MAY 29 1997

Docket No. 030-01301 License No. 07-09495-01

Ms. Adrienne Spivey
1633 Carroll Street
Brooklyn, NY 11213

Dear Ms. Spivey:

This is in reference to your letter dated May 5, 1997, in which you expressed your concern that the former Radiation Safety Officer (RSO) at the Veterans Administration Medical Center in Wilmington, Delaware, Asaf Durakovic, M.D., was being wrongly blamed by Medical Center management for all of the problems identified by NRC during a March 26, 1997 inspection of that licensed program. These problems were discussed with representatives of the Medical Center during the May 1, 1997, predecisional enforcement conference which you attended. In your letter you stated that Medical Center management had to shoulder responsibility for the program rather than conspire to blame Dr. Durakovic and that, prior to the May 1 conference, Dr. Durakovic's performance was deemed "impeccable" by the Medical Center's Director.

We appreciate your taking the time to attend the May 1 conference and for writing to us with your concerns. We agree that facility management, the holder of the NRC license, has ultimate responsibility for the radiation safety program. We believe we emphasized this point at the enforcement conference, and, of course, the enforcement action we took was against the facility, not any individual. Nevertheless, NRC believes that the RSO has direct responsibility for implementing the radiation safety program with the assistance and support of the Radiation Safety Committee (RSC) and executive management. Therefore, the RSO should ensure that radiation safety activities are being performed according to approved policies and procedures, and that all regulatory requirements are complied with in the daily operation of the licensed program. Executive management may depend heavily upon the RSO and the RSC to oversee the day-to-day operations of the program. The RSO and RSC are therefore the informed bodies to which executive management turns for information, yet executive management of the institution has overall responsibility for implementing the licensed program.

We have enclosed copies of our inspection report dated April 11, 1997, our predecisional enforcement conference report dated May 5, 1997, and the Notice of Violation which we issued to the licensee on May 2, 1997. The licensee must decide how to correct the violations. We note your skepticism about their plans. We will review the licensee's written response to our Notice and, later, our routine inspection program will follow-up on the licensee's corrective actions.

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RETURN ORIGINAL TO
REGION I

IE:07

With respect to your concern that Dr. Durakovic may be the subject of unfair employment actions, the NRC takes these matters very seriously. The Department of Labor (DOL) has responsibility for investigating these matters. We have been advised that Dr. Durakovic filed a complaint with DOL and we are presently monitoring the DOL process.

Thank you for your attention.

Sincerely,

Original Signed By:
James P. Dwyer

for Mohamed M. Shanbaky, Ph.D., Chief
Nuclear Materials Safety Branch 1

Enclosures:
1. Inspection Report No. 030-01301/97-001
2. Enforcement Conference Report No. 030-01301/97-002
3. Notice of Violation

Distribution (w/enclosures):
PUBLIC
Nuclear Safety Information Center (NSIC)
Region I Docket Room (w/concurrences)
OCA
A. Blough, RI
F. Costello, RI
D. Vito, RI
RI-97-A-0038

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OFFICE	DNMS/RI		DNMS/RI					
NAME	McKinley /r		Shanbaky /r					
DATE	05/28/97		5/28 /97					

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Encl. 1

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 11, 1997

Docket No. 030-01301
EA No. 97-146

License No. 07-09495-01

Mr. Dexter D. Dix
Center Director
Veterans Administration Medical Center
1601 Kirkwood Highway
Wilmington, Delaware 19805

SUBJECT: INSPECTION NO. 030-01301/97-001

Dear Mr. Dix:

This refers to the inspection conducted on March 26, 1997, of your facilities at Wilmington, Delaware. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with you and those members of your staff identified in the enclosed report.

Areas examined during the inspection are identified in the report. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observation of activities in progress.

