REPORT ON
MEDICAL MISADMINISTRATIONS
FOR THE PERIOD
NOVEMBER 10, 1980 - SEPTEMBER 30, 1981

by the

Office for Analysis and Evaluation

of Operational Data

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EXECUTIVE SUMMARY

Approximately 2200 active licensees are authorized by the Nuclear Regulatory Commission to perform nuclear medicine studies. The Office for Analysis and Evaluation of Operational Data had received reports from 216 of these licensees, who reported one or more medical misadministrations for the period from November 10, 1980 through September 30, 1981, giving a total of 300 reports involving 360 patients (some misadministration events involved more than one patient). Based on this reporting history, AEOD projects that the NRC would receive about 400 reports per year involving approximately 550 patients. Of these 400 reports, AEOD estimates that about ten would involve therapeutic misadministrations. Approximately six to nine million nuclear medicine studies are performed annually by the NRC licensed nuclear medicine facilities; thus, about 0.006 to 0.01 percent of the total are reported as misadministrations. Approximately 10% of the 2200 NRC licensed nuclear medicine facilities reported one or more misadministrations for the period November 10, 1980 through September 31, 1981.

Of the six types of misadminstrations defined in the Nuclear Regulatory Commission Regulations(10 CFR 35.41-45) about 70% of the reported misadministrations involved diagnostic adminstrations of the wrong radiopharmaceutical and about 25% were administrations of a radiopharmaceutical to the wrong patient. The eight reported therapeutic misadministrations came under the following categories: wrong radiopharmaceutical (one), wrong patient (one), and final dose differing from the prescribed dose by more than 10% (six reports).

Although many of the errors associated with the misadministrations are simple personnel errors, AEOD believes the current data highlight potential problem areas that licensees could review to assess the adequacy of their procedures

and training programs. For example, improvements in radiopharmaceutical handling prccedures and patient identification procedures have been proposed by many licensees who reported misadministrations in an effort to minimize the number of misadministrations.

1.0 INTRODUCTION

Subsequent to receiving several reports of serious medical misadministrations throughout the 1970's, the NRC implemented the misadministration reporting rule as set forth in 10 CFR 35.41 through 35.45 effective November 10, 1980. The rule requires the immediate telephone reporting of therapy misadministrations, followed by a written report in 15 days. A quarterly written report is required for diagnostic misadministrations. This report is to be submitted within ten days after the end of the calendar quarter in which the misadministration occurred. Misadministration reports are submitted by licensees to the appropriate NRC regional office which logs and forwards them to Headquarters. The Office for Analysis and Evaluation of Operational Data (AEOD) logs the reports, prepares extracts, and reviews them for generic information.

The Commission's purpose in requiring the submittal of misadministration reports to the NRC is to verify that their causes are properly identified in order to correct them and to prevent their recurrence. The Commission can do this by (1) notifying other licensees if there is a possibility that they could make the same errors, and (2) changing its regulations to help minimize specific errors. The significance of the consequences of a diagnostic misadminstration goes beyond the unnecessary radiation exposure when it results in a misdiagnosis. Seemingly isolated incidents at individual medical institutions can also reveal a generic problem when compared with data on a national scale.

This report is a compilation of data on medical misadministrations extracted from licensee reports for the period November 10, 1980 through September 30, 1981. Approximately 320 reports were received by the NRC Regional Offices during this period, of which 300 were reviewed by AEOD. AEOD had not yet received copies of about 20 reports for review at the time of preparation of this report.

Many of the licensee reports lacked detail; a clear description of the circumstances that led to the misadministration was often not provided. However, most reports provided a relatively clear description of the licensee's corrective action even when the cause of the event was not clearly stated.

2.0 DISCUSSION

Each licensee misadminstration report available to AEOD was reviewed to assign the misadminstration to one of the types defined in the NRC regulations.

Several factors contributing to the misadministrations were identified, based on the most common contributing factors found in the licensee's reports. The same procedure was used to formulate several types of corrective actions that represented most of the corrective actions proposed by licensees. In each case, if the contributing factor or corrective action associated with a report did not conform to one of our standard categories, then it was assigned to the "other," "insufficient information," or "not specified" category.

Table 1[1/] summarizes the occurrences of misadministrations reported to NRC for the period of November 10, 1980 to September 30, 1981. Of the approximately 2200 NRC licensees authorized to perform nuclear medicine studies, 216 (approximately 10%) reported one or more misadministrations for the period, giving a total of 300 reports involving 360 patients.[2/] Based on this reporting history, AEOD projects that NRC would receive about 400 misadministration reports annually involving approximately 550 patients. We estimate that about ten of the 400 reports would involve therapeutic misadministrations.

1/ Tables begin on page 8.

