U.S. NUCLEAR REGULATORY COMMISSION

RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

NRC FOIA REQUEST NUMBER(S)
FOIA — 92-67

RESPONSE TYPE
[ ] FINAL [X] PARTIAL

DATE
JUN 19 1992

DOCKET NUMBER(S) *(If applicable)*

REQUESTER
Mr. F. L. Malphurs

PART I.–AGENCY RECORDS RELEASED OR NOT LOCATED *(See checked boxes)*

[ ]	No agency records subject to the request have been located.
[ ]	No additional agency records subject to the request have been located.
[ ]	Requested records are available through another public distribution program. See Comments section.
[X]	Agency records subject to the request that are identified in Appendix(es) F are already available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W. Washington, DC.
[X]	Agency records subject to the request that are identified in Appendix(es) G are being made available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC, in a folder under this FOIA number.
[ ]	The nonproprietary version of the proposal(s) that you agreed to accept in a telephone conversation with a member of my staff is now being made available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC, in a folder under this FOIA number.
[ ]	Agency records subject to the request that are identified in Appendix(es) _____ may be inspected and copied at the NRC Local Public Document Room identified in the Comments section.
[ ]	Enclosed is information on how you may obtain access to and the charges for copying records located at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC.
[X]	Agency records subject to the request are enclosed. * (Appendices F and G)
[ ]	Records subject to the request have been referred to another Federal agency(ies) for review and direct response to you.
[ ]	Fees
[ ]	You will be billed by the NRC for fees totaling $ _____.
[ ]	You will receive a refund from the NRC in the amount of $ _____.
[ ]	In view of NRC's response to this request, no further action is being taken on appeal letter dated _____, No. _____

PART II. A–INFORMATION WITHHELD FROM PUBLIC DISCLOSURE

[X]	Certain information in the requested records is being withheld from public disclosure pursuant to the exemptions described in and for the reasons stated in Part II, B, C, and D. Any released portions of the documents for which only part of the record is being withheld are being made available for public inspection and copying in the NRC Public Document Room, 2120 L Street, N.W., Washington, DC in a folder under this FOIA number.

COMMENTS

*Copies of the records identified on enclosed Appendices F and G are enclosed. The records identified on enclosed Appendix H are being withheld in their entirety. Several remaining records responsive to your request are still undergoing review. You will be notified promptly once this review has been completed.

SIGNATURE, DIRECTOR, DIVISION OF FREEDOM OF INFORMATION AND PUBLICATIONS SERVICES
Donna H. Hawley

RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST
(CONTINUATION)

FOIA NUMBER(S)	DATE
FOIA – 92-67	JUN 19 1992

PART II.B – APPLICABLE EXEMPTIONS

Records subject to the request that are described in the enclosed Appendix(es) H are being withheld in their entirety or in part under the Exemption No.(s) and for the reason(s) given below pursuant to 5 U.S.C. 552(b) and 10 CFR 9.17(a) of NRC regulations.

	1. The withheld information is properly classified pursuant to Executive Order. (Exemption 1)
	2. The withheld information relates solely to the internal personnel rules and procedures of NRC. (Exemption 2)
	3. The withheld information is specifically exempted from public disclosure by statute indicated. (Exemption 3)
	Sections 141-145 of the Atomic Energy Act, which prohibits the disclosure of Restricted Data or Formerly Restricted Data (42 U.S.C. 2161-2165).
	Section 147 of the Atomic Energy Act, which prohibits the disclosure of Unclassified Safeguards Information (42 U.S.C. 2167).
	4. The withheld information is a trade secret or commercial or financial information that is being withheld for the reason(s) indicated. (Exemption 4)
	The information is considered to be confidential business (proprietary) information.
	The information is considered to be proprietary information pursuant to 10 CFR 2.790(d)(1).
	The information was submitted and received in confidence pursuant to 10 CFR 2.790(d)(2).
X	5. The withheld information consists of interagency or intraagency records that are not available through discovery during litigation. (Exemption 5). Applicable Privilege:
	Deliberative Process. Disclosure of predecisional information would tend to inhibit the open and frank exchange of ideas essential to the deliberative process.
X	Where records are withheld in their entirety, the facts are inextricably intertwined with the predecisional information. There also are no reasonably segregable factual portions because the release of the facts would permit an indirect inquiry into the predecisional process of the agency.
	Attorney work product privilege. (Documents prepared by an attorney in contemplation of litigation.)
	Attorney-client privilege. (Confidential communications between an attorney and his/her client.)
	6. The withheld information is exempted from public disclosure because its disclosure would result in a clearly unwarranted invasion of personal privacy. (Exemption 6)
	7. The withheld information consists of records compiled for law enforcement purposes and is being withheld for the reason(s) indicated. (Exemption 7)
	Disclosure could reasonably be expected to interfere with an enforcement proceeding because it could reveal the scope, direction, and focus of enforcement efforts, and thus could possibly allow recipients to take action to shield potential wrongdoing or a violation of NRC requirements from investigators. (Exemption 7 (A))
	Disclosure would constitute an unwarranted invasion of personal privacy. (Exemption 7(C))
	The information consists of names of individuals and other information the disclosure of which could reasonably be expected to reveal identities of confidential sources. (Exemption 7 (D))
	OTHER

