

U. S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 90-001

Docket Nos. 030-00123
030-01314
070-02199

License Nos. <u>08-00942-04</u>	Priority <u>1</u>	Category <u>G1</u>	Program Code <u>02110</u>
<u>08-00942-05</u>	Priority <u>1</u>	Category <u>G3</u>	Program Code <u>02300</u>
<u>SNM-1605</u>	Priority <u>7</u>	Category <u>K</u>	Program Code <u>22160</u>

Licensee: Veterans Administration Medical Center
50 Irving Street, N.W.
Washington, D.C. 20422

Inspection Conducted: May 30-31, 1990

Inspectors: Francis M. Costello
Francis M. Costello,
Senior Health Physicist

8/8/90
date

Approved by: John D. Kinneman
John D. Kinneman, Chief
Nuclear Materials Safety Section B

8/9/90
date

Inspection Summary: Routine unannounced inspection of radiation safety program on May 30-31, 1990 (Combined Inspection Report Nos. 030-00123/90-001; 030-01314/90-001; and 070-02199/90-001).

Areas Inspected: Organization and scope of licensed activities; training and qualification of personnel; radiation protection procedures; materials, facilities and equipment; personnel monitoring; notifications and reports; teletherapy program.

Results: Two apparent violations were identified: Unauthorized disposal of licensed material (paragraph 7) and failure to evaluate airborne releases to the unrestricted area (paragraph 10).

DETAILS

1. Persons Contacted

- *Wayne Whiting - Deputy Director
- Stephen Lunzer, M.D. - Chief of Radiation Therapy
- Ray Laksham, Ph.D. - Lipid Research
- Richard Levine, M.D. - Associate Chief of Staff, Research and Development
- *James Smith, M.D. - Chief of Nuclear Medicine Service
- *Paul Yurko - Acting Radiation Safety Officer
- Indravadan S. Patel, Ph.D. - Radiation Physicist

* - Present at exit interview

2. Organization and Scope of Licensed Activities

The VA Medical Center has three NRC licenses which authorize activities in nuclear medicine, teletherapy, nuclear pacemakers, and a broad scope research and development program. The Nuclear Medicine Department handles approximately 30 diagnostic doses per week with infrequent therapeutic doses of iodine-131 capsules. The hospital has approximately 700 beds. The nuclear pacemaker program is inactive. There are approximately 27 research sections. The licensee does not use the services of visiting authorized users.

Timothy Williams is the Medical Center Director. James Smith, M.D. is the Radiation Safety Officer and the Chief of the Nuclear Medicine Service. Dr. Stephen Lunzer is the Chief of Radiation Therapy. Dr. Patel is the radiation physicist and is responsible for the daily operation of the teletherapy program. Dr. Frank Vieras is the Assistant Chief of the Nuclear Medicine Service. Paul Yurko is acting as Radiation Safety Officer. His name has been submitted to the NRC for modification of the licensee as the authorized Radiation Safety Officer.

3. Training and Qualification of Personnel

The inspector reviewed the records of the radiation safety training which the licensee provided to the employees in building management, research and nuclear medicine and determined that the required annual training had been provided. Interviews with licensee personnel in nuclear medicine and research indicated their familiarity with applicable radiation safety procedures.

No violations were identified.

4. Radiation Protection Procedures

The inspector toured the licensee's nuclear medicine, teletherapy and research areas. He discussed with licensee personnel in these areas the use of syringe shields and gloves, the disposal of radioactive waste and the performance of radiation surveys. Licensee representatives stated that they use the sanitary sewerage system to dispose of liquid radioactive wastes. They package and ship their solid radioactive wastes to a licensed commercial burial facility for disposal. The inspector reviewed the records of liquid and solid radioactive waste disposal. Most research is performed with sub-millicurie quantities of tritium, carbon-14 and iodine-125. Licensee employees stated, and the inspector observed, that they used syringe shields when required and used gloves when handling radioactive materials. Licensee records indicated that radiation surveys were performed as required.

The inspector observed that all laboratories in which radioactive materials were used or stored were locked when no one was in the laboratories.

