AEOD TECHNICAL REVIEW REPORT

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SUBJECT: REVIEW OF THE 1989 MEDICAL MISADMINISTRATIONS IN COMPARISON TO THE PREVIOUS EIGHT YEARS

SUMMARY

NRC regulates the medical use of byproduct material in approximately 2,200 hospitals and 400 private-practice clinics. Agreement States account for an additional 5,000 medical use licensees. Approximately seven million diagnostic procedures and 180,000 therapy procedures are performed nationwide each year.* NRC estimates that about 40% of all these procedures are performed by NRC licensees and the remaining by the Agreement State licensees. Certain diagnostic and therapy misadministrations by NRC licensees while performing these procedures are reported to NRC pursuant to the requirements contained in 10 CFR 35.2 and 10 CFR 35.33.

The Office for Analysis and Evaluation of Operational Data (AEOD) has reviewed and analyzed these reported medical misadministrations since 1981. There were reports of 3,612 diagnostic and 73 therapy misadministrations received by NRC from 1981 through 1989. The aggregated nine-year data on therapy misadministrations show that the error rate is on the order of 10^{-4}. In 1989, licensees reported 408 diagnostic and 9 therapy misadministrations; AEOD concludes that there has not been a substantial difference in the number, type, or cause of any of the types of medical misadministrations reported to the NRC in any year from 1981 to 1989.

DISCUSSION

Over the last nine years (1981-1989) medical facilities licensed by NRC for the medical use 1/ of byproduct material in nuclear medicine and radiotherapy have been required to report misadministrations. During that period, NRC received an average of 400 diagnostic misadministration and 8 therapy misadministration reports annually.

The number of both diagnostic and therapy misadministrations has not changed substantially over the nine years.

* U.S. Nuclear Regulatory Commission, "Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material (10 CFR Part 35)," Federal Register, Vol. 55, No. 10 January 16, 1990, pp. 1439-1449.

1/ Medical use includes using radiopharmaceuticals to evaluate the presence and extent of disease, or to treat a disease, and using sealed sources for cancer therapy.

From January 1981 to March 1987, licensees were required to report to the NRC all the nuclear medicine events that met the definition of a diagnostic misadministration pursuant to 10 CFR Part 35. However, effective April 1, 1987, per 10 CFR Part 35, a diagnostic misadministration must be reported only if:

- the misadministration involved the use of radioactive material not intended for medical use;
- the administered dosage was five-fold different from the prescribed dosage; or
- the patient was likely to receive an organ dose greater than 2 rem or a whole body dose greater than 500 millirem.

Despite the change in the reporting requirements, the number of misadministrations was not significantly different from the average number reported in previous years. Since the common radiopharmaceutical dosages administered to patients for diagnostic nuclear medicine procedures deliver a dose of 2 rem to at least one organ, most of the diagnostic misadministrations continue to be reportable.

From January 1989 through December 1989, NRC medical licensees reported 408 diagnostic and 9 therapy misadministrations. Table 1 summarizes the statistics for the medical misadministrations reported to the NRC for 1989. Of the approximately 2,500 NRC licensees authorized to perform nuclear medicine or radiation therapy studies, 325 reported one or more misadministrations, for a total of 417 reports involving 486 patients.

Table 2 lists the number of misadministration reports received for the years 1981-1989. About the same number of diagnostic misadministrations was reported for 1989 as reported annually for the previous years. The number of therapy misadministrations reported during 1989 was about the same as the average number reported each year from 1981 through 1989.

Table 2 shows that 2,996 licensees reported 3,685 misadministrations involving 4,167 patients; that is, some licensees have reported more than one misadministration. The table also shows an upward trend in the number of diagnostic iodine-131 misadministrations for the past two years. The staff has noted that, during the same time, the number of diagnostic procedures other than thyroid requiring the use of iodine-131, such as renal and adrenal procedures, has been increasing.

An estimated 35 million diagnostic procedures were performed at NRC licensed facilities during the nine-year period. Table 3 provides estimates of error rates for the various types of therapy procedures and diagnostic procedures. It shows that the error rate per patient is 0.0003 for teletherapy and 0.0001 per procedure for brachytherapy, radiopharmaceutical therapy, and diagnostic procedures (see following section for explanations of these forms of therapy).

Table 1. Medical Misadministrations Reported to NRC During 1989

	Misadministrations		
	Diagnostic	Therapy	Total
No. of reports	408*	9	417
No. of patients involved	477	9	486
No. of licensees reporting	317	8	325

* Of the 408 medical diagnostic misadministrations, 11 involved the diagnostic use of iodine-131.

Table 2. Misadministration Reports for 1981-1989

	1981	1982	1983	1984	1985	1986	1987	1988	1989	Total
Therapy misadministrations	10	4	4	14	4	7	9	12	9	73
Diagnostic misadministrations (involving Iodine-131)	2	3	2	3	3	5	5	7	11	41
Diagnostic misadministrations (other)	428	414	332	395	377	433	409	386	397	3,571
No. of patients	517	451	437	442	410	495	459	470	486	4,167
No. of licensees reporting	351	355	293	318	293	369	348	344	325	2,996

Table 3. Error Rate for Misadministrations (Based on aggregated 9-year data)

Type	Estimated No. of procedures by NRC licensees	No. of misadministrations	No. of patients	Patient error rate
Therapy				
Teletherapy	360,000*	40	112	0.0003
Brachytherapy	180,000	22	22	0.0001
Radiopharmaceutical	110,000	11	11	0.0001
Diagnostic	35,000,000	3,612	4,167	0.0001

* This figure represents the estimated number of patients that received teletherapy treatments.

Therapy Misadministrations

Therapy misadministration, as used in NRC regulations, refers to the misadministration of radiation from cobalt-60 teletherapy or radioisotopes used for radiation therapy, i.e., treatment of patients.

There were nine therapy misadministrations during 1989. Four of the nine 1989 therapy misadministrations involved teletherapy, which refers to the external use of radiation for patient treatment, and five involved brachytherapy or the internal use of radiation for patient treatment. Two of the teletherapy misadministrations involved an error in identifying the correct patient; one involved miscommunication among the licensee's staff regarding the treatment area of the patient's anatomy; and the fourth resulted from human error during the simulation process.

Three of the brachytherapy misadministrations resulted from an inadvertent selection of a source containing the wrong amount of radioactive material by licensee personnel; one brachytherapy misadministration resulted from the wrong isotope being entered into the treatment planning computer; and the fifth resulted from a misinterpretation of a computer error message before the brachytherapy treatment. These therapy misadministrations are discussed in more detail in Appendix A of this report.

Diagnostic Misadministrations

Diagnostic misadministration, as used in NRC regulations, refers to the misadministration of radioisotopes in nuclear medicine studies or patient analyses, such as renal scans and bone scans.

As in the previous eight years, essentially all of the diagnostic misadministrations for 1989 involved either the administration of the wrong radiopharmaceutical or the administration of the radiopharmaceutical to the wrong patient. The causes for these misadministrations reported by licensees are simple errors associated with (1) the preparation of radiopharmaceuticals, and (2) the administration of radiopharmaceuticals.

Of the 408 reports of diagnostic misadministrations received in 1989, 265 (65%) involved the administration of the wrong radiopharmaceutical to a patient and 99 (24%) involved the administration of a radiopharmaceutical to the wrong patient (these two types of misadministrations accounted for 89% of the reported misadministrations.)

The remaining diagnostic misadministrations involved the wrong route of administration or involved a diagnostic dose of a radiopharmaceutical that differed from the prescribed dose by greater than 50 percent.

Diagnostic Misadministrations of Iodine

Eleven of the 408 diagnostic misadministrations reported to the NRC in 1989 invclved the administration of iodine-131 in amounts that resulted in the delivery of patient thyroid or other organ dose that ranged from 2 rad to 9,000 rad. Four of these misadministrations resulted in thyroid doses of more than 800 rad. They are listed in Appendix B of this report. Causes of the iodine-131 misadministrations included (1) failure to verify patient identification; (2) mix-up of radiopharmaceutical labels; (3) misunderstanding a physician's order, and, (4) unfamiliarity of hospital personnel with infrequently performed iodine-131 procedures.

Conclusions

The number of misadministrations reported to the NRC in 1989 was about the same as reported annually in the prior eight years. Even with the change in reporting requirements for diagnostic misadministrations that became effective on April 1, 1987, the number of medical misadministrations reported to the NRC annually from 1987 through 1989 was not significantly different from the average number reported in previous years. Although there were 11 diagnostic iodine-131 misadministrations, the staff believes that the increase may be ascribed to the increase of diagnostic procedures requiring the administration of iodine-131.