Based on the results of this inspection, five apparent violations were identified and are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600. These include: (1) failure to prepare written directives prior to the administration of NaI I-131 doses greater than 30 microcuries; (2) failure to conduct reviews to verify compliance with all aspects of the quality management program at intervals no greater than 12 months; (3) failure to measure each six months the ventilation rates available in areas of use of radioactive gas; (4) failure of the Radiation Safety Committee to meet at least quarterly; and (5) failure to establish a quorum at Radiation Safety Committee meetings. Accordingly, no Notice of Violation is presently being issued for these inspection findings. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

As discussed with you during a telephone call from Richard McKinley on April 9, 1997,a predecisional enforcement conference to discuss these apparent violations has been scheduled for May 1, 1997 at 10:00 a.m., in the NRC Region I office in King of Prussia, Pennsylvania. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information

to enable the NRC to make an enforcement decision, such as a common understanding of the facts, root causes, missed opportunities to identify the apparent violation sooner, corrective actions, significance of the issues and the need for lasting and effective corrective action. In addition, this is an opportunity for you to point out any errors in our inspection report and for you to provide any information concerning your perspectives on 1) the severity of the violations, 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. This conference will be open to public observation in accordance with the Commission's continuing trial program as discussed in the enclosed excerpt from the Enforcement Policy (Enclosure 2). Although not required, we encourage you to provide your comments on how you believe holding this conference open to public observation affected your presentation and your communications with the NRC.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

Sincerely,

A. Randolph Blough, Director
Division of Nuclear Materials Safety

Docket No.: 030-01301
License No.: 07-09495-01
EA No.: 97-146

Enclosures:
1. Inspection Report No. 030-01301/97-001
2. NUREG 1600 (Enforcement Policy)

cc w/enclosures:
Asaf Durakovic, M.D., Radiation Safety Officer
State of Delaware

Distribution: (Hard copy)
PUBLIC
RI Receptionist
DRM Secretary
DRS Div Secretary
DRP Div Secretary
DNMS Div Secretary
RA Secretary
PAO
D. Holody
C. Gordon
D. Chawaga
M. Campion
State of Delaware

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-01301/97-001 Program Code 02120

Docket No. 030-01301

License No. 07-09495-01 Priority 3 Category G

Licensee: Veterans Administration Medical Center
1601 Kirkwood Highway
Wilmington, Delaware 19805

Facility Name: Veterans Administration Medical Center

Inspection At: 1601 Kirkwood Highway
Wilmington, Delaware

Inspection Conducted: March 26, 1997

Inspectors: Michelle Beardsley 4-9-97
Michelle Beardsley date
Health Physicist, Nuclear Materials Safety Branch 1

Richard McKinley 4/9/97
Richard McKinley date
Health Physicist, Nuclear Materials Safety Branch 1

Approved By: M. Shanbaky 4/9/97
Mohamed M. Shanbaky, Chief date
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

Executive Summary: Routine, unannounced safety inspection conducted on March 26, 1997 (Inspection Report No. 030-01301/97-001). Areas reviewed during this inspection included; organization and scope of licensed activities; licensee's actions on previous inspection findings; Radiation Safety Committee (RSC) and management oversight; radiopharmaceutical therapy program and implementation of the Quality Management Program (QMP); radiological safety training; radioactive waste management; and surveys and personnel radiation protection.

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Results: Five apparent violations were identified: (1) failure to prepare a written directive prior to any administration of NaI I-125 or I-131 greater than 30 microcuries (Section 5); (2) failure to conduct a review to verify compliance with all aspects of the QMP at intervals not greater than 12 months (Section 5); (3) failure to establish a quorum at the RSC Meetings (Section 4); (4) failure of the RSC to meet at least quarterly (Section 4); and (5) failure to measure each six months the ventilation rates available in areas of use of radioactive gas (Section 8).

DETAILS

1. Persons Contacted

* Dexter D. Dix, Medical Center Director
* Leonard Katz, M.D., Medical Chief of Staff
* Dale Tobin, Administrative Assistant to the Chief of Staff
* Paul Yurko, Health Physicist, National Radiation Protection Program

Asaf Durakovic, Radiation Safety Officer (RSO) and Authorized User
William Hucker, Patient Support Center Director
Jeff Salas, Facilities Manager
Cathy Burris, Nuclear Medicine Technologist
Karen Kline, Nuclear Medicine Technologist
James Holmes, Maintenance
Jim Hillegas, Student Nuclear Medicine Technologist

* Attended Exit Meeting on March 26, 1997

2. Organization and Scope of Licensed Activities

The licensee is a Veterans Administration hospital which does moderate numbers of diagnostic studies and a small number of radiopharmaceutical therapies. The radiation safety function is administered by the Radiation Safety Committee (RSC) through the RSO, who is also the sole authorized user and Chairman of the RSC. Current plans are to replace the authorized user position with two part time nuclear medicine physicians, one of whom will become RSO. These projected changes are expected to occur during April of 1997. The licensee has submitted the required information to the NRC to amend the license. There are two nuclear medicine technologists who report to the Radiology Manager who reports to the Director of the Patient Support Center. The RSO reports to the Chief of Physicians. There is a consultant physicist who reports to the RSO.