PART II. C – DENYING OFFICIALS

Pursuant to 10 CFR 9.25(b) and/or 9.25(c) of the U.S. Nuclear Regulatory Commission regulations, it has been determined that the information withheld is exempt from production or disclosure, and that its production or disclosure is contrary to the public interest. The persons responsible for the denial are those officials identified below as denying officials and the Director, Division of Freedom of Information and Publications Services, Office of Administration, for any denials that may be appealed to the Executive Director for Operations (EDO).

DENYING OFFICIAL	TITLE/OFFICE	RECORDS DENIED	APPELLATE OFFICIAL		
			EDO	SECRETARY	IG
Thomas T. Martin	Regional Administrator, Reg I	App. H	X		

PART II. D – APPEAL RIGHTS

The denial by each denying official identified in Part II.C may be appealed to the Appellate Official identified there. Any such appeal must be made in writing within 30 days of receipt of this response. Appeals must be addressed, as appropriate, to the Executive Director for Operations, to the Secretary of the Commission, or to the Inspector General, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should clearly state on the envelope and in the letter that it is an "Appeal from an Initial FOIA Decision."

APPENDIX F

DOCUMENTS MAINTAINED AT THE PDR

NUMBER	DATE	DESCRIPTION
1.	3/16/87	Letter from Hill-Zobel to Johansen w/attachments (20 pages) Acc. No. 8708130157
2.	11/26/90	Letter from Malphurs to Eckert (1 page) Acc. No. 9104010261
3.	12/10/90	Memorandum from Shanbaky to Martin. Subject: Enforcement Conference With The Veterans Administration Medical Center, Albany, New York w/attachments (34 pages) Acc. No. 9104010265
4.	1/29/91	Letter from Martin to Malphurs w/attachments (11 pages) Acc. No. 9102010062
5.	2/26/91	Letter from Malphurs to Director, Office of Enforcement, USNRC w/attachments (27 pages) Acc. No. 9103070046
6.	3/11/91	Letter from Knapp to Malphurs (1 page) Acc. No. 9104010256
7.	5/8/91	Letter from Shanbaky to Malphurs w/attachment (3 pages) Acc. No. 9105290012
8.	6/13/91	Letter from Malphurs to Director, Office of Enforcement, USNRC w/attachments (5 pages) Acc. No. 9106260279
9.	6/13/91	Letter from Malphurs to Director, Nuclear Medicine Service (141A5) Department of Veterans Affairs Central Office w/attachemnt (6 pages) Acc. No. 9107010029

Number	Date	Description
10.	6/16/91	Letter from Knapp to Malpurs w/attachments (4 pages) Acc. No. 9107030045
11.	7/3/91	U.S. Nuclear Regulatory Commission Region I Notice Of Licensee Meeting (12 pages) Acc. No. 9107170036
12.	7/18/91	Letter from Bellamy to Malphurs w/attachments (5 pages) Acc. No. 9107240172
13.	8/30/91	Letter from Shanbaky to Malphurs w/attachments (8 pages) Acc. No. 9109240057
14.	8/30/91	Letter from Shanbaky to Malphurs w/attachments (11 pages) Acc. No. 9109240218
15.	11/4/91	Letter from Martin to Malphurs w/attachments (7 pages) Acc. No. 9111110299
16.	11/5/91	Letter from Malphurs to Director, Office of Enforcement, USNRC (4 pages) Acc. No. 9111120413
17.	1/24/92	Letter from Lieberman to Malphurs (3 pages) Acc. No. 9201280124
18.	4/13/92	Letter from Lieberman to Malphurs (3 pages) Acc. No. 9204150015
19.	6/3/91	Letter from Lieberman to Malphurs (4 pages) Acc. No. 9106050053

