

L. Cobb, IE.

September 20, 1984

DCS

MEMORANDUM FOR: James H. Joyner, Chief
Nuclear Materials and Safeguards Branch, RI

Kenneth P. Barr, Chief
Nuclear Materials Safety and Safeguards Branch, RII

William L. Axelson, Chief
Materials and Safeguards Branch, RIII

Ramon E. Hall, Chief
Vendor Programs Branch, RIV

Matthew D. Schuster, Chief
Safeguards and Emergency Preparedness Branch, RV

FROM: Leonard I. Cobb, Chief
Safeguards and Materials Programs Branch, IE

SUBJECT: FREQUENCY OF VIOLATIONS OF NUCLEAR MEDICINE
AND THERAPY LICENSEES

A study by IE of the results of about 400 inspections conducted over a six month period (January 1 - June 30, 1984) showed that 61% of nuclear medicine and 65% of teletherapy inspections were "clear" inspections. Below are listed the most frequently found serious violations.

<u>No. of Inspections</u>	<u>NUCLEAR MEDICINE VIOLATIONS</u>
88	Failure to conduct linearity checks (42), constancy checks (14), and accuracy checks (22)
46	Failure to survey waste storage, preparation, and elution areas
30	Failure to follow procedures for surveying and opening incoming packages
30X	Failure of Isotopes Committees to meet quarterly
20	Failure to leak test sealed sources
18	Failure of workers to wear gloves, protective clothing, or survey themselves
18	Failure to secure licensed material in unrestricted areas
16	Failure to calibrate radiation survey instruments

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Multiple Addressees

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No. of
Inspections

NUCLEAR MEDICINE
VIOLATIONS

16	Failure to have any survey instruments or proper survey instruments
15	Workers not properly trained (10 CFR 19.12)
12	Failure to provide personnel extremity dosimetry
10	Radioactive materials used by unauthorized users
10	Improper disposal of radioactive materials
7	Failure to survey clean trash receptacles that were found to have radioactive materials in them
7	Failure to maintain records of personnel dosimetry
7	Failure to check for molybdenum-99 breakthrough

TELETHERAPY

5	Failure to make spot checks or spot checks incomplete
4	Failure to leak least sealed sources
3	Failure to have spot checks reviewed by a qualified expert
3	Failure to calibrate dosimetry system

There were many other violations equal to or greater in frequency than the above; however, the listed violations appear to be the most critical.

/ s /

Leonard I. Cobb, Chief
Safeguards and Materials Programs Branch, IE

cc: P. Vacca, NMSS

Distribution

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J. Metzger, IR

L. Cobb, IE

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ENCLOSURE 3

RADIOLOGICAL INCIDENTS AT MEDICAL FACILITIES
FROM JANUARY 1982 TO DECEMBER 1984

The incidents below have been reported by medical licensees for the period January 1982 to December 1984. These are incidents, that the medical licensees have reported due to a license condition or a 10 CFR regulation. PNs may or may not have been issued for these incidents.

The incidents are categorized according to the frequency of occurrence.

- A. Reports of Theft or Loss of Licensed Material
- B. Overexposures
- C. Radwaste
- D. Transportation
- E. Equipment Malfunction
- F. Effluent Release
- G. Leaking Sources
- H. Miscellaneous