Licensee representatives stated that thyroid bioassays were performed each time an individual performed a iodination or administered a therapeutic dose of iodine-131. The inspector reviewed the licensee's bioassay records and noted that no uptakes in excess of regulatory limits had occurred. All measured uptakes were less than one nanocurie. The licensee also samples breathing zone air during iodinations and measured no concentrations in excess of regulatory limits.

The inspector reviewed the licensee's records of leak tests and sealed source inventories and noted that they were performed at six-month intervals, as required. The leak tests are performed and evaluated by the licensee.

No violations were identified.

5. Materials, Facilities and Instruments

The inspector reviewed the calibration and use of the licensee's dose calibrator with individuals who work in the Nuclear Medicine Laboratory. These individuals stated that they assay each dose that they administer. They said that they do not use a technetium-99m generator but receive their radiopharmaceuticals from a commercial nuclear pharmacy.

The inspector reviewed the records of calibration of survey meters and noted that they are calibrated annually by Ecology Services. All instruments in use had been calibrated in the last year.

The inspector reviewed the records of checks of linearity and geometrical variation as well as daily constancy checks of the dose calibrator. The inspector noted that these tests were performed at the required frequencies.

The licensee does not use xenon-133. The room intended for this isotope has a problem with its ventilation system resulting in a failure to maintain negative pressure. The licensee representative stated that no xenon-133 would be used until the ventilation system was repaired and operated correctly.

No violations were identified.

6. Personnel Monitoring

The inspector reviewed the licensee's records of whole body and extremity dosimetry for 1989 and 1990. No doses in excess of regulatory limits were noted. The maximum measured dose in a quarter was 0.70 millirem.

The inspector observed that the personnel working in the restricted areas wore the required dosimetry.

No violations were identified.

7. Notification and Reports

The inspector reviewed the licensee's reports of diagnostic misadministrations which were identified by the licensee to have occurred since the last inspection on February 8, 1989. He noted that diagnostic misadministrations occurred on July 21, 1989 and August 10, 1989. These misadministrations did not require reporting to the NRC. The licensee's reports on these misadministrations are included as Attachment 1. The inspector had no further questions about the licensee's reports or corrective actions.

The inspector reviewed the licensee's December 11, 1989 report of an inadvertent disposal of 20 microcuries of cerium-141 and 20 microcuries chromium-51 to a landfill on December 4 or 5, 1989. A copy of the licensee's report is attached (Exhibit 2). Licensee representatives stated that the carcass of a rabbit containing the radioactive material was not placed in the locked freezer and was mistakenly taken to a garbage truck and eventually taken for disposal in a Lorton, Virginia landfill. The licensee's report indicates that corrective actions were taken at the time but that the incident was not reported because the Radiation Safety Committee determined that it was not reportable since a substantial hazard was not created. Since the disposal occurred because one individual left the carcass in an improper location, the licensee counseled this individual. The half-life of cerium-141 is 32.5 days and of chromium-51 is 27.8 days.

The finding that microcurie quantities of cerium-151 and chromium-51 were sent for disposal in a landfill which is not licensed to receive radioactive material constitutes an apparent violation of 10 CFR 20.301.

8. Teletherapy Program

The inspector reviewed the records of the licensee's quality control for the teletherapy program and noted that the monthly spot checks and annual calibrations were performed by the licensee's qualified expert, Dr. Patel. The last maintenance of the teletherapy unit was performed at the time of the source change in August, 1987.

The inspector observed the licensee test the interlocks on the teletherapy unit and observed that all interlocks performed as required.

No violations were identified.

9. Radiation Safety Committee

The inspector reviewed the records of the licensee's Radiation Safety Committee. He noted that meetings were held on June 29, 1989, September 28, 1989, December 28, 1989, and March 29, 1990. He noted that new users and uses of radioactive materials were reviewed and approved by the Committee as required. However, the records indicated that the Radiation Safety Committee had not discussed any of the misadministrations involving licensed materials which had occurred during this time period. Licensee representatives stated that future misadministrations would be reported to and reviewed by the Radiation Safety Committee.

No violations were identified.

10. Effluent Monitoring

The inspector reviewed the licensee's records of monitoring the releases from hoods where iodinations had taken place. There were eight iodinations monitored between May 17, 1989 and May 15, 1990. The licensee's records indicated the following measured concentrations of iodine-125 in releases from its iodination hoods:

<u>Laboratory</u>	<u>Date</u>	<u>Concentration (24-hour average)</u>
Metabolic Research	May 17, 1989	8.2 E-8 $\mu\text{Ci/ml}$
Diabetes Research	June 28, 1989	9.7 E-8 $\mu\text{Ci/ml}$
Metabolic Research	September 19, 1989	1.8 E-10 $\mu\text{Ci/ml}$
Lipid Research	November 16, 1989	1.1 E-10 $\mu\text{Ci/ml}$
Lipid Research	November 17, 1989	4.3 E-10 $\mu\text{Ci/ml}$
Metabolic Research	December 5, 1989	4.3 E-10 $\mu\text{Ci/ml}$
Metabolic Research	March 23, 1990	1.6 E-8 $\mu\text{Ci/ml}$
Lipid Research	May 15, 1990	2.5 E-8 $\mu\text{Ci/ml}$
10 CFR 20.106 limit for release to unrestricted areas		9 E-11 $\mu\text{Ci/ml}$

The acting Radiation Safety Officer stated that, although these values frequently exceeded the discharge limit of 9 E-11 microcurie per milliliter, no further evaluations were performed. The inspector reviewed the licensee's calculations for these measurements and determined that the licensee had mistaken liters for milliliters in the calculation and had thereby over-estimated the releases by a factor of 1,000. The radiation safety staff did not report the measurements in excess of regulatory limits to either the Radiation Safety Committee or to the researchers involved in the iodinations.

The finding that the licensee failed to make an adequate evaluation of the airborne effluent from its iodination facilities represents an apparent violation of 10 CFR 20.201(b).

11. Exit Interview

The inspector met with the licensee representatives denoted in paragraph 1 at the conclusion of the inspection. He summarized the scope and findings of the inspection.

Attachment 1

Combined NRC Region I Inspection Report Nos. 030-01314/90-001,
030-00123/90-001, and 070-02199/90-001

Licensee Records of Misadministrations



Veterans
Administration

Memorandum

Date: July 21, 1989

From: Nuclear Medicine Service (115)

Subj: Misadministration

To: Radiation Safety Office

Date and time: July 21, 1989 8:15 a.m.

Patient:

SSN:

Injector: Julia Ashe

Description of Event:

1. The patient was listed both on the schedule and on the patient jacket for a liver scan rather than a bone scan. As a result, a 99m-Tc sulfur colloid dose was ordered for the patient. A bone scan was requested and the approving Nuclear Medicine Physician wrote 99m-Tc MDP on the consult.
2. The technologist verified the identity of the patient then injected 5.0 mCi 99m-Tc sulfur colloid intravenously without very carefully reviewing the consult.
3. The referring physician was notified and no adverse reactions were observed or are expected.
4. Upon calculation of the organ dose and total body dose received, it was determined that the misadministration is not a reportable incident to the Nuclear Regulatory Commission. The target organ dose was determined to be 1.6825 rads (less than the reportable 2.0 rem) and the total body dose was 0.09 rads (less than the reportable 500 mrem).

Corrective Action:

1. Counseling the personnel involved and the entire staff concerning the need for more care and more attention to details.
2. Before the doses are ordered, the schedule will be checked for accuracy by a staff member who did not prepare the schedule.

NOTE: The Service is understaffed by two technologists and another is hospitalized.

Donna Johnson, CNMT

Donna Johnson, Chief Technologist
Nuclear Medicine Service (115)

Nuclear Medicine Department

Veterans Administration

Date JULY 21, 1989

Name _____

Ward _____

Called _____

Arrived _____

FRIDAY

FRIDAY

FRIDAY

S.S. NO. _____

Age _____ Study _____

Views _____

Views
Remarks

S. THALLIUM

8:15

RESTING MUGA

RESTING MUGA

11:0

BONE

BONE

LIVER/BRAIN

LIVER

LIVER/BRAIN

Bone

VA Medical Center
Radiation Safety Office
Incident Form

1. Date: July 31, 1989
2. Time: 8:15 a.m.
3. Location: Nuclear Medicine
4. Nature of Incident:

Note The Service is understaffed by 2 technologists and another is hospitalized.