RE: FOIA-92-67

APPENDIX G
RECORDS TO BE PLACED IN THE PDR

Number	Date	Description
1.	4/25/90	Memorandum from Martin to Lieberman re: Region I Comments On Sections Of The Draft Enforcement Guidance Memorandum Concerning The Escalation And Mitigation Factors (8 pages)
2.	11/26/90	Telephone or verbal conversation record (1 page)
3.	11/26/90	Memorandum from Acting Radiation Safety Officer to ACDS, Research and Development re: Unscheduled NRC inspection - 11/09/90 (4 pages)
4.	11/29/90	Letter from Knapp to Malphurs (3 pages)
5.	12/3/90	Letter from Martin to White re: Request for Investigation (4 pages)
6.	12/7/90	Letter from Malphurs to Knapp (20 pages)
7.	12/7/90	Letter to Malphurs (8 pages)
8.	12/14/90	Letter from Knapp to Malphurs (6 pages)
9.	4/10/91	Appendix B Nuclear Medicine Inspection Field Notes Region I (19 pages)
10.	5/8/91	U.S. Nuclear Regulatory Commission Region I Open Items Tracking System (4 pages)

11.	7/8//91	U.S. NRC Region I Enforcement Conference (74 pages)
12.	2/5/91	Press Release - NRC Staff Cites VA Medical Center in Albany for Allegedly Violating NRC Guidelines on Handling Nuclear Materials Proposes Fine (1 page)
13.	1/14/92	Appendix B Nuclear Medicine Inspection Notes (17 pages)

RE: FOIA-92-67

APPENDIX H

DOCUMENTS BEING WITHHELD IN THEIR ENTIRETY

Number	Date	Description
1.	12/20/90	Memo for Lieberman from Martin, subject: "Proposed Civil Penalty - Veterans Administration Medical Center, any, NY, (4 pgs.) with losures: Letter to Veterans Administration from Martin, subject: "Notice of Violation and Proposed Imposition of Civil Penalty," (6 pgs.) and Notice of Violation and Proposed Imposition of Civil Penalty, (7 pgs.) - EXEMPTION 5
2.	1/23/91	Summary of 1/17/91, Telephone calls to Veterans Administration, (4 pgs.) - EXEMPTION 5
3.	Undated	Draft Letter to Fred Malphurs from Thomas T. Martin, subject: "Notice of Violation and Proposed Imposition of Civil Penalty - $2,500," (4 pages) with Draft Notice of Violation (3 pages) - EXEMPTION 5
4.	Undated	Draft Letter to Fred Malphurs from Thomas T. Martin, subject: "Notice of Violation and Proposed Imposition of Civil Penalty - $2,500," with handwritten notations, (4 pages) - EXEMPTION 5
5.	Undated	Draft Notice of Violation, with handwritten notations, (2 pages) - EXEMPTION 5

DEPARTMENT OF VETERANS AFFAIRS
Samuel S. Stratton
Medical Center
113 Holland Avenue
Albany NY 12208

February 6, 1992

In Reply Refer To: 500/00

Freedom of Information Act Officer
US Nuclear Regulatory Commission
Mail Stop, P-378
Washington, D.C. 20555

FREEDOM OF INFORMATION ACT REQUEST
FOIA-92-67
Rec'd 2-11-92

SUBJ: FOIA Request

RE: Docket No. 030-10026
License No. 3102755-05
EA 91-050

1. The purpose of this letter is to request copies of all records relating to the above NRC case. This applies to the NRC investigation, inspection, hearings and any related communications or proceedings. Specifically, I am requesting any and all documentation relating to this matter that constitutes the official record of this case.

2. We are requesting this information under the Freedom of Information Act. I specifically request that this include the transcript of the Enforcement Conference conducted in King of Prussia on December 13, 1990 and the Enforcement Conference on July 8, 1991 also conducted in King of Prussia.

3. I would be pleased to accept these copies in whatever format that they are available and to compensate your office for whatever costs or charges that may be appropriate.

4. Your assistance in this matter is appreciated.

F.L. MALPHURS
Director

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

DEC 07 1990

Docket No. 030-10026 License No. 31-02755-05

Veterans Administration Medical Center
ATTN: Fred Malphurs
• Director
113 Holland Avenue
Albany, New York 12208

Gentlemen:

Subject: Inspection No. 030-10026/90-001

This refers to the routine safety inspection conducted by Mr. Christopher J. Eckert of this office on November 20 and 21, 1990, of activities authorized by NRC License No. 30-02755-05, and to discussions of the findings held by Mr. Eckert with you and other members of your staff at the conclusion of the inspection.