2/ Of the 320 reports received by NRC, only 300 were available for use in this report.

Using an estimate of 10 to 14 million nuclear medicine studies performed annually in the United States,[3] AEOD estimates that 6 to 9 million nuclear medicine studies are performed by NRC licensees. The misadministration rate for NRC licensees is thus about 0.006 - 0.01%. The misadministration rate appears to be of the order of 1/100 - 1/1000 of the error rate for administration of medications in the United States, which is of the order of 1 - 15%.[4]

2.1 Types of Misadministrations

Table 2 presents data on the number of reports by type of misadministration. Of the 300 reports reviewed by AEOD, 292 were reports of diagnostic misadministrations. Two hundred and four (~70%) of the diagnostic misadministrations involved administrations of the wrong radiopharmaceutical, while 75 (~25%) involved administrations to the wrong patient. Five of the eight therapeutic misadministrations involved a therapeutic dose of radiation from a sealed source differing by greater than 10% of the prescribed dose. Of the remaining three therapeutic misadministrations, one involved the wrong radiopharmaceutical, one involved the wrong patient, and one involved the therapeutic dose of a radiopharmaceutical differing from the prescribed dose by greater than 10%.

2.2 Contributing Factors for Diagnostic Misadministrations

Since over 90% of the diagnostic misadministrations were either use of the wrong radiopharmaceutical or administration to the wrong patient, our discussion of

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[3] W. Briner, NRC Consultant, personal communication to H. Karagiannis, NRC.

[4] John Spink, Esq., "Medication Errors in Hospitals," Medical Trial Technique Quarterly, 21, No. 3, pp. 271-296, Winter 1975. (Reprinted from Scapel and Quill, VIII, No. 1, March 1974.)

contributing factors is limited to these two types of diagnostic misadministations. Table 3 gives a distribution of diagnostic misadministrations by contributing factor.

Twenty-five (12%) of the misadministrations involving use of the wrong radiopharmaceutical resulted from mislabeled radiopharmaceuticals being received from radiopharmacies. Eighty-three (40%) were equally distributed among: a mixup of radiopharmaceutical preparations stored in lead pigs; misinterpretation of the physician's orders; use of the wrong reagent kit to prepare the dose; mislabeling of lead pigs or syringes; and a mixup of syringes. Ten (5%) were due to the failure of the technologist to check the requisition to verify the type of nuclear medicine study to be conducted. Seventy-one (35%) of the reports contained insufficient information to permit assigning a contributing factor to the misadministration, and 15 reports (7%) had contributing factors that fell into the "other" category. The fact that about one-third of the 204 reports contained insufficient information to determine a contributing factor demonstrates the lack of report detail.

Sixty-five (87%) of a total of 75 reports of misadministrations involving the wrong patient were distributed equally among: the patient answering to the wrong name; the wrong patient's name being on the nuclear medicine requisition; the patient's identification not being correlated with the the type of study ordered; and the wrong patient being delivered to the nuclear medicine department. Three misadministrations (4%) were due to the misinterpretation of physician's orders; three (4%) were assigned to the "insufficient information" category; and four (5%) were assigned to the "other" category.

2.3 Contributing Factors for Therapeutic Misadministrations

Of the eight therapeutic misadministrations reported to NRC, six involved delivery of doses that differed from the prescribed dose by more than 10%. Of these six misadministrations, four were ascribed to calculation errors. The factors contributing to the remaining four therapeutic misadministations were ascribed to: mixup of radiopharmaceuticals stored in lead pigs(wrong radiopharmaceutical); patient answered to wrong name (wrong patient); mixup of radiopharmaceutical doses stored in lead pigs (therapeutic dose of radiopharmaceutical differing from prescribed dose by greater than 10%); and source fell out of applicator and slipped under patient (therapeutic dose from sealed source differing from prescribed dose by greater than 10%).

2.4 Corrective Actions

As noted previously, many reports that did not clearly describe the circumstances that caused the misadministration event did explicitly describe corrective actions to prevent the recurrence of the event.

Table 4 shows the corrective actions proposed by licensees in their misadministration reports. A total of 307 corrective actions were proposed in the 300 reports. Seventy (23%) of the proposed corrective actions involved the development and implementation of new procedures requiring the technologist to check the patient's chart, color coding or other new labeling methods, and improved techniques for patient identification. One hundred twenty-two (40%) of the proposed corrective actions required the retraining of personnel in existing licensee procedures. Thirty-five (11%) of the proposed corrective actions involved either the reprimand of the

responsible personnel or improved supervision of personnel. Twenty-one percent of the reports were assigned to the category "other"; only 5% did not specify the type of corrective action.