The patient was listed both on the schedule and on the ~~over~~ patient packet for S. Liver Scan which was a bone scan. A bone scan was requested and the approving Nuclear Medicine Physician wrote 99m Tc MDP on the consult. The technologist verified the identity of the patient then injected S. O mci 99m Tc sulphur colloid and ~~inadvertently~~ without very carefully reviewing the consult.

5. Employee Statement:

I worked ~~with~~ with Sulfer called Jameson on the schedule Jameson for a liver scan and because we were short staff. I did him his social security # and battery time. I inject a patient I always look @ his consult, but I knew him and on the schedule was liver scan so I just injected him for liver. I look at his SS # but ~~not~~ the consult indicated bone

6. Results of Radiation Safety Office Investigation:

Radiation Safety Office was informed of the incident @ 10:30 A.M. The package insert for Tc 99m S.C. was reviewed and internal dose calculations performed. It was determined that Mr Jameson should receive 1.682 rads to the liver and 0.09 rads T.B. Both are below report levels to NRC.

7. Disposition by Radiation Safety Committee: requested complete report from NM's to RSO.



Date August 15, 1989

From Nuclear Medicine Service (115)

Subj Misadministration

To Radiation Safety Office

Date and time: August 10, 1989, 9:30 a.m.

Patient:

SSN:

Injector: Julia Ashe

Description of Event:

1. The patient was listed both on the schedule and on the patient jacket for a "123-I Thyroid" procedure. As a result, 123-I sodium iodide capsules were ordered for the patient. The consult requested a metastatic survey. A Nuclear Medicine Resident approved the consult but did not indicate the radiopharmaceutical.
2. The technologist verified the identity of the patient then gave him 123-I sodium iodide capsules orally. The combined activity of the capsules was 471 uCi.
3. Upon calculation of the organ dose and total body dose received, it was determined that the misadministration is not a reportable incident to the Nuclear Regulatory Commission. Since the patient's thyroid gland has been surgically removed followed by ablation, the target organ (stomach wall) dose was determined to be 0.153 rads (less than the reportable 2.0 rem) and the total body dose was 20 mrad (less than the reportable 500 mrem).
4. The Assistant Chief of Service met with the patient and the patient's physician. No adverse reactions were observed or are expected.

Corrective Action:

1. Counseling the personnel involved and the entire staff concerning the need for more care and more attention to details.
2. No injections will be given without the radiopharmaceutical indicated on the consult by a Nuclear Medicine Resident or Physician.

3. A memo describing the procedure for radiopharmaceutical administration will be given to every staff member.

NOTE: The Service is understaffed by two technologists and another was on sick leave.

Donna Johnson, C.M.T.

Donna Johnson, Chief Technologist
Nuclear Medicine Service (115)



**Veterans
Administration**

Memorandum

Date August 15, 1989

From Nuclear Medicine Service (115)

Subj: Inadvertent Administration

To Dr. Silva, Endocrinology Service (151J)

1. [redacted] was referred to the Nuclear Medicine Service on August 10, 1989, for a metastatic survey procedure and was inadvertently given 123-I sodium iodide capsules for a diagnostic thyroid procedure. The combined activity of the capsules was 471 uCi. No adverse reactions were observed and none are expected.
2. Upon calculation of the organ dose and total body dose received, it was determined that the 123-I sodium iodide capsules given orally is not a reportable incident to the Nuclear Regulatory Commission. Since the patient's thyroid gland has been surgically removed followed by ablation, the target organ (stomach wall) dose was determined to be 0.153 rads (less than the reportable 2.0 rem) and the total body dose was 20 mrad (less than the reportable 500 mrem).
3. Any questions may be referred to the Chief or Assistant Chief of the Nuclear Medicine Service.

