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Summary of 1991–1992 Misadministration Event Investigations

Prepared by
L. T. Ostrom, T. J. Leahy, S. D. Novack

Idaho National Engineering Laboratory
EG&G Idaho, Inc.

Prepared for
U.S. Nuclear Regulatory Commission

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ABSTRACT

Investigation teams composed of representatives of the Idaho National Engineering Laboratory (INEL), the U.S. Nuclear Regulatory Commission (NRC), and subcontractors investigated and analyzed seven misadministration events selected by the NRC concerning medical radioisotopes. Each team was led by an INEL member and, depending on the nature of the event, included three or more team members with appropriate expertise in radiation oncology, medical physics, nuclear medicine technology, risk analysis, and human factors. The investigations focused on causes of the event, consequences, mitigating actions, and corrective actions. The investigation produced seven major findings:

1. Many misadministrations occurred primarily because procedures did not exist or because existing procedures that were not sufficiently detailed, comprehensive, specific, or clearly written.

2. Although the NRC's quality management (QM) rule can prevent many misadministrations, most licensees in this study had not effectively implemented their QM programs.

3. The lack of substantial, direct involvement by radiation safety officers and authorized users was often a direct cause of misadministration.

4. A change in routine or the advent of a unique condition often predisposed misadministration.

5. Hardware failures, though rare, had severe consequences, particularly when operating procedures, staff training, or other factors were not well implemented.

6. Licensees' corrective actions were often narrow in focus.

7. The licensees lacked systematic methods for detecting and mitigating a misadministration once an error occurred.

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EXECUTIVE SUMMARY

This summary briefly discusses the Misadministration Events Analysis program and highlights the findings and conclusions developed in that project.

In January of 1992, 10 CFR 35 (Medical Use of Byproduct Material) was amended to require that all medical use licensees establish and implement a Quality Management Program (QMP) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. Based on a review of therapy misadministrations, abnormal occurrences, and diagnostic misadministrations in the therapeutic range that had occurred between November of 1980 and December of 1988, the United States Nuclear Regulatory Commission (NRC) concluded that such a program could enhance patient safety. The NRC contracted with the Idaho National Engineering Laboratory (INEL) to perform detailed analyses of misadministration events. The objectives of these analyses were to identify the direct causes, contributing factors, actions the licensee took to mitigate the event, and the consequences of these events. Also, the INEL sought to determine the role of the Quality Management (QM) rule on the event.

The INEL project consisted of a series of team investigations of reported misadministrations and the analysis of the results of those investigations. The results and the conclusions derived from the analyses are the focus of this report.

The team investigations were conducted between December 1991 and December 1992. Factors that were the basis for selection of events included treatment modality, route of administration, isotope used, size and type of facility in which the event occurred, apparent causes and contributing factors, and severity of consequences. The intent was to obtain a sample that included a number of different types of representative events that would provide useful information for licensees. The events investigated represent a cross section of the types of events that occurred each year and did not involve unusual sets of circumstances. This project did not examine the appropriateness of any prescribed diagnostic or therapeutic procedure or any other issue related to the practice of medicine or radiopharmacology. The project focused solely on why patients received radiation doses other than those prescribed by their physicians.

At the request of the NRC, an INEL investigation team was dispatched to the site of each selected misadministration. Depending on the nature of the event and the treatment modality, each team included three or more experts in various disciplines. These disciplines included radiation oncology, medical physics, risk analysis, human factors analysis, and nuclear medicine technology. The team investigations focused on causes and contributing factors, mitigating actions, consequences, and corrective actions. Team investigations generally took between two and three days to complete and consisted of extensive interviews with licensee personnel and physicians who had been involved in the events. Teams also toured the facilities and received walkthroughs of procedures that may have been involved. Interviewees were told that to help facilitate effective information gathering neither they nor their institutions would be identified in this report.

In an attempt to learn more about the nature and causes of misadministrations, the INEL study team conducted a review of pertinent inspection reports, NRC reports and data bases, and the misadministration events that were reported in NUREG-0090 documents issued between January 1987 and December 1992 . The review and analysis of these events served the dual purpose of providing additional data on which to base conclusions regarding the causal factors associated with misadministrations and of helping to validate conclusions based on findings of the team investigations. This analysis also provided useful insights into the degree to which licensee QMPs have met the objectives of the QM rule (10 CFR 35.32).

