MN No. 91-89

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

JUL 03 1991

NOTICE OF LICENSEE MEETING

Name of Licensee:	Veterans Administration Medical Center Albany, New York
Name of Facility:	Veterans Administration Medical Center
Docket No.:	030-10026
Time and Date of Meeting:	10:00 a.m. on July 8, 1991
Location of Meeting:	U.S. Nuclear Regulatory Commission 475 Allendale Road King of Prussia, Pennsylvania 19406
Purpose of Meeting:	Enforcement Conference regarding OI Investigation of apparent falsification of records.
NRC Attendees:	Malcolm R. Knapp, Director, Division of Radiation Safety and Safeguards Daniel J. Holody, Enforcement Officer Karla D. Smith, Regional Attorney Ronald R. Bellamy, Chief, Nuclear Materials Safety Branch Mohamed M. Shanbaky, Chief, Nuclear Materials Safety Section A Mary Cahill, Health Physicist
Licensee Attendees:	Fred Malphurs, Medical Center Director Lawrence Flesh, M.D., Chief of Staff Andrew Kang, M.D., Radiation Safety Officer

Note: Attendance by NRC personnel at this meeting should be made known by 4:30 p.m. on July 5, 1991 via telephone call to Mary Cahill or Dr. Mohamed M. Shanbaky, Region I, at FTS 8-346-5209.

Prepared By: Mary Cahill
Mary Cahill

Distribution:
James M. Taylor, Executive Director for Operations
Hugh L. Thompson, Jr., Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support
James Lieberman, Director, Office of Enforcement
Robert M. Bernero, Director, Office of Nuclear Material Safety and Safeguards
Ken Brockman, Regional Coordinator, EDO
Richard E. Cunningham, Director, Division of Industrial and Medical Nuclear Safety, NMSS
John E. Glenn, Chief, Medical, Academic, and Commercial Use Safety Branch, NMSS
Jack R. Goldberg, Deputy Assistant General Counsel for Enforcement, OGC
Public Document Room (PDR)

F/1 [redacted]

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

Veterans Administration Medical Center
Albany, New York

Enforcement Action Chronology

November 20 and 21, 1991 - Routine inspection conducted

Twenty one apparent violations were identified, including:

-failure to secure licensed material from unauthorized removal
-failure to perform bioassays
-failure to maintain adequate dose calibrator quality control records
-failure to provide an adequate training program
-failure to perform an annual radiation safety program audit

Additional finding:

-apparent deliberate falsification of sealed source inventory records by RSO

November 29, 1991 - CAL issued to VAM

Actions to be taken by licensee:

-complete inventory of all sealed sources to be submitted
-provide training to staff
-obtain consultant services to audit program and submit corrective actions based on audit evaluation

December 3, 1991 - Request for OI investigation of sealed source inventory record falsification

December 7, 1991 - VAM partial response to CAL

Sealed source inventory conducted by licensee and submitted

December 7, 1991 - Inspection report sent to VAM

ENCLOSURE (2)

December 13, 1990 - Enforcement Conference held to address apparent violations not referred to OI

- Three violations withdrawn

December 14, 1990 - Supplement to November 29, 1990 CAL issued

Licensee actions:

-licensee to retain consultant
-licensee to hire new RSO
-submit amendment request to name new RSO

January 17, 1991 Amendment request to change RSO submitted

January 22, 1991 Amendment No. 18 providing new interim RSO and RSC chairman

January 28, 1991 - VAM response to November 29, 1991 CAL

-training program initiated
-consultant audit submitted
-action plan based on audit findings submitted

January 29, 1991 - NOV and Proposed Imposition of Civil Penalty in amount of $3,750 issued

February 26, 1991 - VAM response to NOV and Proposed CP

-three violations denied

March 28 and 29, 1991 - Routine safety inspection conducted

Two violations identified:

-constancy checks of dose calibrator not performed at beginning of each day
-linearity test of dose calibrator did not perform over required range

April 17, 1991 - OI report referred to DOJ

April 24, 1991 - OI report received

Findings:

-RSO falsified January 10, 1990, April 10, 1990, July 10, 1990 and October 14, 1990 sealed source inventory records
-Management beyond RSO not involved

May 8, 1991 - NOV issued for March 28 and 29, 1991 inspection

May 15, 1991 - VAM response to May 8, 1991

June 3, 1991 - NRC response to VAM response to January 29, 1991 NOV and Proposed CP