APPENDIX A

Teletherapy Misadministrations

Misadministration 1

Region:	I
Name of licensee:	Kennebec Valley Medical Center
Location:	Augusta, Maine
License no.:	18-11499-02
Event date:	March 9, 1989
Report date:	March 13, 1989
No. of patients involved:	1

Abstract

A patient received an unintended cobalt-60 teletherapy dose of 100 rads to the brain instead of the floor of the mouth (lower palate).

Two elderly patients were prescribed fractionated cobalt-60 teletherapy treatments. Both patients were brought to the hospital at the same time. One patient was to be treated for a lesion near the lower palate. Because of an identification error (names, physical appearances, and treatment planning pictures were similar), the patient to be treated for the lesion near the lower palate received a brain dose. To prevent a recurrence of this misadministration, the licensee reported that, in the future, each patient's identification will be verified by a photograph and oral communication or positive identification by a second person. In support of this effort, the licensee also stated that only authorized personnel will be transporting teletherapy patients into the treatment room.

Misadministration 2

Region:	I
Name of licensee:	Worcester City Hospital
Location:	Worcester, Massachusetts
License no.:	20-05969-03
Event date:	July 24, 1989
Report date:	July 24, 1989
No. of patients involved:	1

Abstract

A patient was prescribed a cobalt-60 teletherapy treatment for his right lung. The patient, however, received 250 rads to the lumbar/sacral spine. This misadministration occurred because the technologist did not confirm the patient's identity with the available photograph nor did she recognize the absence of treatment-positioning tattoos, which would have indicated that the wrong patient was being treated. To prevent a recurrence of this misadministration, the licensee reported that, in the future, the patient's identification will be verified by a photograph. In questionable cases, the physician will verify a patient's identification and treatment before the treatment is initiated.

Misadministration 3

Region:	III
Name of licensee:	Indiana University School of Medicine
Location:	Indianapolis, Indiana
License no.:	13-02752-08
Event date:	March 27, 1989
Report date:	April 10, 1989
No. of patients involved:	1

Abstract

A patient was prescribed a cobalt-60 teletherapy treatment to the left hip and groin area, consisting of nine individual treatments during which 300 rads were to be delivered each time. Because of miscommunication among the licensee's technologists, the patient's right hip was treated instead of the left hip and groin. As a result, the patient received 2700 rads to the wrong hip. To prevent a recurrence of this misadministration, the licensee developed a comprehensive quality assurance/quality control (QA/QC) program that was subsequently incorporated into their license. In the future, the licensee also will provide training and retraining for radiation therapy technologists and resident physicians in the Oncology Department.

Misadministration 4

Region:	III
Name of licensee:	Abbott-Northwestern Hospital
Location:	Minneapolis, Minnesota
License no.:	22-04588-02
Event date:	January 23, 1989
Report date:	January 23, 1989
No. of patients involved:	1

Abstract

A patient was prescribed 12 cobalt-60 teletherapy treatments to the right thigh of 250 rads for each treatment. The patient, however, received a radiation dose of 250 rads to the left thigh instead of the right thigh as prescribed. This misadministration occurred because the technologist became disoriented when turning the table during the simulation process and marked the wrong leg for treatment.

The licensee reported that in the future, it will provide additional guidance to the simulator technologist, review the completed simulation before the treatment, and establish a quality assurance program that will cover dosimetry, treatment planning, and the implementation of radiation safety practices. The quality assurance program was subsequently incorporated into the licensee's NRC license.

Brachytherapy Misadministrations

Misadministration 1

Region:	I
Name of licensee:	Medical Center of Delaware
Location:	Newark, Delaware
License no.:	07-12153-02
Event date:	September 19, 1989
Report date:	September 28, 1989
Number of patients involved:	1

Abstract

A patient was prescribed a brachytherapy treatment using a Bloedorn vaginal applicator with a single medium ovoid and a cylinder without a sleeve. The ovoid should have contained two sources with a nominal activity of 10 milligrams radium equivalent per source, and the cylinder should have contained three sources with a nominal activity of 15 milligrams radium equivalent per source in order that the patient receive the prescribed dose of 3,091 rads. However, after the treatment was completed and the Bloedorn applicator was removed and returned to the storage room, it was noted that the ovoid contained only one 10 milligram source. As a result, the patient received 1,731 rads instead of the prescribed 3,091 rads.

In order to make up for the difference between the prescribed and actual dose to the patient, the licensee stated that a Manchester medium ovoid was loaded with two sources with a nominal activity of 10 milligrams radium equivalent per source and the patient was treated for an additional 18 hours. This brought the total treatment dose to 3,190 rads.