3. Licensee's Actions on Previous Inspection Findings

The inspector reviewed the actions taken by the licensee to correct and prevent recurrence of the violation identified during the inspection of the licensee's program on June 22, 1994, as documented by Inspection Report 030-01301/94-001 dated July 5, 1994.

(Closed) Failure to do surveys required by 10 CFR 20.1501(a) following the peparation of a radiopharmaceutical for a gastric emptying study, resulting in personnel and facility contaminaton. The inspector examined records of previous surveys and spills, and questioned technologists and found no recurrence of the problem.

(Closed) Failure to dispose of radioactive waste only in designated, labeled, and properly shielded receptacles in accordance with 10 CFR 35.21(a) and License Condition 16.A. Inspector surveys found no new instances of improper disposals.

(Closed) Failure to monitor packages for external contamination as required by 10 CFR 20.1906(b). The inspector checked records and questioned technologists, and found that packages were being surveyed for removable contamination.

(Closed) Failure to train Nuclear Medicine Technologists on how to use a survey meter, or to know trigger levels for surveys, as required by 10CFR 19.12. Interviews by the inspector confirmed that the technologists are now familiar with the above items.

4. Radiation Safety Committee and Management Oversight

The RSC is comprised of members from administration, Nuclear Medicine, Nursing, and the consultant. The RSC meets quarterly and approves the credentials of individuals prior to permitting them to work as authorized users. The inspector noted that the RSC usually met as required, generally with the established quorum. However, during an RSC meeting conducted December 19, 1996, the RSC met and conducted business and the management representative was not present to establish a quorum. 10 CFR 35.22(a)(3) requires, in part, that to establish a quorum and conduct business, at least one half of the RSC membership must be present, including the management representative.

Failure to establish a quorum, due to the absence of the management representative at the RSC meetings, is an apparent violation of 10 CFR 35.22(a)(3).

The inspector also noted that between December 15, 1993 and June 22, 1994, the RSC did not meet. 10 CFR 35.22(a)(2) requires that the Committee must meet at least quarterly.

Failure of the RSC to meet at least quarterly is an apparent violation of 10 CFR 35.22(a)(2).

Through interviews with personnel and a review of the records, the inspector determined that the licensee relied significantly upon information provided by their consultant for the Radiation Protection Program (RPP) with correspondingly less input from the RSO, the RSC, and nuclear medicine staff. Key licensee staff also were not familiar with the regulations and license conditions with regard to the iodine-131 radiopharmaceutical therapy program, particularly the Quality Management Program (QMP) (see Section 5).

The consultant did not adequately identify deficiencies in the RPP and failed to provide recommendations for corrective action, and actions to prevent recurrence. The licensee assumed that there were no issues which needed to be addressed, and failed to review and provide oversight of the consultant's activities. For example, the consultant failed to identify the absence of written directives or of annual audits in the QMP (Section 5). The consultant also failed to identify the absence of ventilation measurements required in the Nuclear Medicine department

semiannually (Section 8). Furthermore, the consultant did not provide written reports to the licensee.

During the exit interview, the inspector addressed management's responsibility for oversight of the licensed program, as well as for verifying that the consultant's services are adequate.

5. Radiopharmaceutical Therapy Program

The licensee uses iodine-131 in quantities greater than 30 uCi for hyperthyroid treatments. Since March 1992, there have been 7 iodine-131 treatments. These treatments occurred on April 28, 1992, August 24, 1994, January 30, 1995, March 10, 1995, April 5, 1995, September 6, 1995, and April 4, 1996. The inspector noted that none of the I-131 administrations had been preceded by a written directive signed by an authorized user. 10 CFR 35.32(a) and Section 3.A, Page 1 of the licensee's QMP, dated March 23, 1992, state that prior to administration a written directive issued by an authorized user will be prepared for any administration of NaI I-125 or I-131 greater than 30 microcuries.

Failure to issue a written directive prior to any administration of NaI I-125 or I-131 is an apparent violation of 10 CFR 35.32(a) and Section 3.A., Page 1 of the licensee's QMP.