Frank Vieras, M.D., Assistant Chief
Nuclear Medicine Service



Veterans
Administration

Memorandum

Date August 17, 1989

From: Donna Johnson, Chief Technologist

Subj: Inadvertent Administrations and JCAHO Requirements

To: Julia, Tommy, Bill, Whit, and Chris, Technologists

To avoid confusion administering doses to patients, please ensure the following are completed for every patient:

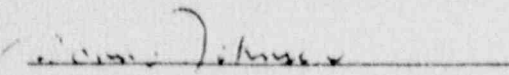
1. The procedure must be clearly indicated on the consult.
2. A Nuclear Medicine Physician or Resident must:
 - a.) approve the procedure (initial or countersign) in the "Approved" box on the consult
 - b.) write the radiopharmaceutical and initials on the consult
 - c.) write all therapy doses (activity) on the consult
3. All consults must be checked by an experienced technologist prior to ordering doses from the central radiopharmacy.
4. Doses must be ordered from the consults; NOT the schedule.
5. Every patient must be positively identified either by a hospital wrist/ankle bracelet or by asking the patient to recite his social security number.
6. Use the consult to verify the patient's social security number, procedure, radiopharmaceutical, and dose (therapy).

PROCEDURE MANUAL

1. Please follow the procedures as outlined in the Procedure Manual. If there are any problems or questions concerning a procedure, please discuss with one of the Physicians or Residents; the procedures can be revised as necessary. No permanent changes will be in effect without the approval of the Chief and the Assistant Chief of the Service.
2. It is very important to resolve all difficulties and concerns about any study as soon as possible since the JCAHO will be using the Procedure Manual to evaluate the Service during the inspection.

CONSULTS

1. Please clearly write the radiopharmaceutical, activity, time of administration, and initials on the consult.
2. Non-Nuclear Medicine personnel review the consults for completeness which is a JCAHO requirement.


Donna Johnson, Chief Technologist



Veterans
Administration

Memorandum

Date August 17, 1989

From Donna Johnson, Chief Technologist

Subj: Inadvertent Administrations and JCAHO Requirements

To Julia, Tommy, Bill, Whit, and Chris, Technologists

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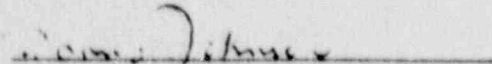
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Donna Johnson, Chief Technologist

Misadministration of Sulphur Colloid

Med. + physics from package inserts

Technetium Tc-99m Product No 4325

Table 4 Absorbed Radiation Dose - Adult

ORGAN	Normal Liver		
Liver	40.5	mGy/12 mCi	3.375 mGy/mCi
Whole body	2.3	mGy/12 mCi	0.1916 mGy/mCi

conversion + Rads

$$0.01 \text{ mGy} = 1 \text{ mRad}$$

from above

$$\begin{aligned} \text{Liver dose} &= 3.375 \text{ mGy/mCi} = 337.5 \text{ mRads/mCi} \\ \text{Whole body} &= 0.1916 \text{ mGy/mCi} = 19.16 \text{ mRads/mCi} \end{aligned}$$

$$\text{patient dose} = 5 \text{ mCi}$$

$$\text{Liver dose} = 337.5 \text{ mRads/mCi} = 0.3375 \text{ Rads/mCi} \times 5 \text{ mCi} = 1.6875 \text{ Rads}$$

$$\text{Whole body} = 19.16 \text{ mRads/mCi} = 0.01916 \text{ Rads/mCi} \times 5 \text{ mCi} = 0.09 \text{ Rads}$$

Patient dose

1.6825 Rads	reported
0.09 Rads	reported

Ref: Title 10, Chap 1, part 35.33, c. CFR.



VA Medical Center
Radiation Safety Office
Incident Form

1. Date: August 10, 1989
2. Time: 9:30 a.m.
3. Location: Nuclear Medicine Service
4. Nature of Incident: The patient was listed both on the schedule and on the patient jacket for a "123-I Thyroid" procedure. As a result, 123-I sodium iodide capsules were ordered for the patient. The consultant requested a metastatic survey. A Nuclear Medicine Resident approved the consult but did not indicate the radio-pharmaceutical. The technologist verified the identity of the patient when he gave him the 123-I sodium iodide capsules. The combined activity of the capsules was 471 uCi.