3.0 FINDING AND CONCLUSIONS

The data taken from reports over the period November 10, 1980 through September 30, 1981 indicate that most of the misadministrations involved the diagnostic administration of radiopharmaceuticals. This is expected, considering that the diagnostic application of radionuclides far exceeds the therapeutic application.

The administration of the wrong radiopharmaceutical to a patient or the administration of a radiopharmaceutical to the wrong patient accounted for over 90% of the diagnostic misadministrations. The primary contributing factors appear to be simple errors associated with (1) labeling and identifying radiopharmaceuticals stored in lead shields or untagged reagent kits, (2) the processing of nuclear medicine requisitions, and (3) patient identification.

The mislabeling of radiopharmaceuticals by radiopharmacies would appear to have the same causal factors as the mislabeling of radiopharmaceuticals in hospital nuclear medicine departments. However, since several hospitals could receive mislabeled radiopharmaceutical preparations due to a single mislabeling event at a radiopharmacy, the impact could be far greater for radiopharmacy mislabeling than for hospital nuclear medicine department mislabeling.

Although many of the errors associated with the misadministrations are simple personnel errors, we believe the data highlight potential problems

areas that licensees could review to assess the adequacy of their procedures and training programs. For example improvements in radiopharmaceutical handling procedures and patient identification procedures have been proposed by many licensees who reported misadministrations in an effort to minimize the number of misadministrations.

Table 1

SUMMARY OF NUCLEAR MEDICINE MISADMINISTRATIONS

REPORTED TO NRC

NOVEMBER 10, 1980 - SEPTEMBER 30, 1981

Number of NRC Licensees (Nuclear Medicine)	2220
Number of NRC Licensees Reporting Misadministrations	216
Diagnostic Misadministrations	292 (352 patients)
Therapeutic Misadministrations	8 (8 patients)
Total Nuclear Medicine Administrations by NRC Licensees	6 - 9 million/yr (est.)
Total Nuclear Medicine Misadminstrations by NRC Licensees	400/yr (est.)
Misadministration Rate	.006 - .01% (est.)

Table 2

NUMBER OF REPORTS BY TYPE OF

MISADMINISTRATION (AS DEFINED IN 10 CFR 35.41)

Type Misadministration	Therapy	Diagnostic	Patients
A radiopharmaceutical or radiation from a sealed source other than the one intended	1	204	264
A radiopharmaceutical or radiation to the wrong patient	1	75	76
A radiopharmaceutical or radiation by a route of administration other than the one intended by the prescribing physician	0	1	1
A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent	NA	12	13
A therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10%	1	NA	1
A therapeutic radiation dose from a sealed source such that the error in the source calibration, time of exposure, and treatment geometry results in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10%	5	NA	5
TOTAL	8	292	360

Table 3

FACTORS THAT CONTRIBUTED TO DIAGNOSTIC MISADMINISTRATIONS

GROUPED BY THE TYPE OF MISADMINISTRATION

Wrong Radiopharmaceutical

Contributing Factors	Diagnostic Cases	%	Number of Patients
Radiopharmaceuticals received from radiopharmacy were mislabeled	25	12	46
Mixup of radiopharmaceutical doses stored in lead pigs	21	10	22
Physician's order misinterpreted	16	8	16
Wrong reagent kit used to prepare dose	18	9	35
Mislabeled lead pigs or syringes	11	5	19
Mixup of syringes containing radiopharmaceuticals.	17	8	19
Nuclear medicine requisition was not checked to verify type of study	10	5	10
Insufficient information	71	35	79
Other	15	7	17
TOTAL	204		263

Table 3 (Continued)

FACTORS THAT CONTRIBUTED TO DIAGNOSTIC MISADMINISTRATIONS

GROUPED BY THE TYPE OF MISADMINISTRATION

Wrong Patient

Contributing Factors	Cases	%	Number of Patients
Patient answered to wrong name	20	27	20
Wrong patient's name on requisition	14	19	14
Patient's ID was not correlated with type of study ordered	13	17	13
Wrong patient delievered to nuc. med. department	18	24	18
Physician's order misinterpreted	3	4	3
Insufficient information	3		3
Other	4	5	4
TOTAL	75		75

Table 4

CORRECTIVE ACTIONS PROPOSED BY LICENSEES

Type Corrective Action	Number of Reports	Percent
Implement new procedures requiring technologist to check patient's chart for physician order	20	7
Implement new radiopharmaceutical labeling and handling procedures, e.g., color coding, segregation of radiopharmaceuticals, etc.	38	12
Implement new procedures for patient identification, i.e., ask patient to state or write name, check patient SSAN, use of secondary identification, as well as patient ID bracelet	12	4
Reinstruct personnel	122	40
Reprimand technologist or other personnel	21	7
Improve supervision of personnel	14	4
Not specified	15	5
Other	65	21
TOTAL	307	