Areas examined during the inspection are described in the NRC Region I Inspection Report which is enclosed with this letter. Within these areas the inspection consisted of selective examinations of procedures and representative records, interviews of personnel, and observations by the inspector.

As discussed during the telephone conversation on November 28, 1990, between you, Dr. Lawrence Flesh of your Medical Center and Dr. Ronald Bellamy of my staff, an enforcement conference is scheduled to be held on Thursday, December 13, 1990 at 10:00 a.m., at our office in King of Prussia, Pennsylvania. The purposes of this conference are to: discuss the apparent violations, their causes and safety significance; provide an opportunity for you to present your corrective actions accomplished and proposed; and discuss any other information that will help us determine appropriate enforcement action. In particular, you should be prepared to discuss the apparent lack of management oversight and control of the licensed program that lead to the apparent violations.

Enforcement action for these apparent violations will be considered by the NRC following the conference. The NRC Enforcement Policy is described in 10 CFR Part 2, Appendix C, a copy of which is enclosed for your information. Also enclosed are directions to the Region I office.

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 your reply will be placed in the Public Document Room.

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U. S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-10026/90-001

Docket No. 030-10026

License No. 31-02755-05 Priority I Category G Program Code 2110

Licensee: Veterans Administration Medical Center
113 Holland Avenue
Albany, New York 12208

Inspection Conducted: November 20 & 21, 1990

Inspector: Christopher J Eckert 12/6/90
Christopher J Eckert date
Health Physicist

Approved by: M Shanbaky 12/7/1990
Mohamed M. Shanbaky, Ph.D., Chief date
Nuclear Materials Safety Section A

Inspection Summary: Routine, unannounced, safety inspection conducted November 20 & 21, 1990 (Inspection Report No. 030-10026/90-001)

Areas Inspected: Action on previous violations; organization and scope of licensed activities; licensee internal audits; training and qualification of personnel; radiation protection procedures; use of radioactive materials; storage of radioactive materials; facilities; radiation safety committee and authorized users; receipt and transfer of material; personnel radiological protection - external exposure; personnel radiological protection - internal exposure; radioactive waste disposal; misadministrations; and instruments.

Results: Twenty one apparent violations were identified: failure to perform an annual radiation safety program audit (Section 4); failure to provide an adequate training program (Section 5); consumption of food and beverages in radioactive material use areas (Section 5); failure of individuals to survey themselves for radioactive contamination (Section 6); failure to perform calculations to determine compliance with 10 CFR 20, Appendix B (Section 6); failure to calculate spilled gas clearance times (Section 6); failure to measure imaging room ventilation rates (Section 6); failure to establish area survey trigger levels (Section 6); failure to perform contamination swipes in a radiopharmaceutical therapy room prior to release for unrestricted use (Section 6); failure to perform sealed source leak tests (Section 6); failure to obtain a license amendment prior to using xenon in a new location (Section 9); failure of authorized users to notify the RSO and Radiation Safety Committee of personnel and laboratory location changes (Section 10); failure to secure licensed material from unauthorized removal (Section 11); failure to wear required personnel dosimetry (Section 12); failure to perform bioassays

DETAILS

1. Persons Contacted

*Fred Malphurs, VAMC Director
*Mary Ellen Piche, QA Coordinator
*Sue Lawrenson, Nuclear Medicine Technologist
*Kristine Cipperly, Nuclear Medicine Technologist
*Lawrence H. Flesh M.D., Chief of Staff
*Andrew Kang M.D., Radiation Safety Officer
Dr. Arnold Johnson, Researcher
Dr. Min Fu Tsan, Researcher
Dr. Patricia Phillips, Researcher
Dr. Donald Pasquale, Researcher
Dr. Richard Chu, Researcher
Peter McCarthy, Administrative Officer for Research
James Zhang, Acting Radiation Safety Officer
Walter McDonald, Housekeeping
Sue Cahill, Secretary
James Baegly, Laboratory Technologist
Andrew Dickson, Laboratory Technologist

*Indicates those present at exit interview

2. Licensee Action on Previous Violations

(Open) Inspection No. 89-001, failure to perform sealed source inventories on a quarterly frequency. The inspector reviewed inventory records for 1990. This area will remain open pending further review by the NRC.