-two violations withdrawn
-CP reduced by $416.67

June 13, 1991 - VAM response to June 3, 1991 NOV

June 18, 1991 - DOJ declines to take OI case

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

Veterans Administration Medical Center, Albany, New York

Inspection History

Inspection	Results
91-001 (March 28 and 29, 1991)	Violation - 10 CFR 35.50(b)(1) - Failure to perform constancy check of dose calibrator at the beginning of the day. Violation - 10 CFR 35.50(b)(3) - Failure to perform dose calibrator linearity over range of use.
90-001 (November 20 and 21, 1990)	Violation - 10 CFR 20.207(a) - Failure to secure licensed material against unauthorized removal. Violation - 10 CFR 35.315(a)(8) - Failure to perform bioassay on an individual who prepared an Iodine-131 therapy dose. Violation - 10 CFR 35.22(b)(6) - Failure to conduct an annual review of the radiation safety program. Violation - 10 CFR 35.21 - Failure to make surveys to demonstrate compliance with 10 CFR 20.103 and 20.106 in accordance with licensee's procedures. Violation - 10 CFR 35.205(c) - Failure to calculate and post spilled gas clearance times. Violation - 10 CFR 35.70(d) - Failure to establish dose rate trigger levels for area surveys. Violation - 10 CFR 35.59(b)(2) - Failure to perform sealed source leakage tests at the required frequency. Violation - 10 CFR 35.205(e) - Failure to measure imaging room ventilation rates.

Inspection	Results
90-001 (continued)	Violation - 10 CFR 35.315(a)(7) - Failure to assess limits of removable contamination before releasing a radiopharmaceutical therapy room for unrestricted use.
	Violation - 10 CFR 19.12 - Failure to adequately instruct all occupationally exposed individuals in the health protection problems associated with exposure to radioactive materials.
	Violation - 10 CFR 35.25 - Evidence of eating and drinking in areas where radioactive materials are used or stored.
	Violation - 10 CFR 35.25 - Failure to notify Radiation Safety Officer of changes in laboratory personnel and location.
	Violation - 10 CFR 35.13(e) - Failure to apply for and receive a license amendment before changing areas of radioactive material use.
	Violation - 10 CFR 35.50(e)(3) - Failure to maintain adequate dose calibrator linearity records.
	Violation - 10 CFR 35.50(e)(4) - Failure to maintain adequate dose calibrator geometry records.
	Violation - 10 CFR 20.303 - Failure to maintain adequate records of sewer disposal of radioactive materials.
89-001 (October 30, 1989)	Violation - 10 CFR 35.59(g) - Failure to conduct sealed source inventories at the required quarterly frequency.
88-001 (November 14 and 15, 1988)	

Inspection	Results
86-001 (October 23 and 24, 1986)	Form 591
84-001 (September 26, 1984)	Clear Letter
80-001 (May 1 and 2, 1980)	Violation - 10 CFR 20.207 - Licensed material not secured against unauthorized removal and not under an constant surveillance and immediate control of the licensee. Violation - License Condition 20 - Failure to use syringe shields while preparing and administering radiopharmaceuticals. Violation - 10 CFR 20.201(b) - Failure to make such surveys as may be necessary to comply with all sections of Part 20. Specifically, failure to assure compliance with 10 CFR 20.106, "Concentrations in effluents to unrestricted areas".
78-001 (August 3 and 4, 1978)	Clear letter
76-001 (September 13, 1976)	Violation - 10 CFR 20.201(b) - Failure to make such surveys as may be needed to comply with all Sections of Part 20. Specifically, failure to make surveys to determine that persons handling significant quantities of iodine-125 were not exposed to airborne concentrations in excess of the limits in 10 CFR 20.103.
73-001 (August 15 and 17, 1973)	Violation - 10 CFR 20.201(b) - Failure to make such surveys as may be necessary to comply with all sections of Part 20. Specifically, failure to adequately evaluate hand exposures incurred by technologists administering 15 millicurie doses of 99m technetium.

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

JUN 26 1991

Docket No. 030-10026 License No. 31-02755-05
EA No. 91-84

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

Dear Mr. Malphurs:

Subject: Sealed Source Inventory Records

On November 20 and 21, 1990, the NRC conducted an inspection of activities authorized by the above listed NRC license. During the inspection, numerous violations of NRC requirements were identified. As a result of the inspection, Confirmatory Action Letters were sent to you on November 29, 1990 and December 14, 1990; an enforcement conference was conducted with you and members of your staff on December 13, 1990; and a $3,750 civil penalty was issued to you on January 29, 1991 based on a determination that the violations indicated a breakdown in control and oversight of your Radiation Safety Program.