The inspector also noted that no audits of the QMP had been performed between March 23, 1992 and March 26, 1997. Audits are required at intervals of no more than 12 months by 10 CFR 35.32(b) and Section H., Pages 4-5 of the licensee's QMP.

Failure to conduct audits of the QMP at intervals not exceeding 12 months is an apparent violation of 10 CFR 35.32(b) and Section H., Pages 4-5 of the licensee's QMP.

6. Radiological Safety Training

The licensee's training program includes in-service education provided by the RSO to the nuclear medicine staff and other personnel in radiation safety. The licensee also provides annual hospital wide training which also includes radiation safety. Through interviews with personnel, with regard to the apparent violations identified previously, the inspector concluded that training in general was adequate and that the violations were related to inadequate verification by licensee management that the regulatory requirements were being implemented. One weakness in training was the apparent failure of the authorized user to recognize the need for completing written directives as required by the regulations, and the failure of Nuclear Medicine Technologists to question the absence of written directives prior to the administration of I-131.

7. Radioactive Waste Management

The inspector reviewed the licensee's decay in storage (DIS) records from March 1994 through February 1997. Waste is held in the hot lab in a large, shielded wooden box. The inspector surveyed the waste, as well as nonradioactive waste, and found no improper disposals or excessive dose rates. The inspector also examined waste disposal records and found no evidence of the disposal of material prior to proper decay in storage. Interviews with technologists revealed an adequate understanding of waste disposal regulations and procedures.

The inspector identified no safety concerns with respect to waste disposal.

8. Personnel Radiation Protection and Surveys

The inspector reviewed the licensee's personnel dose records for the period covering January 1994 through October 1996. The dosimetry records are reviewed by the RSO on a monthly and quarterly basis, and all ALARA reports are discussed during the RSC meetings. The inspector's review of the records indicated that no monitored personnel exceeded the regulatory limits during the referenced period.

The inspector identified no safety concerns in this area.

The inspector reviewed records of area surveys and interviewed Nuclear Medicine Technologists. Personnel demonstrated adequate knowledge of survey methods and spill response procedures. A review of survey records showed no omissions or anomalies, and documentation of spill cleanups was adequate. The inspector noted that the current Nuclear Medicine area was first occupied in October of 1995. At that time ventilation measurements were made of areas where xenon gas would be used and it was decided by the licensee facility maintenance staff that negative pressure had been established. Due to an apparent lack of communication between the RSO and Facilities Management, the semiannual ventilation measurements required by 10 CFR 35.205(e) were not made between October 3, 1995 and March 26, 1997. At the time of inspection, Facilities Management had decided that the ventilation in the Hot Lab (a hood) was inadequate, and modifications were begun.

Failure to measure each six months the ventilation rates available in areas of use of radioactive gas is an apparent violation of 10 CFR 35.205(e).

9. Exit Meeting

An exit meeting was held on March 26,1997 with the individuals identified in Section 1 of this report.

Encl. 2

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

MAY 5 1997

Docket No. 030-01301
EA No. 97-146

License No. 07-09495-01

Dexter D. Dix
Center Director
Veterans Administration Medical Center
1601 Kirkwood Highway
Wilmington, Delaware 19805

SUBJECT: PREDECISIONAL ENFORCEMENT CONFERENCE CONDUCTED MAY 1, 1997

Dear Mr. Dix:

This letter refers to the Predecisional Enforcement Conference held with you and other members of your staff on May 1, 1997. This meeting enabled us to gain a better understanding of your position and your completed and planned actions to correct the apparent violations identified at your facility. A report summarizing the meeting is enclosed.

Enforcement action was transmitted to you under separate cover.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosure will be placed in the Public Document Room.

No reply to this letter is required. Your cooperation with us is appreciated.

Sincerely,

M. Shanbaky

Mohamed M. Shanbaky, Ph.D., Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

Enclosure:
NRC Region I Enforcement Conference Report No. 030-01301/97-002

cc w/enclosure:
Martin Zloty, M.D., RSO
State of Delaware

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-01301/97-002

Docket No. 030-01301

License No. 07-09495-01 Priority 3 Category G2 Program Code 02120

EA No. 97-146

Licensee: Veterans Administration Medical Center
1601 Kirkwood Highway
Wilmington, Delaware 19805

