DEPARTMENT OF VETERANS AFFAIRS
Medical Center
3001 Green Bay Road
North Chicago IL 60064-3096

JAN 12 1993

In Reply Refer To: 556/00A

United States Nuclear Regulatory Commission
ATTN: Mr. Roy Caniano
Acting Chief, Nuclear Materials Safety Branch
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Mr. Caniano:

This regards our telephone conference on Thursday, January 8, 1992. During that conference you asked for: 1) further response to the Notice of Violation based on the special safety inspection conducted by Evelyn Matson of your office on November 12, 1992, to "review concerns associated with activities authorized by NRC Byproduct Material License No. 12-10057-04"; and 2) that we further describe the actions taken to prevent recurrence of the management deficiencies cited therein.

First, I have enclosed (Enclosure 1) the addendum to our initial response to the items specifically cited in the Notice of Violation provided by your office. This addendum was prepared by Dr. Sanda Loga, Radiation Safety Officer at this medical center. We remain confident and pleased that all items identified in the Notice of Violation are now resolved and that appropriate actions have been taken to prevent and/or minimize the possibility of their reoccurrence.

Second, we have aggressively acted to ensure that the management deficiencies and related staffing concerns raised are fully addressed. To reemphasize information presented in earlier communications:

a. the temporary shortage of technical staff is resolved. There are now four technologists on duty (since the return of one from maternity leave on December 14, 1992);

b. the majority of workload related to RIA testing is now being done with different (non-RIA) procedures by Laboratory Service. Some RIA procedures, i.e., Amikacin, Gentamicin and Digoxin levels, are now being performed using non-RIA techniques in the Clinical Laboratory. Hepatitis and HIV testing, now referred to private laboratories, will be performed in house by the Clinical Laboratory by no later than the end of January 1993;

c. the remaining RIA workload is being shifted to the Endocrinology Laboratory. This remaining RIA workload (thyroid studies) will be transferred to Endocrinology Laboratory, also by no later than the end of January 1993; and

d. plans and actions integrating radiology, scanning and ultrasound procedures under the umbrella of a Diagnostic Imaging Service will allow the sharing of reception, administration, clerical, procurement and supervisory support duties, affecting economies of administrative and technical support. The Clinical Executive Board (CEB) of the Medical Center met November 19, 1992.

JAN 13 1993

The minutes and attachments reflect discussion and concurrence with the actions listed above. Since this is a confidential Quality Management Record under 38 USC 3305, 38 CFR 17, the document has been redacted and reflects only that portion relevant to discussion of the Nuclear Medicine Service (Enclosure 2). The recommendations were approved by the Medical Center Director and the Chief of Staff. Ongoing monitoring of issues related to Nuclear Medicine Service will be documented in successive minutes of the CEB.

Furthermore, the next level of action, that is, reorganization of the Nuclear Medicine Service, requires concurrence by Mr. Al Zamberlan, Regional Director, Central Region, and approval by Milton Gross, M.D., Program Director, Nuclear Medicine Service, VA Central Office. These approvals are now being sought (Enclosure 3).

As I stated during our telephone conference and am restating now for the record, Dr. Gergan's allegations regarding a staffing "crisis" are knowingly false and due to his deliberate granting of time and leave requests. Additionally, the record should reflect that he has, with malice and forethought, threatened the Chief of Staff and me with the escalation of a negative letter writing campaign. We will submit reports of contact attesting to this upon your request. Dr. Gergans negative letter writing campaign has thus far included the NRC, the Occupational Health and Safety Administration, members of Congress, the Secretary of Veterans Affairs and senior VA leadership, i.e., the Under Secretary for Health, Veterans Health Administration Nuclear Medicine Program Director, etc., and veterans service organizations. I fully expect that this behavior will persist, consistent with his threats. The tone of several letters he has written to me require little interpretation: his actions are intended to cloak himself as a whistle blower in the hope of avoiding correction for his incompetent administration of the Nuclear Medicine Service at this facility.

Nonetheless, in good conscience, we will not be dissuaded from pursuing actions appropriate to ensure cost effective and high quality patient care, including the utilization of non-RIA techniques whenever possible, the shifting of workload from the Nuclear Medicine Service, and reorganization of the Service to achieve economies of scale.

If further information is required, please contact me on FTS 700-384-3700, or the Executive Staff Assistant, Michael A. Tyllas, Ph.D. on FTS 700-384-3702.

Sincerely,

A. S. PATE

Enclosures: 3

cc:

Chief, Continuous Quality Improvement Center (556/00Q)
Regional Director (132), Ann Arbor
Director, Field Support (132), VACO

ENCLOSURE 1

ADDENDUM TO THE REPLY TO A NOTICE OF VIOLATION

Item 1. Checking Xenon Trap Effluent

a. Reason for Violation

The violation was due to a misinterpretation of the NRC Regulatory Guide 10.8, Appendix O, paragraph O.3, points 1 and 3.

b. Corrective Action

1. The form used for "Checking Xenon Trap Effluent" has been modified (see Attachment).

2. Training sessions on how to test the Xenon alarm were performed on December 15, 1992, and on January 5, 1993. All Nuclear Medicine Technicians attended the training session.

3. The Radiation Safety Officer (RSO) will review quarterly, the records pertaining to the checking of Xenon Trap Effluent.

Item 2. Weekly Laboratory Survey

a. Reason for Violation

It was a misinterpretation in allowing old pratices to continue, out of fear that new procedures would be confusing (e.g. we were doing daily wipe tests in one hot area, instead of weekly in all areas).

b. Corrective Action

The weekly laboratory surveys will be reviewed quarterly by the RSO.

Item 3. Inventory of Sealed Sources

Corrective Action

The RSO has a check list of all the items that need to be done quarterly and which presently are being carried out.

Item 4. Daily Checks of Survey Meters

Corrective Action

1. A reminder training for the daily checks of survey meters was performed on January 5, 1993. All Nuclear Medicine technicians attended.

2. The RSO will quarterly review the records.

Item 5. Records of Disposal of By-Product Material.

a. Reason of Violation

1. Our records were maintained for all kinds of radioactive waste.

2. The RSO failed to survey the records for sharp needle boxes and these records were inadvertently incomplete.

b. Corrective Action

The RSO will check the records quarterly.

Sanda Loga

SANDA LOGA Ph.D.
Radiation Safety Officer

January 7, 1993

Attachment

MONTHLY CHECK OF XENON TRAP EFFLUENT

XENAMATIC 3000
MODEL:3000s
SERIAL:1189136

CESIUM-137
LOT:4070

NOTE: IF THE ALARM IS NOT WORK[illegible] THE XENAMATIC WON'T BE USED AND THE MANUFACTURER WILL BE CONTA[illegible]ED.

DATE	CS-137 RADIONUCLIDE ACTIVITY(uCi)	DISTANCE(inches) FROM DETECTOR	RESULT (ALARM WORKING)	INITIAL
12/15/92	281.06	4.0	yes	TR
1/5/93	281.06	4.0	yes	TR

ENCLOSURE 2

CONFIDENTIAL
QUALITY MANAGEMENT RECORD
38 USC 3305, 38 CFR 17

VETERANS AFFAIRS MEDICAL CENTER
North Chicago, Illinois 60064

Clinical Executive Board

November 19, 1992

PRESENT: Carter E. Mecher, M.D., Chief of Staff; Dr. Kepley, Chief, Dental Service; Ms. Pusateri, Chief, Continuous Quality Improvement; Dr. Moga, Acting Chief, Surgical Service; Jan Waller, f/Acting Chief, Medical Service; Mr. Alexander, Chief, Medical Administration Service; Ms. Bolling, Chief, Social Work Service; Dr. Chun, Chief, Radiology; Dr. Rubinstein, Chief, Laboratory Service; Dr. Pinto, f/ACOS/Ambulatory Care; Ms. J. Bauer-Green, f/Chief, Recreation Therapy Service; Dr. Agrawal, Chief, Rehabilitation Service; Ms. Weichers, f/Chief, Psychiatry Service; Randy Gartner, Consumer Affairs/Patient Relations Representative; Greg Gola, Chief, Domicilliary Service; Rosie Harris, R.N., Acting Chief, Nursing Service; Dr. Singh, ACOS/Research & Development; Chaplain Mateo, f/Chief, Chaplain Service; Mr. Patterson, Acting Director, Clinical Operations; Steve Thomas, Acting Chief, Pharmacy Service; Ms. Dong, Chief, Audiology/Speech Pathology Service; Dr. Rice, Acting ACOS/Geriatrics and Extended Care Service; and Dr. Vuckovich, Chief, Neurology Service.

ABSENT: Dr. Lips, Chief, Psychology Service; Dr. Barsano, ACOS/Education Service; Dr. Gergans, Chief, Nuclear Medicine Service; and Linda Cobine, Legal Counsel.

GUESTS: Mary France, AA to the ACOS/Research & Development.

1. APPROVAL of MINUTES: The minutes of October 7, 1992, were discussed and approved with one correction: Ms. K Dong, Chief, Audiology/Speech Pathology Service present vice Janet Toole. No endorsements sheets were received at the time of this meeting.

2. OLD BUSINESS:

a. Action/Evaluation Problem List (Attachment 1)

(1) A/E 9/92: Delay in turn-around time for HIV testing. The committee decided that this item should be appropriately combined with the issue of RIA testing and will now be addressed/dialogued under A/E 15/92.

[redacted]

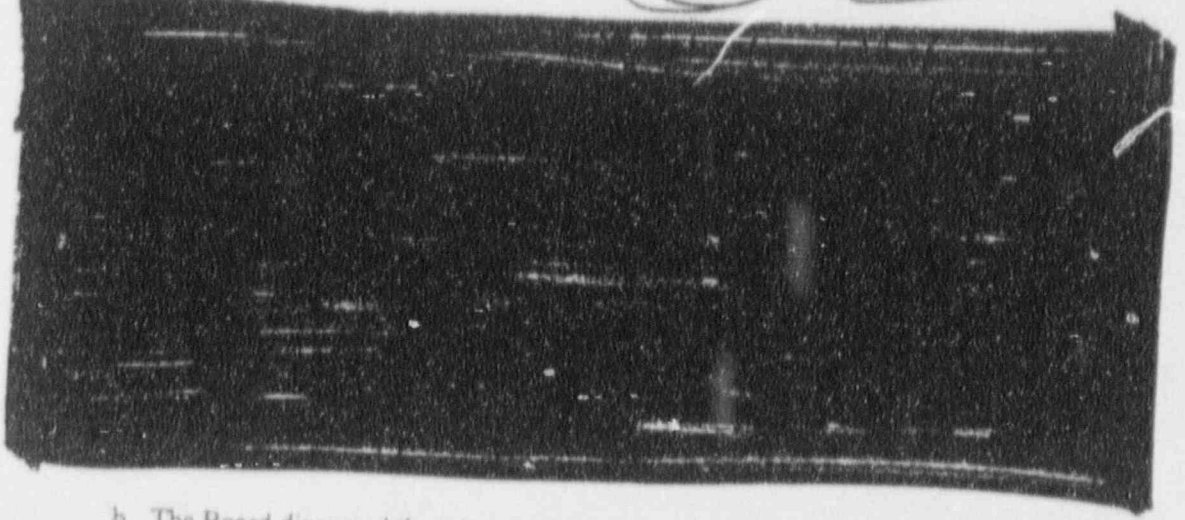
[redacted]

11 and 001 should coordinate recruitment of this position ASAP.

AR

[redacted]

Approved/Disapproved



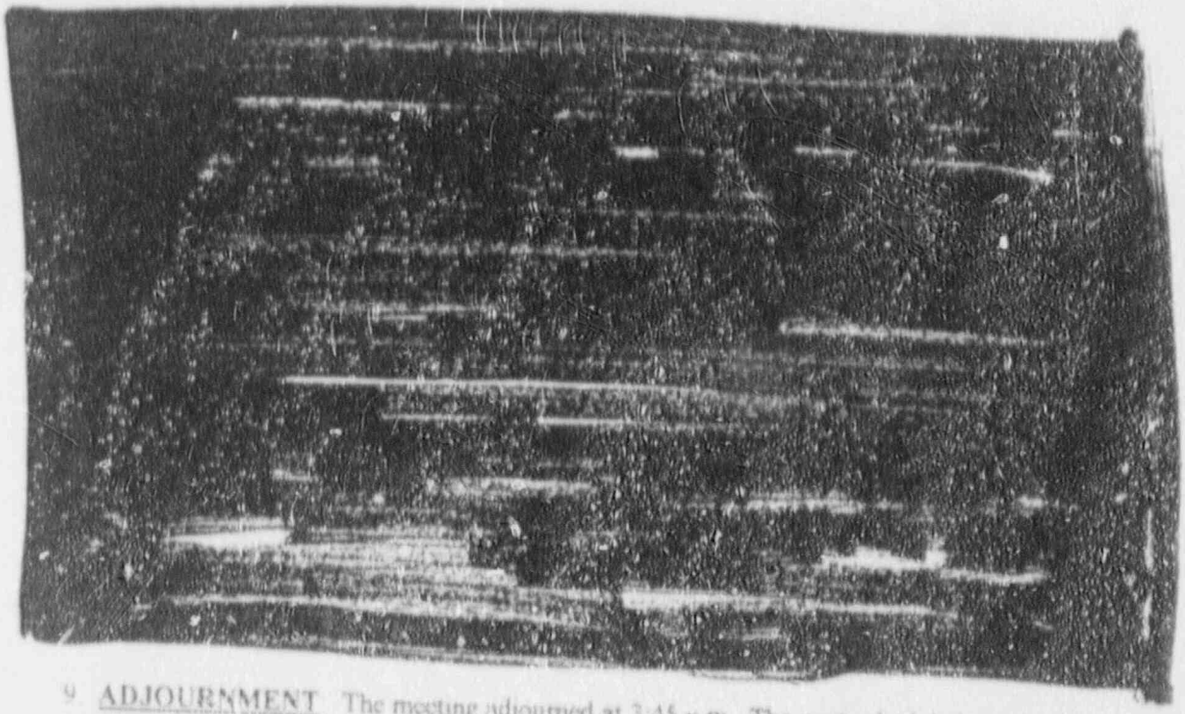
b. The Board discussed the minutes of the subcommittee of the Clinical Executive Board which was charged with addressing Nuclear Medicine issues (Attachment 3). The subcommittee developed two options: (1) maintaining RIA testing within the Nuclear Medicine Service (hiring more technicians to maintain the RIA workload), and (2) transferring the RIA workload to the Laboratory Service and Endocrine Section and switching to equivalent non-RIA procedures. This would be associated with a combining of the Nuclear Medicine Service under Radiology Service into one Imaging Service. The first option provided for additional FTEE to meet the current work load/demands including RIA testing. To continue utilizing RIA procedures would incur the following: (1) the costs for RIA tests (running tests in duplicate as well as the calibrations for each batch); (2) the costs for performing these tests during off hours, holidays, and weekends; (3) the costs of testing by outside labs; (4) the costs for handling, storage, and removal of radioactive waste; and (5) personnel costs, i.e., the number of man hours necessary per quarter to perform laboratory testing in RIA and the cost of additional FTEE. The second option included transferring the RIA work load to Laboratory Service and the Endocrine Service Section with an ultimate goal of phasing out RIA testing by utilizing equivalent non-RIA procedures. Provisions of the second option were: (1) reduced laboratory costs including costs for performing each test and estimated costs per quarter; (2) estimated man hour costs for performing these tests in the laboratory; (3) personnel support, i.e., laboratory service offers 24 hour, seven days a week capabilities, enhanced flexibility due to the absence of batch testing, faster turn-around time for results, and a significant costs savings to the medical center (Attachment 4). The advantages of performing thyroid function tests by the Endocrine Section were also noted (Attachment 5). The Board expressed concern with Dr. Gergans absence, however, it was pointed out that Dr. Gergans received prior notification, during a meeting in which these issues were discussed, and was well aware that this issue would be discussed at this meeting. After lengthy discussion, the Board

recommended that RIA testing be transferred to Laboratory Service with the ultimate goal of replacing RIA testing with non-RIA procedures. The Board further recommended that Nuclear Medicine and Radiology be combined into one Imaging Service. Dr. Mecher indicated that this motion will be presented to the Medical Center Director and then forwarded through the appropriate channels for consideration of this proposal. Medical Center Director Comments:

11 and 001 to Coordinate w/05 -

DP

Approved/~~Disapproved~~



9 ADJOURNMENT The meeting adjourned at 3:45 p.m. The next scheduled meeting will be held December 10, 1992, at 12:00 noon, Building 5, Room 204.

Carter E. Mecher MD

CARTER E. MECHER, M.D.
Chief of Staff/Chairman

APPROVED

A. S. PATE
Medical Center Director

Attachments 7

A/E 15/92: RIA Testing vice Non-RIA Testing
Date Identified: 10/92
Responsible Party: Chief of Staff
Review Date: 12/92

The Board discussed the minutes of the subcommittee of the Clinical Executive Board which was charged with addressing Nuclear Medicine issues. The subcommittee developed two options: (1) maintaining RIA testing within the Nuclear Medicine Service (hiring more technicians to maintain the RIA workload), and (2) transferring the RIA workload to the Laboratory Service and Endocrine Section and switching to equivalent non-RIA procedures. This would be associated with a combining of the Nuclear Medicine Service under Radiology Service into one Imaging Service. After lengthy discussion, the Board recommended that RIA testing be transferred to Laboratory Service with the ultimate goal of replacing RIA testing with non-RIA procedures. The Board further recommended that Nuclear Medicine and Radiology be combined into one Imaging Service. Dr. Mosher indicated that this motion will be presented to the Medical Center Director and then forwarded through the appropriate channels for consideration.

REVIEW 12/92.

Special Meeting Concerning Nuclear Medicine Issues
SubCommittee of the Clinical Executive Board
November 4, 1992

Present: Carter E. Mecher, M.D., Chief of Staff; Osvaldo Rubinstein, M.D., Chief, Laboratory Service; Wonsang Chun, M.D., Chief, Radiology Service; and Thalerng Balachandra, Acting Chief, Nuclear Medicine Service.

Dr. Mecher informed the committee of a letter that Dr. Gergans sent to the Director of the Nuclear Regulatory Commission in which he expressed his concerns regarding inadequate staffing in Nuclear Medicine Service (Attachment 1). Dr. Mecher stated that the Department of Nuclear Medicine is responsible for ultrasounds, nuclear medicine diagnostic and therapeutic procedures, as well as RIA testing. He also indicated that at Nuclear Medicine's Annual Management Briefing for fiscal year 1993, the work load data from fiscal year 1991 revealed the following: RIA testing 17,866 tests; imaging 1,706 procedures; therapy 12 procedures; and ultrasound 1,095 procedures (Attachment 2).

In view of Dr. Gergan's concerns the committee discussed two options: (1) increase FTEE within the Department of Nuclear Medicine to satisfy Dr. gergan's concerns; and (2) evaluate the work load that the Department of Nuclear Medicine is presently responsible for and evaluate the feasibility of transferring a portion of this work load to other services, specifically, the RIA work load/laboratory testing to Laboratory Service.

Dr. Rubinstein presented a cost analysis of RIA testing versus non-RIA testing. He discussed the various tests presently performed in the Nuclear Medicine Service including Digoxin, Gentamicin, Amikacin, Hepatitis serology, thyroid function tests, serum folate, RBC folate, vitamin B12 levels, CEA and PSA levels. The RIA testing performed in Nuclear Medicine Service is presently done in batches of twice per week. They are only able to perform testing eight hours per day five days per week during weekdays. There are no provisions for RIA testing either in the off hours or during the weekends or on holidays. All RIA testing is done in duplicate. Therefore the cost of RIA testing must be multiplied by two times the number of tests performed per quarter. Batch testing is performed twice a week (26 per quarter) for each test. There are six calibrations done for each batch. Hence, 24 calibrations are done for each test per week. Accordingly, 312 calibrations are performed per quarter for every single RIA test. Therefore the total cost for any specific RIA work load per quarter is equal to the cost of the RIA test multiplied by the sum of twice the number of tests performed per quarter plus 312. Additional costs for RIA testing include both the storage and ultimate removal of radioactive waste from the Department of Nuclear Medicine. It has been determined that approximately 600 pounds of radioactive waste is generated each year as a result of RIA testing alone (equivalent to 3 dry waste 55 gallon containers). The costs involved were not available at the time of this meeting. Also, the man hour costs for performing the RIA testing versus the performance of the tests in a standard laboratory with non-RIA materials was not available at this meeting. However, a significant cost differential in favor of the non-RIA tests being performed in the laboratory was noted. The recommendation of the committee was that Dr. Rubinstein obtain the information necessary to calculate

2. SubCommittee of the Clinical Executive Board

the total costs for work load of these RIA tests in Nuclear Medicine versus the cost of these tests being performed in the Laboratory Service. For RIA tests, these cost would include: (1) performance of RIA tests, running tests in duplicate as well as the calibrations for each batch; (2) the costs of performing these tests during off hours, weekends, and holidays; (3) the cost of handling, storage, and removal of radioactive waste; and (4) personnel costs, i.e., number of man hours necessary per quarter to perform laboratory testing in RIA. Laboratory costs include: (1) cost per test and estimated cost per quarter; and (2) estimated man hour costs for performing these tests in the laboratory. Dr. Rubinstein is responsible for providing this information to the Chief of Staff's office with a cost analysis of RIA testing in Nuclear Medicine versus total cost of performing the tests within the Laboratory. Dr. Rubinstein recommended that measurement of serum folate levels be transferred to the Endocrine Section. He also informed the committee that serum folate levels as well as B12 levels could be performed by non-RIA assay within the year.

The committee agreed that the advantages of transferring the performance of these particular tests from Nuclear Medicine Service to Laboratory Service include convenience, which allows 24 hour, seven days a week capability, enhanced flexibility due to the absence of batch testing, faster turn-around time for results, and a significant cost savings which is to the benefit of our patients and our medical center.

The committee concluded that if it is feasible and cost effective to transfer RIA testing to Laboratory Service from Nuclear Medicine, then an evaluation of the clinical activity within the Department of Nuclear Medicine and the staffing needs must also be addressed. The committee agreed that Dr. Chun and Dr. Balachandra would meet (until Dr. Gergans is available) to discuss staffing needs and the feasibility of placing Nuclear Medicine as a "section" under Radiology Service and combining the two to form a service of Imaging. The Chiefs of Nuclear Medicine and Radiology were asked to obtain information from other VA medical centers in which Nuclear Medicine and Radiology have been combined into one Imaging Service and to provide estimations of the staffing needs, specifically for Nuclear Medicine in ultrasound and imaging. The committee agreed to provide this information to the Chief of Staff's office no later than November 11, 1992.

This information will be incorporated into a report generated from the Chief of Staff's office to be presented at the Clinical Executive Board November 19, 1992, subsequent to Medical Center Director review.

Carter E. Mecher MD

CARTER E. MECHER, M.D.

Attachments

PROPOSAL

In an attempt to optimize resources and increase efficiency it is proposed that Nuclear Medicine Service be restructured by redistributing all in vitro tests to Laboratory and Endocrinology Services and combining all scanning and ultrasound activities with Radiology Service under an Imaging Department.

RATIONALE

In recent years, new technology and equipment has become available to allow more than 80% of the in vitro tests currently being conducted using the RIA (Radioisotope Immunoassay) method to be performed in a non-RIA manner. The equipment to perform these non-RIA tests is automated and currently on station. Nuclear Medicine Service now sends out all of the Hepatitis Series, HIV tests, and Amikacin levels to a private laboratory. By doing these tests on station, the results will be immediately available on DHCP and included in the recently activated "lab alert" system which automatically notifies practitioners of abnormal values, via E-mail. Laboratory Services provides coverage 24 hours a day, seven days a week, whereas Nuclear Medicine is only available 8 AM - 4:30 PM Monday through Friday. By performing these tests without using radioactive material the overhead of handling, storage, and disposal would be eliminated.

Combining the scanning and ultrasound procedure with Radiology will allow the sharing of reception, administration, clerical, procurement, and supervisory support. (See Attached Organizational Chart)

SAVINGS

Besides the obvious efficiencies gained by doing all tests on station, the actual cost savings based on FY92 workload would be as follows:

	RIA Method	Non-RIA Method	Savings
In Vitro Testing	$68,600	$39,500	$29,100
Radioactive Waste	17,000	0	17,000
Outside Testing	38,906	2,350	36,556
FTEE Savings	3 technologists @ $31,000		93,000
	Fringe benefits @ 26%		24,180
Total Savings			$199,836

Attachment 5

Department of Veterans Affairs

Memorandum

Date: November 18, 1992

From: ACOS/Education (141) CB

Subj: Reassignment of Thyroid Function Tests

To: Chief of Staff (11)

1. At the time of tomorrow's CEB meeting I will be giving Psychiatry Grand Rounds and can not reasonably be present at the meeting. I would however like to urge, very strongly, that if the thyroid function tests (T4, T3 Resin Uptake, FTI, and TSH) are reassigned from Nuclear Medicine, they should be reassigned to the Endocrinology Lab and conducted by the same RIA techniques as are currently in use. This recommendation is based on the following considerations.

   a. If the assays are changed to non-radioactive assays (or even different radicassays), new normal references intervals must be determined. These would probably be similar but would almost certainly be different. This causes not inconsiderable clinical hassles since thyroid function tests are often clinically relevant for years, e.g. in patients with slowly evolving primary or secondary hypothyroidism and in patients on thyroid replacement. Thus, changing to a new assay not only means you must reestablish new reference intervals and disseminate them to the staff and trainees, but you must retain the old values as well. The patient's past thyroid function laboratory data remains relevant for years and must be interpreted with the corresponding reference intervals of the past.

   b. From time to time we do change assays if the new assay offers a great clinical advantage and/or a considerable reduction in price. From substantial clinical use and from my research experience with the assays we have been using, I know that the assays employed here are quite good. There is a more sensitive chemoluminescent TSH assay which does not involve radioactive isotope but it is much more expensive. Since it is extremely sensitive, it is also more difficult to perform and less forgiving in the hands of the technician. Its unusual sensitivity is of negligible clinical value however since the highly sensitive assay we have now clearly distinguishes between suppressed and lower normal TSH values.

   c. If the thyroid function assays need to be reassigned, the Endocrinology laboratory would be their best home. The abnormal and borderline values are of interest to the endocrinologists much beyond being simple lab abnormalities which have to be brought to the attention of an ordering physician. The assays would also become a more accessible clinical research asset.

   d. The Endocrinology fellows are required to have experience in radioimmunoassays of hormones. This experience would be much more accessible if the assays were being done under the auspices of the Endocrinology section.

2. I hope this information is helpful for your considered reassignment of the thyroid function tests.

ENCLOSURE 3

Department of
Veterans Affairs

Memorandum

Date JAN 0 1993

From Medical Center Director (556/00A)

Subj Table of Organization

To Regional Director, VACO (132/13)

1. Attached is a revised Table of Organization for VAMC North Chicago. The proposed table differs from the currently approved table in two ways. First, it figuratively reflects the organizational element, "Management Support Office" (which has been approved in previous functional statements). This change is graphical rather than substantial.

2. Second, when approved, it will reflect the reorganization of two services, Nuclear Medicine Service, and Radiology Service, into one organizational element, "Diagnostic Imaging" Service. This reorganization was recommended and endorsed by the Clinical Executive Board of the medical center and by the Chief of Staff on November 19, 1992. The purpose of this reorganization is twofold:

a. recognizing the functional relationships of the services provided in each of the two current services; 2) realizing economies of scale by integrating the technical staff of each service; and 3) eliminating unnecessary layers of supervision; and

b. improving patient care by 1) facilitating the cross-training of technologists and promoting better coverage, and 2) increasing communications between technologists and supervisors.

3. If further information is required please contact me on FTS 700-384-3700, or the Executive Staff Assistant, Michael A. Tyllas, Ph.D., on FTS 700-384-3702.

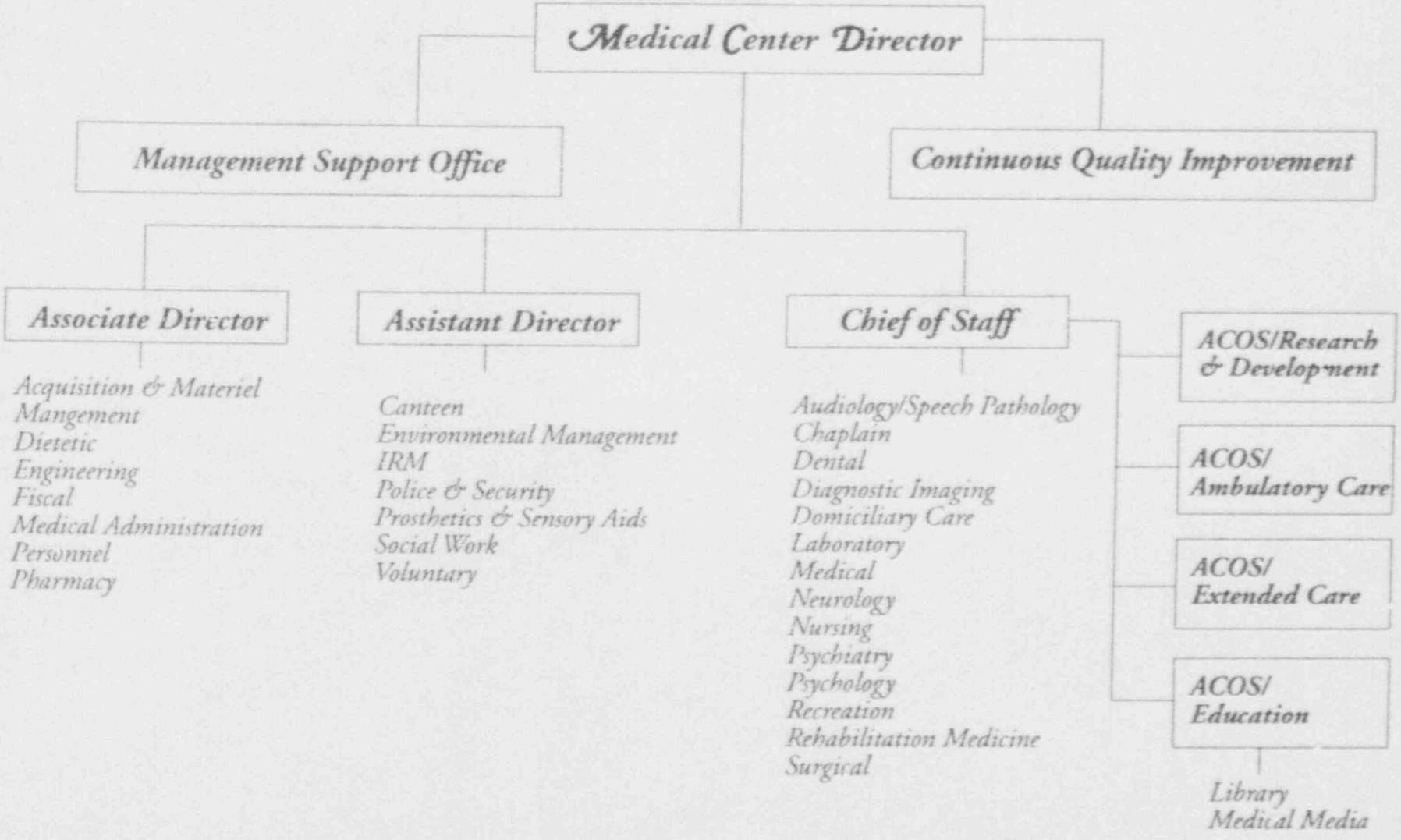
A. S. PATE

Attachment: 1

cc:

05
Regional Director (132), Ann Arbor
Director, Nuclear Medicine Service (111E)

Department of Veterans Affairs
Medical Center
North Chicago, Illinois



APPROVED: _____ *DATE:* ___/___/___

Sanford M. Garfunkel
Associate Chief Medical Director for Operations

CONVERSATION RECORD

TIME 0730 DATE 01/05/93

O VISIT O CONFERENCE Ø TELEPHONE

Ø INCOMING
O OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: Al Pate

ORGANIZATION (OFFICE, DEPT.ETC.) TELEPHONE NO. N/A

SUBJECT
RESPONSE TO NOTICE OF VIOLATION DATED 12/18/92

SUMMARY

Mr. Pate returned my call from the previous day. I discussed with Mr. Pate the response received from him regarding our recent inspection. I indicated to Mr. Pate that additional information was required in the response. I discussed in detail the response to our concern over the management issue which resulted in decreased staff levels for a period of time. Mr. Pate indicated that the root cause was poor management by Dr. Gergans. He indicated that it was his opinion that there was not a staffing problem but a management problem in that several individuals were approved leave at the same time. If this had not occurred, in his opinion, there would not have been a shortage of staff at certain times.

Mr. Pate also stated that a reorganization was in progress with the department. He stated that Dr. Gergans had been assigned to the Hines V. A. Med. Ctr. and another doctor named as the section chief. He also stated that the nuc. med. service had been moved to a diagnostic imaging section which would provide an additional level of management oversight of nuclear medicine. He indicated that this was stiil in the process of being approved but was confident that final approval would be received soon.

Based on the information provided I told Mr. Pate that additional information would not be necessary regarding the management concern via letter. I did indicate however that additional information was necessary regarding the violations and that this had been discussed with Dr. Loga the RSO. He stated that he understood.

ACTION REQUIRED
Second response due in 15 days. Update response evaluation form.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Gary Shear	Gary Shear	1/5/93

ACTION TAKEN Updated response evaluation form

CONVERSATION RECORD

(X) TELEPHONE ( ) INCOMING ( ) OUTGOING ( ) CONVERSATION TIME 3:15pm DATE 01/04/93

NAME OF PERSON(S) CONTACTED ORGANIZATION TELEPHONE NO.

Dr. Sanda Loga, Ph.D. V.A. Medical Center-North Chicago 708-688-1900x3125

SUBJECT

Response to Notice of Violation dated Dec 18, 1992

SUMMARY

We need additional information regarding the corrective actions that were identified in our Notice of Violation dated 12/4/92. Please submit the following information within 15 days:

1. xenon gas trap
   - describe root cause (example- misinterpretation of requirements)
   - describe corrective actions (example- training, date, etc.)
   - change record to include whether the test results were ok.
   - action to prevent recurrence (i.e.- quarterly audit of record)
2. weekly surveys
   - root cause (misjudgment by RSO)
   - preventative measures (quarterly audit of records)
3. inventory of sealed sources
   - preventative actions (scheduled on an annual calendar)
4. survey meter checks
   - route cause (misunderstanding of use of meter)
   - corrective actions (refresher training)
   - preventative actions (quarterly audit of records)
5. disposal record incomplete
   - root cause (oversight and lack of RSO review)
   - corrective actions (training on requirements)
   - preventative actions (quarterly review)

ACTION REQUIRED

RSO agreed to submit second response as we discussed within 15 days.

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE

Evelyn R. Matson | Evelyn R Matson | 1/4/93

ACTION TAKEN

Review second response when submitted

SIGNATURE TITLE DATE

Gergans transferred?

V.A. - North Chicago
Response 12-18-92

concern - staffing shortage

1. why occurred -
   poor management by Dr. Gergans
   * allowed too much leave time by staff
   * failed to communicate urgency & need timely
   * poor decision making

management of section / continuous dissatisfaction of staff

2. action taken to correct poor management:
   - Gergans will receive guidance & instruction

3. actions taken to correct staffing shortage:
   - one technologist returned
   - reduced workload ie RIA
   - reassigned ultrasounds from technologist

? reorganization of one need not approved by internal procedures yet?
when? meantime? what if?

I think management (Pete & Chief of Staff) could have responded better to Gergans' requests & could have made a decision sooner on relocating the RIA workload. They did not address this issue delay in doing this.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

DEC 04 1992

V. A. Medical Center
North Chicago
ATTN: Al Pate
Medical Center Director
3001 N. Green Bay Road
North Chicago, IL 60064

License No. 12-10057-04
Docket No. 030-15269

Dear Mr. Pate:

This refers to the special safety inspection conducted by Evelyn Matson of this office on November 12, 1992, to review concerns associated with activities authorized by NRC Byproduct Material License No. 12-10057-04, and to the discussion of our findings with you and other members of your staff at the conclusion of the inspection.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

In addition to the above areas, the inspector examined actions described in your letters dated June 4, 1991 and July 25, 1991, regarding violations found during our April 16, 1991 inspection. We have no further questions regarding these violations.

During this inspection, certain of your activities were found to be in violation of NRC requirements, as described in the enclosed Notice. A written response is required.

In addition to the violations, we are concerned that management deficiencies appear to have allowed staffing shortages to occur which could have led to safety issues. Therefore, in your response to this letter, (1) describe the reason why a staffing shortage occurred, (2) the actions you have taken or plan to take to address the reason the shortages occurred, (3) the action you have taken or plan to take to correct the shortage itself, (4) the dates when corrective actions will be completed, and (5) describe the actions you will take to prevent recurrence of the management deficiencies which allowed it to occur.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room.

The response directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

9212140096

OCA 009,00D

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Roy Kanaval for

John A. Grobe, Chief
Nuclear Materials Safety
Branch

Enclosure:
1. Notice of Violation
2. Inspection Report No.
030-15269/92001(DRSS)

cc w/enclosure:
DCD/DCB (RIDS)
D. Funk, RIII

NOTICE OF VIOLATION

V. A. Medical Center
North Chicago, IL

License No. 12-10057-04
Docket No. 030-15269

During an NRC inspection conducted on November 12, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992), the violations are listed below:

1. 10 CFR 35.205(e) requires, in part, that a licensee check each month the operation of reusable collection systems for radioactive gases.

   Contrary to the above, as of November 12, 1992, the licensee failed to check a reusable collection system for radioactive xenon-133 gas each month of operation.

   This is a Severity Level IV violation (Supplement VI).

2. 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.

   Contrary to the above, as of November 12, 1992, the licensee did not survey for removable contamination once each week in all areas in the hot lab and in the room used to inject patients; both are areas where radiopharmaceuticals were routinely prepared for use or administered.

   This is a Severity Level IV violation (Supplement VI).

3. 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.

   Contrary to the above, 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.

   This is a Severity Level IV violation (Supplement VI).

4. 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.

   Contrary to the above, as of November 12, 1992, the licensee routinely did not check its stationary Texas Nuclear survey meter with a dedicated check source on days when the instrument was used.

   This is a Severity Level IV violation (Supplement VI).

9212140101

5. 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.

   Contrary to the above, 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.

   This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, V. A. Medical Center-North Chicago is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, within thirty days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

DEC 04 1992
Dated

Roy J. Zimmerman
John A. Grobe, Chief
Nuclear Materials Safety
Branch

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 Caron 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 weekl, removable contaminatio 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.