Analysis and synthesis of information collected led to a number of conclusions regarding the causes and severity of misadministration events and the effectiveness of corrective actions implemented by licensees to prevent the recurrence of similar events. These conclusions are detailed in Section 4, Lessons Learned, of this report.

Some of the major lessons learned include the following:

1. Many misadministrations occurred primarily because procedures did not exist or because existing procedures were not sufficiently detailed, comprehensive, specific, or clearly written.

2. Although the QM rule has the potential to prevent many misadministrations, most licensees in this study had not effectively implemented their QM programs.

3. The lack of substantial, direct involvement on the part of radiation safety officers and authorized users is often a direct cause of misadministration.

4. A change in routine or the advent of a unique condition is a factor that often predisposes misadministration.

5. Hardware failures occur very infrequently, but can lead to severe consequences, particularly when operating procedures, staff training, or other factors are not well implemented.

6. Licensees' corrective actions were often narrow in focus.

7. The licensees lacked systematic methods for detecting and mitigating an misadministration once an error occurred.

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Principal credit goes to Patricia Rathbun, Ph.D., of the U.S. Nuclear Regulatory Commission's Office of Nuclear Material Safety and Safeguards.

Dr. Rathbun served as the NRC's Project Manager for this work and in that capacity participated in methodology development, team investigations, document review, and overall management of the work. Other NRC staff members who participated in the work include Carl Paperiello, Ph.D., the NRC's Director of the Division of Industrial and Medical Nuclear Safety; Richard Cunningham, Director of Radiation and Nuclear Material Safety; John Glenn, Ph.D., Chief of the Medical, Academic, and Commercial Use Safety Branch; Myron Pollycove, MD, the NRC's Visiting Medical Fellow; Linda Kasner a medical licensee inspector in the NRC's Region IV office; and Janet Schlueter a health physicist in the Medical, Academic and Commercial Use Branch, headquarters. Each of these persons provided technical guidance and served as a technical reviewer of this report.

Our appreciation is also extended to the subcontractors who served as technical experts in the development of methodology and in the investigations of the seven misadministrations examined in this project. These technical experts include Jonathan Young, a risk assessment expert with Science Applications International Corporation; John Horton, Ph.D., a medical physicist and Associate Professor at the University of Texas MD Anderson Cancer Center; Robert Gastorf, a medical physicist at the University of Texas MD Anderson Cancer Center; Richard Cumberlin, MD, radiation oncologist at Georgetown University Medical Center; Wui Jin Koh, MD, radiation oncologist at the University of Washington Medical Center; Michael Caprio, a self-employed medical physicist; Sally Hartnett, a Nuclear Medicine Technologist at the University of Washington; Gregory Wiseman, MD, a radiopharmaceutical physician at the University of Washington; Roger Stano, a medical physicist with Treasure Valley Medical Physics; and Mr. Kenneth Weeks, medical physicist at the Duke University Medical Center.

ACRONYMS

AP-PA	anterior posterior—posterior anterior
BFI	Browning-Ferris Industries
Co-60	cobalt-60
Cs-137	cesium-137
CT	computerized tomography
HCS	hospital computer system
HDR	high dose rate
I-131	iodine-131
INEL	Idaho National Engineering Laboratory
Ir-192	iridium-192
MIRD	medical internal radiation dose
MS3	third year medical student
NMR	Nuclear Medicine Department's receptionist
NMT	nuclear medicine technologist
NMTS	nuclear medicine technologist supervisor
NRC	Nuclear Regulatory Commission
OPN	outpatient nurse
PGI	first year resident
Point A:	Point A is actually two reference points, one each on the left and right, and defined as being two cm superior to the cervical Os and two cm lateral on each side.
PTU	propthiouracil
QM	Quality Management
QMP	Quality Management Program
RSO	radiation safety officer
RTA	Radiation Technologist A
RTB	Radiation Technologist B
RTC	radiation therapy supervisor
SSD	source to skin distance
ST	simulation technologist
T4	thyroxin
TSH	thyroid stimulating hormone
TS+U	thyroid scan and thyroid I-131 uptake
TWBS	thyroid whole body scan