Facility Name: Veterans Administration Medical Center

Pre-decisional Enforcement Conference Conducted at: King of Prussia, PA

Pre-decisional Enforcement Conference Conducted: May 1, 1997

Prepared by: Richard W. McKinley
Richard W. McKinley, Health Physicist

5/5/97
date

Approved by: M. Shanbaky
Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Branch 1

5/5/97
date

Pre-decisional Enforcement Conference Summary: A pre-decisional enforcement conference was held at NRC Region I in King of Prussia, Pennsylvania, on May 1, 1997, to discuss the apparent violations identified as a result of NRC Inspection No. 030-01301/97-001. The apparent violations and oversight by the Radiation Safety Officer, Radiation Safety Committee, and hospital management were discussed. The licensee provided corrective action to prevent recurrence of similar violations. Enforcement options available to the Commission were discussed. The meeting was open to the public.

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Details

1.0 Attendees

Veterans Administration Medical Center

Dexter Dix, Center Director
Leonard Katz, M.D., Chief of Staff
Carl Howe, Veterans Administration Office of General Counsel
Paul Yurko, Veterans Administration Health Physicist
Martin Zloty, M.D., Radiation Safety Officer
Dale Tobin, Administrative Assistant
Lynn McGuire, Veterans Administration Health Physicist
Jeffrey Salas, Facility Manager

NRC

A. Randolph Blough, Director, Division of Nuclear Materials Safety
Daniel J. Holody, Manager, ORA Technical Program Staff
J. Bradley Fewell, Regional Attorney
Mohamed Shanbaky, Chief, Nuclear Materials Safety Branch 1
Richard McKinley, Health Physicist
Michelle Beardsley, Health Physicist
Thomas Thompson, Senior Health Physicist
David Everhart, Health Physicist

2.0 Summary

Mr. Blough opened the Conference by stating that the purpose of the meeting was to provide the licensee an opportunity to discuss the events surrounding the apparent violations, to accept or deny the apparent violations, provide corrective actions taken as a result of the apparent violations, and provide any additional information that would enable the Commission to make an enforcement decision. Dr. Shanbaky explained the purpose of the inspection and the nature of the violations. He emphasized the need to identify the root causes of the violations. Mr. Dix explained the institutional context of the violations with respect to the licensee's compliance history and personnel changes. He then requested that licensee personnel be allowed to address each apparent violation, and NRC representatives agreed.

Dr. Zloty stated that he would spend one day per week at the Wilmington VA and that his assistant would spend three hours per day on four days per week. He discussed corrective actions relating to the licensee's Quality Management Program as including an audit of past iodine-131 administrations, distribution of QMP forms, an in-service to technologists on May 2, 1997, and independent audits to be done by the hospital Office of Quality Management.

Mr. Tobin reported that he had been appointed the permanent administrative representative to the Radiation Safety Committee. A second representative has also been appointed. If neither can attend a meeting, then Mr. Dix will go. Mr. Tobin also reported that he would monitor the meeting minutes, and that the Office of Quality Management would also monitor them. Mr. Tobin also took issue with Violation D. of the Draft Notice of Violation. He then produced minutes for the Radiation Safety Committee meeting of March 23, 1994. NRC representatives agreed to withdraw this violation.

Mr. Salas then characterized the current ventilation system for areas of xenon use as inadequate. He stated that a temporary system which assures negative pressure had been tested on April 24, 1997, and that a permanent installation would be in place by May 16, 1997. Mr. Tobin added that a computer-based system had been developed for automatic scheduling of ventilation measurements every six months. Mr. McGuire stated that he had done a consequence analysis on the 55 xenon studies performed since the current facilities were put into use.

The Manager, ORA Technical Program Staff explained the NRC's enforcement options.

The meeting was adjourned.

Encl. 3

May 2, 1997

EA 97-146

Mr. Dexter D. Dix, Center Director
Veterans Administration Medical Center
1601 Kirkwood Highway
Wilmington, Delaware 19805

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-01301/97-001)

Dear Mr. Dix:

This refers to the NRC inspection conducted on March 26, 1997, at your facilities at Wilmington, Delaware, to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. During the inspection, five apparent violations of NRC requirements were identified, as described in the NRC inspection report transmitted with our letter, dated April 11, 1997. On May 1, 1997, a predecisional enforcement conference was conducted with you and members of your staff to discuss the violation, their causes, and your corrective action. A copy of the enforcement conference report will be sent to you by separate correspondence.

Based on the information developed during the inspection, and during the enforcement conference, the NRC has determined that four violations of NRC requirements occurred, and are cited in the enclosed Notice of Violation (Notice). The circumstances surrounding them are described in detail in the Notice and the subject inspection report. The violations involve (1) failure to prepare written directives prior to the administration of iodine-131 doses greater than 30 microcuries; (2) failure to measure, each six months, the ventilation rates available in areas of use of radioactive gas; (3) failure to conduct reviews to verify compliance with all aspects of the quality management program (QMP) at intervals no greater than 12 months (a review was not done between 1992 and 1997); and (4) failure to establish a quorum at Radiation Safety Committee (RSC) meetings. One of the apparent violations, involving failure of the RSC to meet at least quarterly, is being withdrawn based on your presentation of records at the conference indicating that the meetings were held at the required frequency.

These violations disclose a significant lack of attention to licensed activities by the Radiation Safety Officer (RSO) and the RSC. Specifically, the RSO or RSC failed to fulfill their direct responsibilities to assure conduct of an annual review, and assure a quorum when the RSC meetings were held. Management attention to the radiation safety program is warranted to ensure that licensed activities are conducted safely and in accordance with requirements. While the violations in question did not have an impact on the health and safety of the public, or your staff, such violations are potential precursors to more serious problems. For example, the failure to prepare written directives reduces one of the barriers which are necessary to prevent the misadministration of material. Accordingly, it is important that the RSO and RSC

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actively look for, identify, and correct such problems. At your facility, this did not occur. Therefore, these violations have been classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation. Because your facility has not been the subject of an escalated enforcement action within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were both prompt and comprehensive. These actions, which were described during the enforcement conference, and/or during the inspection, included, but were not limited to: (1) replacement of the RSO and RSC Chairman; (2) increased involvement of the facility management in overseeing the radiation safety program, including monitoring by the clinical executive board, the Chief of Staff, and your consultants; and (3) planned training of your technologists regarding QMP requirements.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized not to propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room (PDR).

Sincerely,
ORIGINAL SIGNED BY
WILLIAM L. AXELSON

FOR Hubert J. Miller
Regional Administrator

Docket No. 030-01301
License No. 07-09495-01

Enclosure: Notice of Violation

cc w/encl:
State of Delaware

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ENCLOSURE

NOTICE OF VIOLATION

Veterans Administration Medical Center
Wilmington, Delaware

Docket No. 030-01301
License No. 07-09495-01
EA 97-146

During an NRC inspection conducted on March 26, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600, the violations are listed below:

A. 10 CFR 35.32(a)(1)(iv), in part, requires that prior to administration, a written directive be prepared for any administration of quantities greater than 30 microcuries of iodine-131. 10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation and containing certain specified information.

Contrary to the above, on April 28, 1992, August 24, 1994, January 30, 1995, March 10, 1995, April 5, 1995, September 6, 1995, and April 4, 1996, an authorized user administered 28.8, 6, 10, 7, 10, 7.8, and 28.3 millicuries, respectively, of NaI I-131 to patients, but on no occasions was a written directive prepared. **(01013)**

B. 10 CFR 35.32(b) requires, in part, that the licensee develop procedures for and conduct a review to verify compliance with all aspects of the quality management program at intervals no greater than 12 months.

Contrary to the above, the licensee did not conduct a review to verify compliance with the quality management program between March 23, 1992 and March 26, 1997, an interval greater than 12 months. **(01023)**

C. 10 CFR 35.205(e) requires, in part, that a licensee that administers radioactive aerosols or gases measure each six months the ventilation rates available in areas of use of radioactive gas.

Contrary to the above, between October 3, 1995 and March 26, 1997, the licensee used radioactive xenon-133 gas in the planar camera room and did not, on any occasion, measure the ventilation rates therein. **(01033)**

E. 10 CFR 35.22(a)(3) requires, in part, that to establish a quorum and conduct business, at least one half of the Radiation Safety Committee's membership must be present, including the management representative.

Contrary to the above, on December 19, 1996, the licensee's Radiation Safety Committee met and conducted business without the management representative being present to establish a quorum. **(01043)**

These violations are categorized in the aggregate as a Severity Level III problem (Supplement VI).

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Pursuant to the provisions of 10 CFR 2.201, Veterans Administration Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to 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.

Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated at King of Prussia, Pennsylvania
this 2nd day of May 1997