To prevent recurrence of this misadministration, the licensee stated that the departmental procedures were revised to require an independent check of the source loading.

Misadministration 2

Region:	I
Name of licensee:	The Children's Hospital
Location:	Boston, Massachusetts
License no:	20-09568-17
Event date:	October 25-30, 1989
Report date:	November 9, 1989
No. of patients involved:	1

Abstract

The misadministration involved a temporary brachytherapy iodine-125 brain implant where a tube containing 189.14 millicuries of iodine-125 was to be placed inside surgically implanted catheters for the treatment. However, an

error occurred in loading an individual iodine-125 tube where one of the seeds loaded had an activity of 6.73 millicuries rather than 16.46 millicuries prescribed by the therapy plan. As a result, the total activity of iodine-125 placed in the catheters was 179.40 millicuries instead of the prescribed 189.14 millicuries. As a result, the patient received a dose of 3,952.25 rad instead of the prescribed dose of 4,534 rad.

To prevent recurrence of this misadministration, the licensee stated that in the future, prior to implantation, each tube containing iodine-125 seeds will be placed into a dose calibrator to determine if the total activity in the tube is the sum of the individual sources. In addition, the remaining sources in the storage containers will be counted for accuracy.

Misadministration 3

Region:	III
Name of licensee:	St. Luke's Hospital of Kansas City
Location:	Kansas City, Missouri
License no.:	24-00889-02
Event date:	January 31, 1989
Report date:	February 7, 1989
No. of patients involved:	1

Abstract

A patient was prescribed a brachytherapy treatment of the cervix for which two cesium-137 sources were to be used. The prescribed source strengths were 25 milligrams (mg) radium-equivalent and 20 mg radium-equivalent. The prescribed total implant time was 26 hours. After the treatment was completed and the sources were returned to the storage facility, it was discovered that a 5-mg radium-equivalent source was used rather than the prescribed 25 mg radium-equivalent source. As a result, the patient was underdosed by about 56 percent. The licensee reported that although the cesium-137 sources were appropriately color coded and the safe-source storage drawers were clearly labeled with the strength as well as the color of the sources contained therein, there was one drawer that contained sources of two different strengths. The licensee believes that the mix-up was due to a human error that led to the selection of the wrong color source. To prevent this type of misadministration from occurring again, the sources have now been arranged so that each drawer contains a source of only one strength.

Misadministration 4

Region:	I
Name of licensee	Yale New Haven Hospital
Location	New Haven, Connecticut
License No.:	06-00819-03
Event Date:	December 21, 1989
Report Date:	December 22, 1989
No. of Patients involved:	1

Abstract

A patient was treated with interstitial hyperthemia. Both iodine-125 and iridium-192 seeds were discussed as potential candidates due to considerations of cost and availability. A final decision was made to use high activity iodine-125 seeds. However, in the final dose calculations, the dosimetrist erroneously entered iridium-192 instead of iodine-125 into the treatment. As a result, the patient received 500 rad instead of the prescribed 2,500 rad. The error was discovered after a regular monthly brachytherapy conference review of the patient's chart.

To prevent recurrence of this misadministration, the licensee stated that in the future, a dosimetrist other than the one performing the original plan will review brachytherapy dosages to confirm the proper isotope, activity, distribution, and other important parameters. Both dosimetrists will initial the distributions. Also, the dosimetry staff will include all brachytherapy charts in its regular independent chart checking routine.

Misadministration 5

Region:	I
Name of licensee:	Yale New Haven Hospital
Location:	New Haven, Connecticut
License no.:	06-00819-03
Event date:	January 23, 1989
Report date:	January 27, 1989
No. of patients involved:	1

Abstract

This misadministration involved a Gamma Med IIi, a high dose rate, remote afterloading brachytherapy device containing 10 curies of an iridium-192 source. The prescribed Gamma Med treatment called for a total dose of 1500 rads delivered in three event doses. During the last treatment, the therapy technologist entered the treatment protocol into the Gamma Med computer but misinterpreted a computer error message. As a result, a decay factor of 267 instead of the correct factor of 128 was used. The patient received, for the third treatment, 1000 rads instead of the prescribed 500 rads. The Gamma Med treatment as delivered resulted in a total dose of 2000 rads. The licensee established new procedures to prevent a recurrence of this misadministration.