Summary of 1991–1992 Misadministration Event Investigations

1. INTRODUCTION

Effective in January 1992, 10 CFR 35 was amended to require all medical use licensees to establish and implement a basic Quality Management Program (QMP). After reviewing misadministration events that occurred between November of 1980 and December of 1988, the United States Nuclear Regulatory Commission (NRC) concluded that such a program could significantly reduce the frequency or severity of these events. The Quality Management (QM) rule, as set forth in 10 CFR 35.32, requires that each medical licensee prepare written policies and procedures that meet the following objectives:

- A written directive must be prepared prior to administering certain specific types of medical isotopes.
- The patient's identity must be verified by at least two independent means prior to each administration.
- The final plan of treatment must be in accordance with the instructions of the authorized user as specified in the written directive
- Each administration must be carried out according to the written directive
- Any unintended deviation from the written directive is to be identified and evaluated, and appropriate corrective action is to be taken
- Prescribed reporting and record keeping activities must be performed.

In an effort to determine whether the scope and depth of the QM rule is adequate to address the causes of misadministrations of medical radioisotopes, the NRC, through its contractors at the INEL, performed detailed analyses of seven selected misadministration events. The primary objective of these analyses was to develop a more complete understanding of the major causes and contributing factors that resulted in these events.

Investigation teams composed of INEL, NRC, and subcontractor personnel performed detailed investigations and analyses of the seven selected misadministrations. Each investigation team was led by an INEL team leader and, depending on the nature of the event, included three or more team members with appropriate expertise in various areas. These areas included radiation oncology, medical physics, nuclear medicine technology, risk analysis, and human factors. The investigations focused on the causes of the event, consequences, mitigating actions, and corrective actions.

The major objective of this document is to provide information to licensees who use medical radioisotopes to perform teletherapy, brachytherapy, gamma stereotactic radiosurgery, and other therapeutic and diagnostic procedures covered under 10 CFR 35. It is hoped that, by better understanding the nature and major causes of misadministration events, licensees will have a better basis for evaluating their QMPs to determine their effectiveness in preventing misadministrations and recordable events.

Section 2 of this document describes each of the seven misadministrations that were investigated for the project. The medical consequences, direct causes and contributing factors, and licensee corrective actions associated with each event are also discussed in detail. Section 3 summarizes the direct causes, contributing factors, and consequences of the seven misadministrations and defines and discusses the direct causes and contributing factors. Section 4 identifies and discusses the major lessons learned from the seven misadministration investigations. This section presents the interpretations and conclusions

of the INEL project team with respect to the data collected for each of the events. Section 5 presents the results of an analysis of the misadministrations that were reported to the NRC between January 1987 and September 1992. This analysis was performed to gather additional information about the nature of past misadministrations and to provide a basis for validating the team's findings.

2. EVENT DESCRIPTIONS

This section describes each of the seven events investigated, the direct cause and contributing factors for each event, and any mitigating factors taken by the licensee, and it discusses the licensee's corrective actions.

2.1 Event A

Event A involved the high dose rate (HDR) remote brachytherapy treatment modality and was categorized as a misadministration involving delivery of a dose to the wrong site.

2.1.1 Description of the Event. On the afternoon of November 27, 1991, the day before Thanksgiving holiday, a male patient scheduled to receive his fifth and final radiation therapy treatment for cancer of the nasal septum was placed in the HDR treatment room. A catheter was attached to the patient's nose. This catheter was attached to the HDR unit by a trained resident physician. When the patient was ready to be treated, a physicist was paged to operate the unit. The physicist who operated the HDR unit during this particular patient's first four treatments was not available. A second authorized physicist proceeded to the treatment area where he picked up a patient's chart located to the left of the HDR console and programmed the unit's computer with the treatment card taken from the chart. Entry of the information from the treatment card into the unit's console produces a printout of the treatment parameters (source dwell times and positions). The HDR unit was activated after the physicist and the resident physician verified that the treatment parameters on the chart corresponded with those on the printout. As the treatment began, one of the three observers standing near the console inquired about the length of the treatment. The resident physician indicated that the treatment would last about one and one-half minutes, whereas the physicist indicated a time greater than 400 seconds. