 and was operational at that time.

However, due to the fact that the meter is not checked each day of use, it cannot be determine when the meter began malfunctioning. The meter was tagged by the inspector and removed from service on November 12, 1992.

The safety significance of this violation is mitigated somewhat by the fact that the inspector observed technologists wearing gloves and lab coats while handling radiopharmaceuticals. Therefore, personnel contamination was unlikely. Further, the unit was used to monitor packages containing only 1 mCi quantities or less of I-125, P-32, H-3, and C-14 for research purposes. Another instrument was used to survey other incoming packages.

The radiation safety officer stated that all portable survey instruments had dedicated check sources attached and the technologists had been instructed how to perform the daily operability checks. She stated that they overlooked the stationary Texas Nuclear meter because it was continuously plugged in and no one expected the battery to die. She stated that meter would not be placed back into service until it was repaired. As corrective action, she stated that the technologists would again be instructed in the proper procedure for checking each meter. Operable survey meters are readily available for use in the nuclear medicine department.

One violation of NRC requirements was identified.

8. Materials

10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source conduct a quarterly physical inventory of all such sources in its possession. The RSO stated and a review of records confirmed that the licensee did not conduct a physical inventory of its sealed sources from January 29, 1992 to July 29, 1992, a period in excess of one calendar quarter. Failure to conduct quarterly inventories of sealed sources is a violation of 10 CFR 35.59(g).

The safety significance of this violation is mitigated by the fact that the RSO conducts physical inventories every six months rather than quarterly. A review of the inventory records revealed that all sealed sources were inventoried and accounted for on July 29, 1992. The RSO stated that she was not aware that the inventory was due every quarter and that now she will perform them quarterly. No sealed sources were missing or reported as missing.

One violation of NRC requirements was identified.

9. Radioactive Effluent and Waste Disposal

The inspector observed that the licensee collects used syringes and needles contaminated with radioactive material into a sharps box stored behind a lead shield in the hot lab. A licensee representative stated

that when the waste is no longer radioactive, it is then placed into a second, larger sharps box in the hot lab. When full, the larger box is surveyed and if no radioactivity is present, the box is transferred and undergoes biohazard control procedures prior to ultimate disposal. However, on the day of the inspection, the inspector surveyed the non-radioactive large sharps box and discovered that it read 22 millirem per hour (mr/hr) at the surface. A technologist stated that apparently someone had erroneously placed radioactive waste into this container. The acting RSO stated that the container would be held until it decayed to background radiation levels before it was released.

The acting chief technologist stated that the large box is surveyed prior to release as waste and he showed the inspector a record which contained only the dates the sharps boxes were surveyed and released. However, 10 CFR 35.92(b) requires that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

As of November 12, 1992, the licensee's records of disposal of contaminated syringes and needles permitted under 10 CFR 35.92(a) did not include the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, and the dose rate measured at the surface of each waste container. Failure to maintain complete records is a violation of 10 CFR 35.92(a).

Since the records were incomplete, the inspector could not verify that the sharps boxes previously disposed of were not radioactive. The individual who reportedly performed the surveys was not available during the inspection. However, according to statements of personnel interviewed during the inspection, all waste is surveyed prior to disposal to ensure it is at background levels before disposal.

The technologists, the acting RSO and the RSO (interviewed by telephone) stated that they were not aware that the required records were not kept. The acting RSO stated that he would provide training to the technologists and establish a complete form for recording the survey results.

One violation of NRC requirements was identified.

10. Other Areas Inspected

In addition to the areas described in this report, the inspector reviewed all areas of the radiation safety program including the radiation safety committee, internal audits, training, instrument calibrations, radiological protection procedures, possession and use of radioactive materials, leak tests of sealed sources, receipt and

transfer of radioactive materials, external exposure records, radioactive waste disposal, notifications and reports, misadministrations, posting and labeling, and transportation.

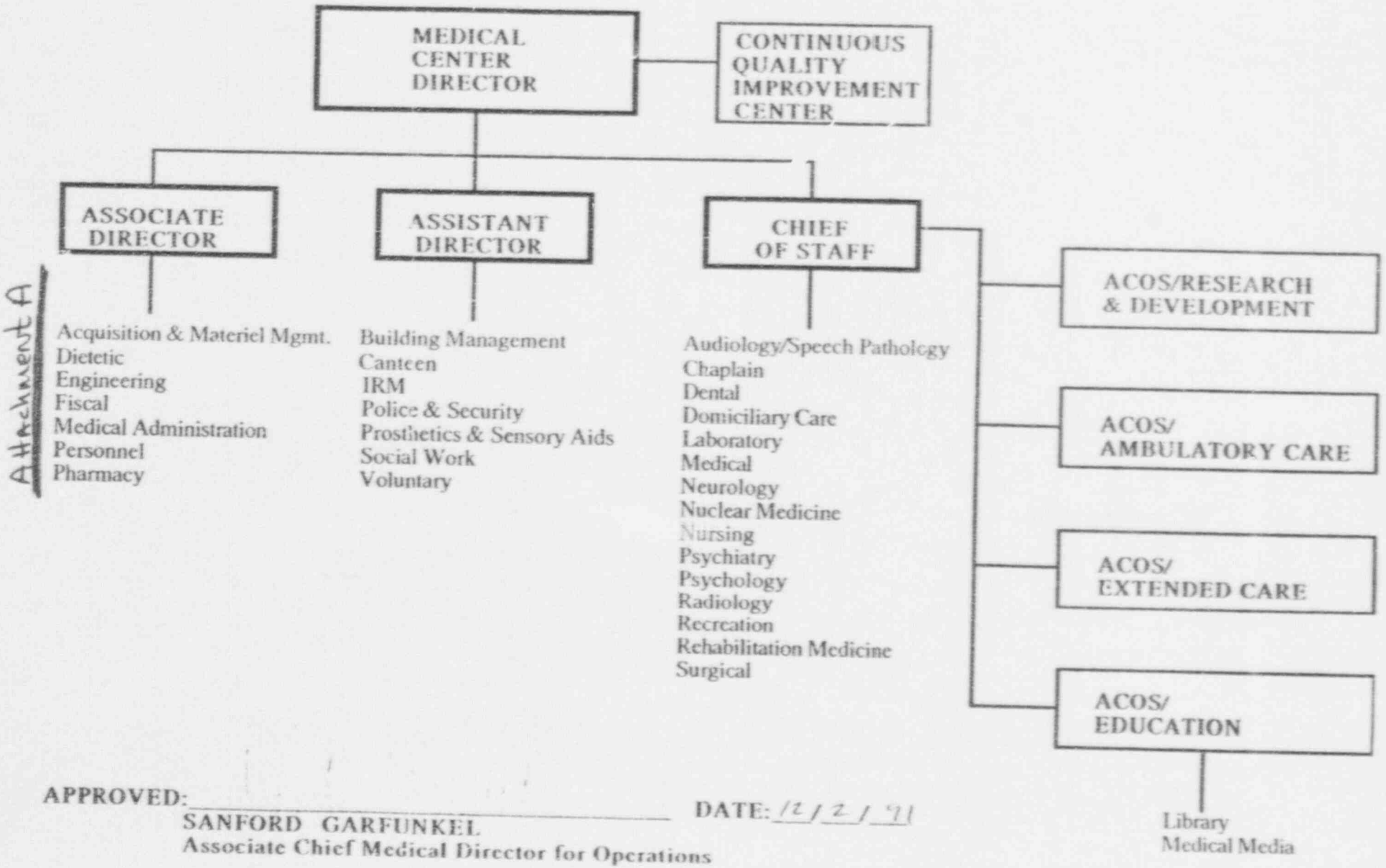
No violations of NRC requirements were identified.

11. Exit Meeting

At the conclusion of the inspection on November 12, 1992, the inspector met with those individuals identified in Section 1 of this report. A summary of the areas inspected, the apparent violations, the NRC enforcement policy, and the forthcoming letter were discussed as well as the licensee's proposed corrective actions. Nothing contained in this report was identified as proprietary by the licensee.

Attachments:
A. V.A. Medical Center Organizational Chart
B. Nuclear Medicine Service Organization Chart

Department of Veterans Affairs
MEDICAL CENTER
North Chicago, Illinois



Attachment A

APPROVED: _____ DATE: 12/2/91

SANFORD GARFUNKEL
Associate Chief Medical Director for Operations

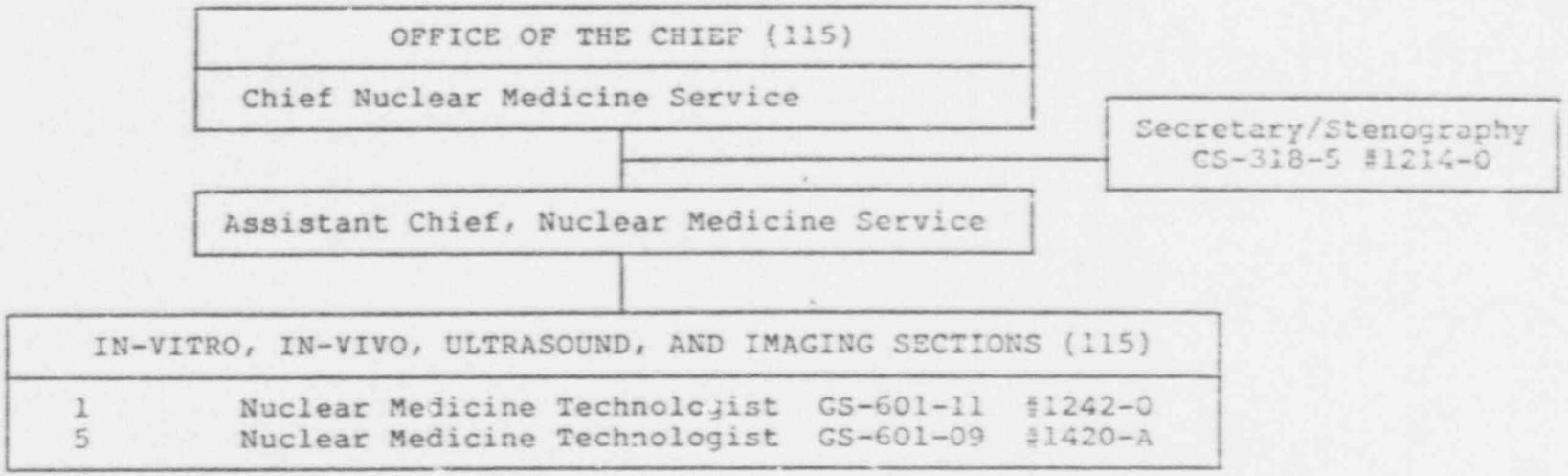
NUCLEAR MEDICINE SERVICE
VA Medical Center
North Chicago, IL 60064

Ceiling: Physicians FTP ... 2
Others FTP ... 7

TOTAL: 9

Attachment B

ORGANIZATIONAL CHART



Revised 12-13-91 CWF

Gregory A. Gergans M.D.

Gregory Gergans, M.D. Date
Chief, Nuclear Medicine Svc

Robert Grant Date
Chief, Personnel Svc

Carter Mecner, M.D. Date
Acting Chief of Staff

Hugh Doran Date
Associate Medical Center
Director/Chairman, Resource
Committee

A. S. Pate Date
Medical Center Director