In addition, some of the findings of the inspection were the subject of a subsequent investigation by the NRC Office of Investigations (OI) to determine if records of sealed source inventories were deliberately falsified and the extent of licensee management's involvement. Based on that investigation, OI has found that certain inventory records of sealed sources were falsified by a member of your staff. Specifically, the then Radiation Safety Officer (RSO) falsified certain sealed source inventory records for January, April, July, and October of 1990.

OI did not find that management was involved in the falsification. A copy of the synopsis of the OI investigation is enclosed.

As discussed during the telephone conversation between Dr. Lawrence Flesh, Chief of Staff and Dr. Ronald Bellamy, Chief, Nuclear Materials Safety Branch on June 24, 1991, the apparent falsification of required sealed source inventory records identified during the OI investigation constitutes an apparent violation of NRC requirements set forth in 10 CFR 30.9. The failure to perform the sealed source inventory during the indicated calendar quarters constitutes an apparent violation of 10 CFR 35.59. These apparent violations are of a significant and serious nature, and will be discussed at an Enforcement Conference at our office in King of Prussia, Pennsylvania at 10:00 a.m. on July 8, 19[illegible]

9107030045

ENCLOSURE (4)

JUN 26 1991

During the telephone call, Dr. Bellamy indicated that because of the seriousness of these issues, you may find it appropriate to have the individual who is the subject of the OI investigation findings (namely, the former Radiation Safety Officer) present at this meeting. Based on that call, we understand that you, the former Radiation Safety Officer and other members of your staff will attend the conference. Also, you and the former RSO may bring legal counsel to be with you during the conference.

At the conference, which will be transcribed, you should be prepared to discuss the causes of these apparent violations and your proposed corrective actions. In particular, you should be prepared to discuss (1) why the NRC should have reasonable assurance that the subject individual will conduct licensed activities in accordance with requirements; (2) your hospital policies regarding safe handling, inventory and accounting for all licensed materials in your possession and forthright communications with management and the NRC, and (3) the extent to which all of your employees understand and adhere to these policies.

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

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.

If you or any staff member have any questions concerning this matter, you may contact Dr. Bellamy of my staff at (215) 337-5200.

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

Sincerely,

R. W. Cooper II for MRK

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

Enclosures:
1. Synopsis of NRC Office of Investigations Report No. I-89-019
2. 10 CFR Part 2
3. Directions to Region I Office

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

bcc:
H. Cahill
M. Shanbaky
M. Knapp
R. Cooper
R. Bellamy
D. Holody
T. Easlick
K. Smith
T. Martin
J. Lieberman, OE

SYNOPSIS

On December 3, 1990, the Regional Administrator, NRC Region I, requested that the Office of Investigations (OI) conduct an investigation to determine if the Acting Radiation Safety Officer (RSO), Veterans Administration Medical Center, Albany, New York, deliberately falsified radioactive sealed source inventory records dated October 14, 1990, and the extent of licensee management's and the RSO's involvement.

The investigation disclosed that the RSO, and not the Acting RSO, falsified the October 14, 1990, sealed source inventory record, and that the involvement of management did not extend beyond the RSO.

The investigation disclosed that: the January 10, 1990, sealed source inventory was [illegible] signed by the RSO as complete; the RSO only added three [illegible] to the January 10, 1990 inventory, signed the inventory, and submitted it as the completed April 10, 1990, inventory; and the inventory dated July 10, 1990, was not conducted as required, but signed by the RSO as complete.

APPENDIX A

DRAFT

NOTICE OF VIOLATION

Veterans Administration Medical Center
Albany, New York 19406

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

During an NRC inspection conducted on November 20 and 21, 1990, as well as a subsequent investigation by the NRC Office of Investigations, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Action," 10 CFR Part 2, Appendix C (Enforcement Policy) (1988), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee or information required by the Commission's regulations to be maintained by the licensee shall be complete and accurate in all material respects. 10 CFR 35.59(g) requires a licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession and that inventory records be retained for five years. The inventory records must contain the model number of each source, and serial number of one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

9104010274

ENCLOSURE (6)

Contrary to the above, information provided to the Commission by the licensee and required by the Commission's regulations to be maintained by the licensee was not complete and accurate in all material respect. Specifically, sealed source inventory records dated January 10, 1990, April 10, 1990, July 10, 1990 were incomplete in that a physical inventory of all sealed sources or brachytherapy sources was not performed but signed by the Radiation Safety Officer as being complete and accurate.

This is a Severity Level III violation. (Supplement VIII)

Civil Penalty -

Pursuant to the provisions of 10 CFR 2.201, Veterans Administration Medical Center is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.