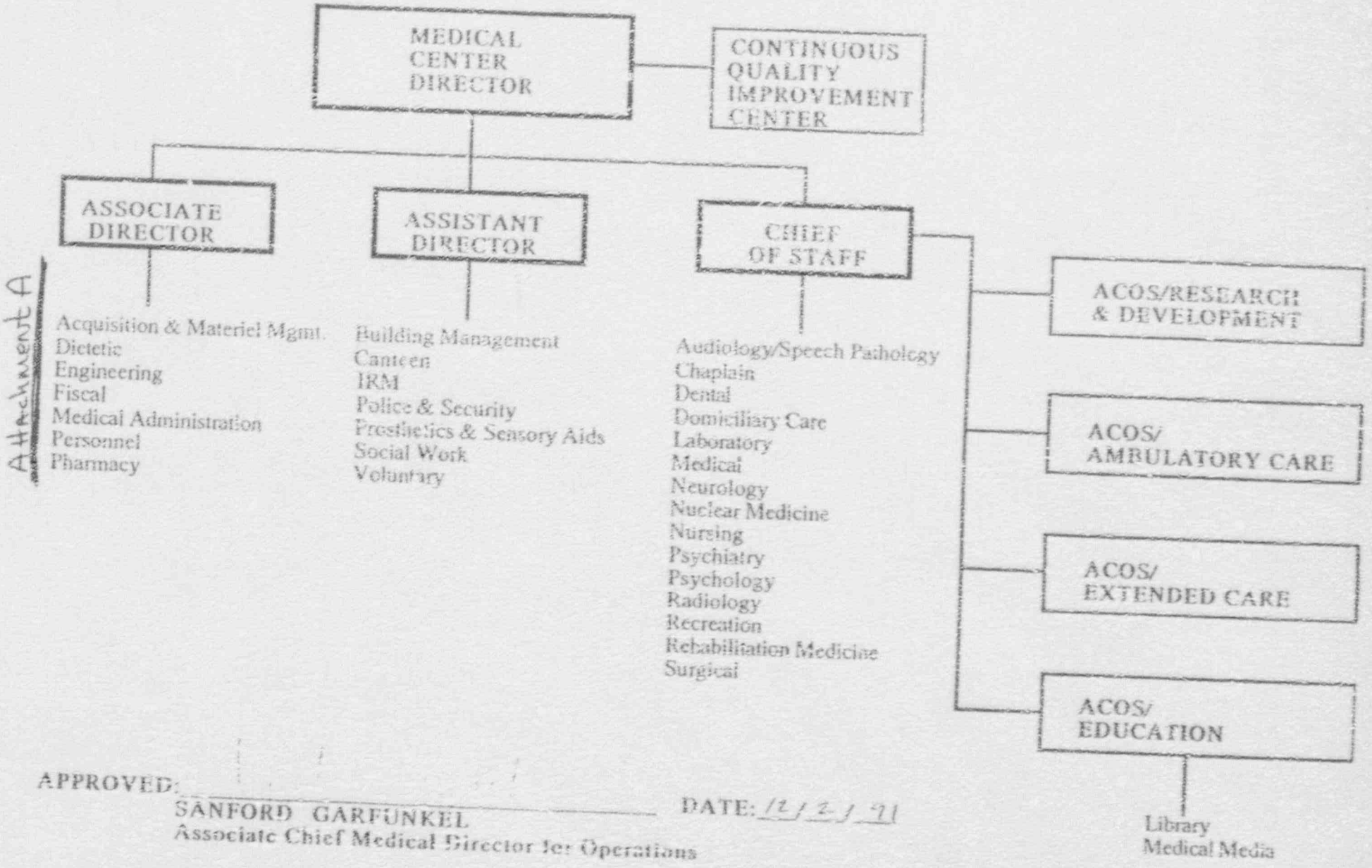
No violations of NRC requirements were identified.

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

Attachment B

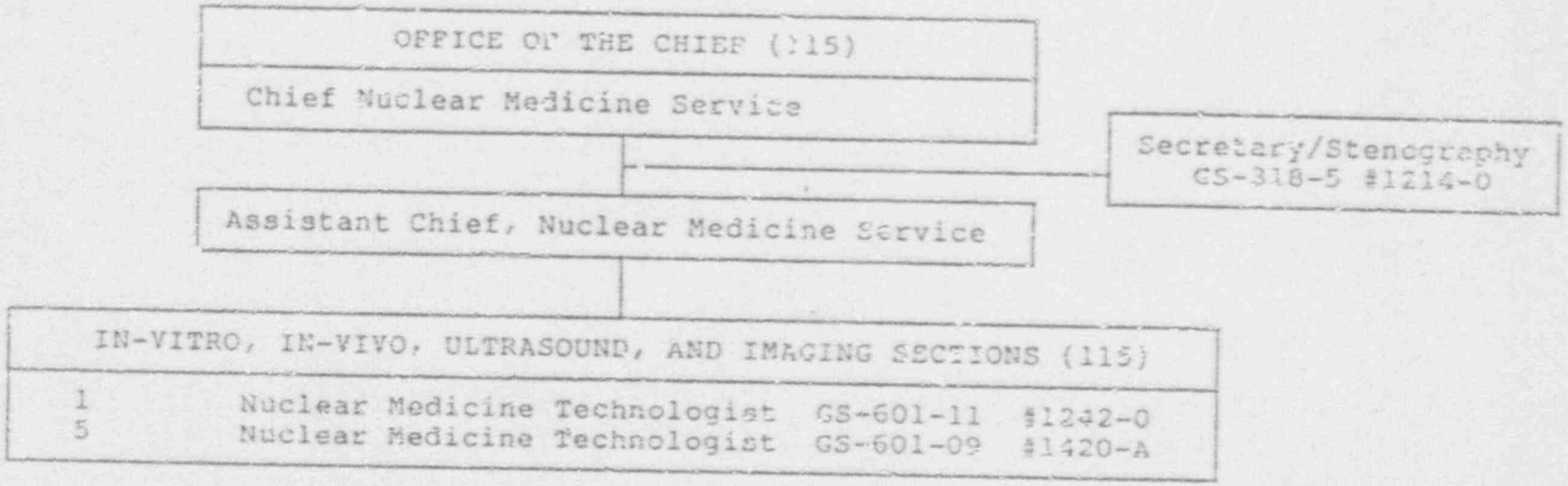
NUCLEAR MEDICINE SERVICE
VA Medical Center
North Chicago, IL 60064

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

TOTAL: 9

Routed 12-13-91 CJF

ORGANIZATIONAL CHART



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

Robert Grant Date
Chief, Personnel Svc

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

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

A. S. Pate Date
Medical Center Director