A. REPORTS OF THEFT OR LOSS OF LICENSED MATERIAL

1. A shipment consisting of a 6 millicurie (mCi) I-131 capsule was lost during delivery. The loss was not detected until the capsule was needed for treatment.
2. Several mCi of H-3 and C-14 were missing from the licensee's unlocked storage facility and thought to be stolen.
3. Two seeds of I-125 expelled with the patient's urine were set aside for the RSO. When the RSO arrived shortly thereafter, only one of the two seeds remained. A thorough search did not reveal the missing seed.
4. One strip of three Ir-192 seeds 1.6 mCi removed from a patient was lost. Surveys of the area and the patient showed no radioactivity.
5. A nuclear medicine technologist used a 6.3 microcurie (μ Ci) source for instrument calibration and returned the source to storage. However, the source could not be located afterwards.
6. A dose consisted of capsules of cyanocobalamin 0.8 mCi Co-58 and 0.5 mCi Co-57 were lost when the locker in which they were packed fell out of the truck.
7. Two mCi of H-3 were missing from the licensee's lab. Probably thrown out with trash.
8. A 6.7 μ Ci Cs-137 source reported lost was found undamaged in the top portion of a lead container used to store reference sources.
9. Seven Ir-192 seeds around 4.4 mCi were found missing. The ribbon containing the seeds had come out of the tongue implant in spite of having been sutured in place.
10. A Mo-99/Tc-99m generator, 880 mCi, delivered by a Nuclear Pharmacy to a licensee could not be found.
11. Seeds totaling 57 mCi were discovered to be missing after being removed from a patient. Loss discovered approximately five weeks after sources had been removed from a patient.
12. A 50 mCi Cs-137 seed was discovered to be lost.
13. Seven Ir-192 seeds were lost. The seeds were lost during a therapy procedure, a total of 16 Ir-192 ribbons. It is theorized that the patient swallowed the ribbon and subsequently passed it in a bowel movement.
14. An Ir-192 seed containing 0.77 mCi was lost.
15. A 100 mCi Cs-137 source was lost. Licensees found to have a poor accountability process.
16. A 50 mCi Cs-137 brachytherapy source was lost after removal from patient.

17. One Ir-192 seed .77 mCi after removal from patient was lost. Survey failed to turn up seed.
18. A source used with an anatomical marker was lost sometime during the last four years. The source discovered missing when wipe test was to be conducted.
19. Fifty I-125 seeds totaling about 25 mCi were lost. They had been sent to the facilities sterilization center where the label had been removed.
21. Three Ir-192 seeds were unaccounted for and presumed lost, most probably disposed of to sanitary landfill with trash. Seeds had activity of 3 mCi total.
22. Four I-125 seeds implanted in patient were lost.
23. Three sources were lost (Co-57, Cs-137, Ba-133).

B. OVEREXPOSURES

1. An individual working in a restricted area received a 1.279 rem whole body dose.
2. A medical technologist received a whole body dose of 9.710 rems while attempting to correct a malfunction of a Co-60 teletherapy machine.
3. A thyroid bioassay indicated an employee uptake of I-131 of 400 MPC-HRS. Two other individuals showed uptakes of 156 and 56.3 MPC hours.
4. A film badge showed 5.1 rem to a therapy physicist.
5. A radiation therapist received a dose of 2.15 rads. Therapist removed applicators from two patients believing sources had already been removed. The brachytherapy sources were still present in one applicator.
6. An individual working in a restricted area in a nuclear medicine department received 1.330 rem.
7. An individual working in a restricted area received a whole body exposure of 1.270 rem.
8. An individual received a whole body exposure of 1.79 rem.
9. An exposure of 1.34 rem was received in the 4th quarter of 1983.
10. A radiation therapy employee indicated a 1.45 rem whole body dose for the month of January. However, the employee's work activities did not support such an exposure. Lab coat with film badge attached had been thrown into linen bag in a Co-60 room.
11. An individual working in a medical facility received a total absorbed dose to the thyroid of approximately 2000 rad.
12. About 50 hospital employees received radiation exposures as a result of nine iridium-192 seeds found in a strand of nylon ribbon in one of the needles. Hospital personnel thought there were no ribbons or seeds remaining in the needles. An administrative worker who is considered a member of the public and not a radiation worker, received a whole body dose estimated to be between 750 and 800 millirems and, in addition, received dose of between 15 and 18 rems to the hands.
13. Iodine-125 seed containing approximately 38-40 millicuries of iodine-125 used for brachytherapy was found inadvertently crushed during manipulation in the brachytherapy room. The rupture of the seed caused contamination problems. The highest dose in the exposed individuals was approximately 0.77 rad.
14. Occurrence of badge overexposure of 18.7 rem.
15. Occurrence of hand exposure of 18.8 rem.
16. Deliberate badge overexposure of 1,850 mrem.

C. RADWASTE

1. Radioactive gloves used in the nuclear medicine department were disposed in the normal waste.
2. A contaminated disposable surgical glove was found in a laboratory receptacle for nonradioactive waste.
3. A 2 mCi tritiated waste disposed of with normal trash.
4. A vial containing 97 microcuries of radioactive solution, a glove, gauze pad, a towel, and a syringe contaminated with radioactive materials were found in a receptacle for non-radioactive materials.
5. Seven plastic bags of dry solid waste containing H-3 and C-14 were disposed of as ordinary trash.
6. A box of radioactive waste was shredded in error and placed in a dumpster.
7. Fifty microcuries of iodine-125 was released as nonradioactive trash to the hospital incinerator. This material was incinerated with the normal trash. The event resulted from a failure of the licensee to conduct proper surveys of potentially radioactive material prior to disposal.

D. TRANSPORTATION

1. 10 spent Tc-99m generators were lost during transportation and recovered from a field.
2. Lead cover on 300 mCi package of Tc-99m doses had opened in transit because tape securing it did not cover both sides and edges of cover.
3. A delivery agent from a radiopharmaceutical distributor removed seven decaying Mo-99/Tc-99m generators from a nuclear medicine department without authorization of shipping paper.
4. Shipment of a 6100 mCi iodine-131 capsules shipped to a hospital were lost during transportation.

E. EQUIPMENT MALFUNCTION

1. An installed radiation monitor, located in the teletherapy treatment room, failed to operate in the battery backup mode when tested by the NRC inspector.
2. Teletherapy room radiation monitoring device was not equipped with a battery backup.
3. A malfunction in an AECL Theratron resulted from a loop being thrown off the cord reel.

F. EFFLUENT RELEASE

1. A release of iodine-131 occurred during iodination.
2. Xenon 133 was released in a stack effluent.

G. LEAKING SOURCES

1. A Cs-137 needle was found to be leaking. Patients were not treated with suspect needle.
2. A 430 microcurie Fe-55 source was found to be leaking.

H. MISCELLANEOUS

1. Unauthorized nuclear medicine procedures were performed in medical facilities.
2. Two radiopharmacies received faulty Mo-99m/Tc-99m generators. Molybdenum breakthrough was not performed. As a result, a few hospitals received contaminated doses.

CONCLUSION

This report includes a review of incidents in medical facilities from January 1982 - December 1984. The enclosed chart illustrates the various categories of incidents versus the frequency of each category. Most of the incidents have occurred due to the theft or loss of licensed material and overexposures. The highest activity of the lost source was an 800 mCi Mo-99/Tc-99m generator. The highest overexposure was a total absorbed dose of 2,000 rad to an employee's thyroid. Two overexposures included nonradiation workers. Such incidents may be a result of inadequate management direction. This is demonstrated by examples of insufficient supervision, limited or nonexistent instruction to radiation workers, improper surveillance techniques, and the inadequate implementation of procedures and licensed requirements.

Also these incidents indicate that licensees

- (1) Fail to read and understand the conditions of the license.
- (2) Fail to train employees in the conditions of the license including the radiation safety procedures that are incorporated into the license.
- (3) Fail to control operations including failure of licensee employees to follow approved radiation safety procedures.

CHART I

INCIDENTS AT MEDICAL FACILITIES 1982-1984

N U M B E R O F I N C I D E N T S	23-I	***							
	22-I	***							
	21-I	***							
	20-I	***							
	19-I	***							
	18-I	***							
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	8-I	***	***						
	7-I	***	***	***					
	6-I	***	***	***					
	5-I	***	***	***					
	4-I	***	***	***	***				
	3-I	***	***	***	***	***			
	2-I	***	***	***	***	***	***	***	***
	1-I	***	***	***	***	***	***	***	***
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	A	B	C	D	E	F	G	H	

TYPE OF INCIDENTS

- | | |
|----------------------------|--------------------------|
| A. Lost or Stolen Material | E. Equipment Malfunction |
| B. Overexposures | F. Effluent Release |
| C. Radioactive Waste | G. Leaking Sources |
| D. Transportation | H. Miscellaneous |

ENCLOSURE 4

IE Staff Opinion:

MOST EFFECTIVE MEDICAL LICENSEE INSPECTION METHODS