5. Employee Statement:

As stated above, the pt was listed on the jacket & schedule for I-123, which was ordered. When an order is called in, we go by the schedule for ordering. I ck the pt. SSN and gave him the I-123 capsules. The consult stated thyroid follow up. ^{Dr. Farhat's Office} *Julien Ashe*

6. Results of Radiation Safety Office Investigation:

7. Disposition by Radiation Safety Committee:

Attachment 2

Combined NRC Region I Inspection Report Nos. 030-01314/90-001,
030-00123/90-001, and 070-02199/90-001

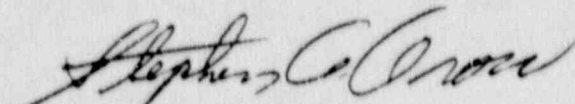
Licensee Report of Lost Radioactive Material



Memorandum

Date: December 5, 1989
From: Administrative Officer, R&D (151)
Subj: Report of Contact-Improper Disposal of Radioactive Waste.
To: Radiation Safety Office

1. At 12:45 P.M., on 12/5/89, Dr. Bass reported to me that an accident had occurred in her laboratory regarding improper disposal of radioactive waste. She had been informed by Dr. Fernicola, a surgical resident, that the carcass of a rabbit which had been injected with 20 uci of ce141 and 20 uci of cr51 had been inadvertently discarded with trash and not frozen and discarded as radioactive waste.
2. I met with Dr. Fernicola at 1:00 P.M. and she confirmed the above. She was in the laboratory until 5:30 P.M. on 12/4/89 and had placed the rabbit on top of a trash can because she found the radioisotope waste cold room full when she went there to discard the carcass. When she opened the laboratory, room GD215, this morning, she discovered that the trash and rabbit had been disposed of by Building Management Service.
3. I called Building Management and was informed that the trash had already been removed to the Lorton Landfill.
4. The employee has been counselled and Dr. Lakshman has been informed of the incident.


Stephen A. Aron



Date December 11, 1989

From Paul Yurko, Radiation Safety Officer (115)

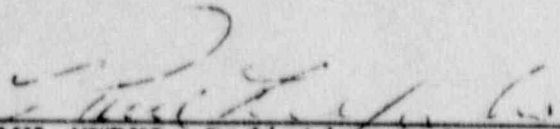
Subj Report of Loss of Control Incident

To Kenneth Lindsay, M.D., Chief of Staff (11)

Thru: James J. Smith, M.D., Chairman, Radiation Safety Committee (115)

1. Attached please find a copy of a memorandum from Stephen Aaron reporting an incident of improper disposal of radioactive waste.
2. 10 CFR Part 20. 402 NRC regulations addresses this situation and states in part "each license shall report to the Commission, by telephone, immediately after it determines that a loss or theft of licensed material has occurred in such quantities and under such circumstances that it appears to the licensee that a substantial hazard may result to persons in unrestricted areas."
3. In my opinion this incident should be defined as a loss to an unrestricted area. Therefore, the question becomes, whether or not it involves a "substantial hazard" to persons in an unrestricted area. The definition of a "substantial hazard" can be found in 10 CFR part 20. 403 (2) which states "The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limits specified for such materials in Appendix B, table II of this part."
4. The values specified in Appendix B, table II for Cr-51 and Ce-141 are 2×10^{-3} , uCi/ml(gm) and 3×10^{-3} , uCi/ml (gm) respectively. Assuming the rabbit weighed 3 kilograms, the concentrations for 20 uCi of both Cr-51 and Ce-141 would be approximately 0.007 uCi/gm for each. The reportable limit for Cr-51 would be 5,000 times 2×10^{-3} uCi/gm or 1.0 uCi/gm and for Ce-141 would be 5,000 x 3×10^{-3} uCi/gm or 1.5 uCi/gm. Therefore, neither limit was exceeded by this release and therefore, the incident, in my opinion, does not need to be reported to the NRC. This will be my recommendation to the Radiation Safety Committee at its next meeting.
5. A complete file on this incident will be kept at the Radiation Safety Office for review.

6. Individuals involved have been notified and the employee has been councelled on proper disposal procedures for radioactive materials.


PAUL YURKO, Radiation Safety Officer
Radiation Safety Office (115)