APPENDIX B

Diagnostic Iodine Misadministrations

Misadministration 1

Region:	I
Name of licensee:	New England Medical Center Hospital
Location:	Boston, Massachusetts
License no.:	20-03857-06
Event date:	March 14, 1989
Report date:	March 28, 1989
No. of patients involved:	1

Abstract

A patient was to receive 1 millicurie of iodine-123 for thyroid uptake and scan. This would result in an exposure to the thyroid of about 7 rad. However, the technologist administered 5 millicuries of iodine-131, a dosage intended for a whole-body iodine scan. This occurred because the technologist misunderstood the wording in the notes made by the referring physician on the patient's chart. As a result, the patient received an unintended dosage of between 1,200 and 9,000 rads to the thyroid. The licensee stated that the misadministration was caused by human error and lack of training of involved personnel and that, in the future, the requested study for each patient will be verified.

Misadministration 2

Region:	III
Name of licensee:	Abbott-Northwestern Hospital
Location:	Minneapolis, Minnesota
License no.:	22-04588-01
Event date:	May 23, 1989
Report date:	June 16, 1989
No. of patients involved:	1

Abstract

A patient was prescribed 300 microcuries of iodine-123 for a diagnostic thyroid procedure. The patient, however, was administered a 3-millicurie dosage of iodine-131. The licensee stated that this misadministration occurred because the technologist misunderstood the referring physician's requested study as well as the radiopharmaceutical and dosage that was to be administered. The licensee calculated the dose to the patient's thyroid to be about 4,700 rad. To prevent a recurrence of this misadministration, the licensee stated that, in the future, no iodine-131 radiopharmaceuticals will be administered to a patient without prior approval by the nuclear medicine physician. The licensee also developed a quality assurance/quality control program that was subsequently incorporated into its NRC license.

Misadministration 3

Region:	III
Name of licensee:	Mayo Clinic
Location:	Rochester, Minnesota
License no.:	22-00519-03
Event date:	October 18, 1989
Report date:	October 23, 1989
No. of patients involved:	1

Abstract

A patient was administered a 1 millicurie dosage of iodine-131 instead of the intended dosage of 100 microcuries. This misadministration occurred because of two errors. First, the referring physician wanted an iodine-131 neck scan for ectopic thyroid tissue, which requires the administration of 100 microcuries of iodine-131. However, the box on the nuclear medicine referral sheet for iodine-131 neck scan, post thyroidectomy for carcinoma, which requires a 1 millicurie dosage of iodine-131, was checked.

The nuclear medicine physician approved the neck scan but did not specify that 100 microcuries of iodine-131 should be used. He assumed that the iodine was for a thyroid cancer procedure. The usual dose at the Mayo Clinic for diagnosis of thyroid cancer is 1 millicurie of iodine-131. The dose was, therefore, ordered and administered. The licensee calculated the dose to the patient's thyroid to be about 1,300 rad.

The licensee stated that the following steps will be taken in order to prevent recurrence of this misadministration:

- The patient to be dosed should be seen by the responsible nuclear medicine physician at the time of iodine administration and a history and physical performed to be certain of the indications for the dose.
- The physician should see the dose in the dose calibrator and document in a log book his verification of both the isotope and activity which he had previously ordered in writing.
- The technologist may then administer the iodine-131 without the physician necessarily being present.
- If the patient is female and between the ages of 11 and 55, a serum quantitative pregnancy test should be obtained prior to administration.

Misadministration 4

Region:	V
Name of licensee:	Kuakini Medical Center
Location:	Honolulu, Hawaii
License no.:	53-17797-01
Event date:	November 30, 1989
Report date:	November 30, 1989
No. of patients involved:	1

Abstract

A patient was intended to receive a 20 millicurie dosage of technetium-99m diphosphonate for a bone scan. In addition to this administration, the same patient was inadvertently administered a dosage of 9 millicuries of iodine-131. The misadministration occurred due to the patient responding to another patient's name. This misadministration resulted in an estimated dose to the thyroid of from 560 to 820 rad. The patient was given potassium perchlorate and Lugol's solution to limit thyroid exposure.

The licensee stated that the following steps will be taken in order to prevent recurrence of this misadministration in the future:

(1) special training will be provided for all technologists;
(2) only one technologist will handle all aspects of the iodine-131 therapy, and recognize the correct patient prior to the treatment; and
(3) the technologist, physician, and patient will be required to sign the therapy worksheet concurrently, prior to the administration.