(Closed) Inspection No. 89-001, failure to record the required information for molybdenum concentration checks. The inspector reviewed molybdenum concentration records. The records indicate that the licensee is now recording all required information.

3. Organization and Scope

The licensee conducts activities under a broad scope license which includes a small nuclear medicine clinic, a radioimmunoassay laboratory (RIA) and a research program. The nuclear medicine clinic is staffed by 1 full time physician who also is the RSO, 1 part time physician and 3 nuclear medicine technologists. The technologists stated and records confirmed, that 5-6 patients per day are treated and radioiodine therapy procedures are performed 1 - 2 times per year.

The RIA laboratory is staffed by 2 technologists who perform several hundred assays per week. The technologists stated that only iodine-125 is used and the radioactive material inventory seldom exceeds 200 microcuries.

The licensee is required by 10 CFR 35.22 and their established ALARA program to conduct a formal audit of the radiation safety program annually. The inspector reviewed the audit report for 1988 which was prepared by the previous RSO. There was no audit report available for 1989 and the current RSO confirmed that an audit had not been performed.

The inspector stated that the failure to perform an annual radiation safety program audit for 1989 is an apparent violation of 10 CFR 35.22. Furthermore, the failure to perform an annual audit indicates a lack of management oversight of the licensed program.

5. Training and Qualification of Personnel

The inspector interviewed staff members from Nuclear Medicine, Research and Housekeeping. All individuals seemed to be aware of their applicable duties and radiation safety practices with the exception of some research workers. Interviews with the research staff indicated that not all laboratory personnel knew that contamination surveys were required after performing experiments with radioactive material, or the requirement for maintaining accurate radioactive material inventories and waste disposal records. The inspector noted that the research staff training was limited to reading the radiation safety manual without any apparent additional clarification or guidance. The inspector questioned one authorized user regarding his authorization to dispose of licensed material through the sanitary sewer and how much material had been disposed of in this manner. The authorized user did not know whether he was authorized to dispose of radioactive material to the sanitary sewer or whether any individuals under his supervision had been utilizing the sanitary sewer for liquid radioactive waste disposal.

The inspector stated that the failure to provide an adequate training program is an apparent violation of 10 CFR 19.12.

A laboratory technologist working under the supervision of a different authorized user was questioned by the inspector as to the maintenance of solid waste disposal records. The technologist stated that he knew the approximate amount of radioactive material that he placed into the waste barrel after each experiment but did not keep an actual record because the amount was so small, and that he could remember the total amount of radioactive material disposed of from one waste pickup to another.

The inspector asked the RSO if he had performed calculations to determine if the room air flow rates were sufficient to assure that the concentration of radioactive gases in the room would not exceed the limits established in 10 CFR 20, Appendix B. The RSO stated that these calculations had not been performed for this room prior to use and further stated that spilled gas clearance times had not been calculated and that the room air flow rates were not being checked at the required 6 month frequency.

•The inspector stated that failure to perform calculations to determine compliance with 10 CFR 20, Appendix B, in accordance with the licensee's established procedure, is another example of an apparent violation of 10 CFR 35.21. The inspector also stated that failure to calculate and post spilled gas clearance times is an apparent violation of 10 CFR 35.205. Furthermore, the failure to measure the imaging room air flow rates at the required 6 month frequency is another example of an apparent violation of 10 CFR 35.205.

Records of area surveys were reviewed for the Nuclear Medicine Department. The records did not contain established trigger levels for each area surveyed as required by 10 CFR 35.70. The licensee stated that no trigger levels for area surveys have been established.

The inspector stated that failure to establish trigger levels for area surveys is an apparent violation of 10 CFR 35.70.

A discussion with the RSO revealed that a radioiodine therapy procedure utilizing in excess of 100 millicuries of iodine 131 had been performed in July 1990. A review of the records indicated and the RSO confirmed that no swipes to detect removable radioactive contamination had been performed in the therapy room prior to its release for unrestricted use. The RSO stated that he obtained advice on the appropriate radiation safety procedures for radioiodine therapies from the radiation staff at a nearby medical center and felt that an area survey was adequate to detect residual contamination.

The inspector stated that failure to perform removable contamination surveys before releasing the radiopharmaceutical therapy room for unrestricted use is an apparent violation of 10 CFR 35.315.

The inspector reviewed radioactive sealed source leak test records for 1989 and 1990. 10 CFR 35.59 requires that sealed sources be tested for leakage at intervals not to exceed six months. Records indicated and the RSO confirmed that sealed source leak tests had not been performed since October 1989, a period in excess of six months.

The inspector stated that failure to perform sealed source leakage tests at intervals not to exceed 6 months is an apparent violation of 10 CFR 35.59.

10 CFR 35.59 requires that a physical inventory of all sealed sources in the licensees possession be conducted quarterly. The inspector reviewed inventory records for 1990. The adequacy of the sealed source inventories and associated records will be further reviewed by the NRC.

10. Radiation Safety Committee and Authorized Users

The Radiation Safety Committee is charged with the task of overseeing the safe use of radioactive material at their facility in accordance with applicable federal regulations, license commitments and acceptable radiation safety practices. The committee is responsible, in part, for approving the qualifications of new users, the locations of radioactive material use and storage, and the qualifications of new laboratory personnel. In addition the committee must ensure that all occupationally exposed individuals receive the necessary radiation safety training commensurate with their responsibilities.

While touring the research facilities with the Acting RSO it became apparent to the inspector, and the Acting RSO confirmed, that he was not aware of the status of all areas where radioactive materials were being used. One example of this was Room 627B which the Acting RSO stated was a research laboratory. However, upon entering the room it was discovered that the room had been converted into a general storage area to which many individuals had access. Also, there was one laboratory which the Acting RSO indicated was no longer used for radioactive material work but remained posted as a restricted area. The inspector entered the laboratory and asked a technologist if radioactive materials were being used and the technologist stated that he was currently conducting an experiment using radioactive material (tritium).

The inspector stated that failure by an authorized user to notify the RSO and Radiation Safety Committee of a change in laboratory location or use, in accordance with the licensee established procedure, is an apparent violation of 10 CFR 35.25.

Also, while touring the facility and reviewing authorization records, it became evident that some of the authorized users had undergone staffing changes without notifying the RSO and Radiation Safety Committee. In one laboratory the individual responsible for performing contamination surveys had terminated employment and the Acting RSO and RSO were not aware of her departure.

The inspector stated that failure by an authorized user to notify the RSO and Radiation Safety Committee of changes in personnel, in accordance with the licensee's established procedure, is another example of an apparent violation of 10 CFR 35.25.

11. Receipt and Transfer of Licensed Material

The inspector reviewed records and procedures for the receipt and transfer of licensed material.

The inspector observed numerous individuals frequenting areas restricted to radioactive material use without wearing film badges. The inspector noted that the licensee's procedures required the use of film badges by personnel in these areas.

The inspector stated that failure of personnel to wear film badges while frequenting radioactive material areas is another example of an apparent violation of 10 CFR 35.25.

13. Personnel Radiological Protection - Internal Exposure

The licensee is authorized to perform in-vivo radioiodine therapy treatments and in-vitro experiments using hydrogen-3 (tritium). A review of the applicable records indicated that the amount of hydrogen-3 being used did not exceed the licensee's established trigger level (use of 10 millicuries or more at one time) which required a bioassay.

An interview with the RSO and a Nuclear Medicine Technologist revealed that the technologist prepared and administered a therapy dose of liquid iodine-131 (>100 millicuries) during a radioiodine therapy procedure which occurred in July 1990. The technologist stated that she did not undergo a bioassay after preparation and administration of the radioiodine. The RSO was not able to explain why the technologist did not receive the bioassay but did state that bioassays would have to be performed at another hospital because the licensee's equipment was not capable of detecting iodine-131. Bioassay records were available for the period 12/14/86 through 11/7/88 which demonstrated the licensee's familiarity with this requirement.

The inspector stated that failure to measure the thyroid burden (bioassay) of an individual who prepared and administered a therapy dose of iodine-131 is an apparent violation of 10 CFR 35.315.

14. Waste Disposal

The Acting RSO stated that all radioactive waste from research activities was placed in metal waste barrels and transferred to a central waste storage area in the animal facility. A record review at the central waste storage area indicated that all waste collections were recorded and the waste was transferred to a licensed waste broker.

The licensee established procedures which required authorized users to maintain records of solid and liquid radioactive waste disposal. During a tour of one research laboratory, a technologist stated that he did not keep an actual written record because he could remember the amount placed into the waste barrel after each experiment. The inspector stated that each authorized user was required to maintain records of waste disposal in accordance with established procedures.

17. Exit Interview

The inspector reviewed the inspection findings with the individuals listed in Section 1. At the close of the exit interview the inspector indicated that the number and type of violations, the length of time they continued undetected by management, and the failure to perform adequate internal program audits indicated an apparent lack of management oversight and control of the licensed program.

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

NOV. 29 1990

Docket No. 030-10026
CAL No. 1-90-019

License No. 31-02755-05

VA Medical Center
ATTN: Fred Malphurs, Director
113 Holland Avenue
Albany, New York 12208

Gentlemen:

Subject: Confirmatory Action Letter No. 1-90-019

On November 20-21, 1990, Mr. Christopher J. Eckert of this office conducted an inspection of NRC licensed activities at the above addressed facility. Several radiological safety weaknesses and apparent violations of NRC requirements were identified. The identified problems indicate an apparent lack of radiological safety program oversight at your facility.

Pursuant to a telephone conversation between you, Dr. Ronald Bellamy and Dr. Mohamed Shanbaky of this office on November 28, 1990, it is our understanding that you have taken or will take the following actions, which will be completed by the dates specified:

1. Perform a complete inventory of all your radioactive sealed sources. Provide the inventory results to this office by December 7, 1990. The results should indicate the serial number, activity and location of each source. Lost sources will be immediately reported to this office in accordance with 10 CFR 20.402 requirements.

2. Provide by January 31, 1991, training to your staff commensurate with their program functions and responsibilities. The training should include: (a) applicable NRC requirements; (b) your procedural requirements and (c) appropriate radiological safety precautions.

3. Obtain the services of an independent consultant to perform a comprehensive evaluation (audit) of your radiation safety program, to be completed by December 31, 1990.

4. Review the results of this audit, and provide, to this office, by January 31, 1991:

   (a) a written response detailing your planned action for each audit finding

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(b) a written plan for improving your radiation safety program at the Veterans Administration Medical Center. This plan will address, in addition to improvements discussed above:

1. Your management controls system and oversight of program activities,

2. staffing requirements and assignments of program responsibilities,

3. your procedures for performing radioactive sealed source inventory and control,

4. your iodine therapy program and associated radiological controls, and

5. your procedures for radioactive material package receipt and security

In addition, it is our understanding that you have already revised your existing procedures to preclude the loss of licensed material from your radioactive materials receipt area.

During the above referenced November 28, 1990, telephone call, you also agreed to attend an Enforcement Conference to discuss the radiological safety weaknesses and apparent violations identified during the November 20-21 inspection. The Conference is to be held at our Region I office in King of Prussia, Pennsylvania, at 10:00 a.m. on December 13, 1990.

The responses directed by this letter are not subject to the clearance procedures of the Office of Management and Budget, as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511. In accordance with 10 CFR 2.790(a), a copy of this letter will be placed in the NRC Public Document Room.

Issuance of this Confirmatory Action Letter does not preclude the issuance of an Order formalizing the above commitments. If your understanding differs from that set forth above, please call me immediately.

Sincerely,

Richard W. Cooper II for MRK

Malcolm R. Knapp, Director
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New York

bcc:
Region I Docket Room (w/concurrences)
J. Lieberman, OE
J. Goldberg, OGC
R. Cunningham, NMSS
J. Glenn, NMSS
D. Holody, RI
M. Knapp, RI
R. Cooper, RI
R. Bellamy, RI
M. Shanbaky, RI
C. Eckert, RI

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
Albany NY 12208

June 13, 1991

In Reply Refer To:

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

RE: Docket No. 030-10026
License No. 31-02755-05
EA No. 90-209

Gentlemen:

This correspondence, with attachments, is forwarded in response to your letter, dated June 3, 1991.

VIOLATION E:

10CFR 20.303 describes requirements for the disposal of radioactive materials by release into the sanitary sewerage system. 10CFR 20.401(c)(3) requires that each licensee maintain records of disposals made under 10CFR20.303.

Contrary to the above, as of November 21, 1990, adequate records were not maintained, as required under 10CFR 20.401, of disposals in 1988 and 1989 of radioactive material released into the sanitary sewerage system. For 1988, the records were disorganized and confusing in that one record indicated that 24,014.9 microcuries were disposed while another record indicated that 971.4 microcuries were disposed. For 1989, no records were maintained.

ACTION: Disposal of radioactive materials by release into the sanitary sewerage system records are being monitored on a monthly basis by the Radiation Safety Officer and staff. Each Authorized User must submit a monthly inventory form, "Radioactive Material Utilization Log" (See Attachment I) for each different radionuclide and compound that he/she possess to the Radiation Safety Office in a timely manner. This form requires the Authorized User to list the amount he/she used or disposed of after each use and the method of disposal. Although this form was previously used and kept on file, the Radiation Safety Office did not verify that the User was submitting the correct information each month. As of January 1991, the Radiation Safety Office on a monthly basis verifies that the information received from each User is correct. The sewer disposal data is compiled, quarterly, for total hospital disposal, as well

as by individual User. These forms are then filed under the appropriate Authorized User for future reference. In addition, each lab must retain a copy for their files.

The Radiation Safety Office monitors and enforces the use of the following two forms in areas were radioactive materials are disposed of via the sewerage drain system.

A. "Radioactive Material Sewer Disposal Log" form (Attachment II) affixed to their radioactive labeled sinks. Every time an individual disposes of any radioactive material down the drain the following information is added to this form: the date, isotope, form, and amount (in mCi).

B. "Sewage Disposal Of Radioactive Materials" form (Attachment III), which explains for each isotope the method and maximum daily amount that can be disposed of for the entire hospital. This form is posted near each radioactive labeled sink.

We are now in full compliance with this requirement.

Please communicate with us, if the above cited actions are not totally responsive to your specified request.

Sincerely,

F. L. MALPHURS,
Director

Attachments

ATTACHMENT I

RADIOACTIVE MATERIAL UTILIZATION LOG

R.S LOG #_____ RADIONUCLIDE_____

DATE REC'D_____ COMPOUND_____

FOR_____ ASSAY DATE_____

DATE ISSUED_____ ASSAY SPEC. ACTIVITY_____

VENDOR_____ ASSAY ACTIVITY_____

LOT #_____ ASSAY VOLUME_____

DATE	AMOUNT USED		BALANCE	USE (*)	INITIALS
	Activity	Volume			

* USE = In Vitro studies, In Vivo Animals studies, Human studies, other.

DISPOSAL RECORD

DATE	ACTIVITY DISPOSED	DISPOSAL METHOD (**)	ACTIVITY BALANCE	INITIALS

** DISPOSAL--- VENDOR: 1-Solids; 2-Liquids; 3-Liq. Scint.; 4-Animal Carcasses; DECAY-IN-STORAGE: 5-Solids or Liquids; 6-Animal Carcasses; SEWER:7-Certain Liquids; 8-DEREGULATED H-3 & C-14 to Safety Officer or Industrial Hygienist; 9-HOOD RELEASE of Volatiles.

RADIOACTIVE MATERIAL SEWER
DISPOSAL LOG

ATTACHMENT II

DATE	ISOTOPE	FORM	AMOUNT (mCi)

ATTACHMENT III

SEWAGE DISPOSAL OF RADIOACTIVE MATERIALS

ISOTOPE	SEWAGE DISPOSAL OF RADIOACTIVE MATERIALS DISPOSAL METHOD*	MAX uC/DAY
I-131 and I-125	If less than 1.0 uC is to be disposed, run water for 5 minutes. Run water 7 minutes for each additional uC disposed	200
Cr-51	If less than 1.0 uC is to be disposed, run water for 2 minutes. Run water 3 minutes for each additional uC disposed.	300
P-32	If less than 1.0 uC is to be disposed, run water for 2 minutes. Run water 4 minutes for each additional uC disposed.	1000
C-14	Same As Cr-51	1000
Fe-59	Same As Cr-51	200
S-35	Same As Cr-51	1000
H-3	If less than 1.0 uC is to be disposed, run water for 1 minute. Run water 2 minutes for each additional uC disposed.	2000
Co-57	Same as Cr-51	200

*The Yearly Gross Quantity Of Radioactive Material, Excluding H-3 and C-14, Released In The Sewer System By The VA Medical Center Shall Not Exceed One (1) Curie Per Year. In Addition, The Quantities Of H-3 And C-14 Released Into The Sewer System May Not Exceed Five (5) Curies Per Year For H-3 and One (1) Curie Per Year For C-14.

NOTE: THE ABOVE VALUES ARE FOR THE ENTIRE VA MEDICAL CENTER, AND THE DISPOSED RADIONUCLIDE WILL BE MONITORED BY THE RADIATION SAFETY OFFICER ON A MONTHLY BASIS TO MAKE SURE THAT THE AMOUNT STAYS WITHIN THE PERMITTED LEVEL.

REF.: (1) Attachment #1, Chief of Staff Memorandum No. 11-172-8 January 29, 1973.
(2) 10CFR20 Appendix 23 B and C.
(3) VA Medical Center Radiation Safety Manual, Page 4.15.

Updated 5/91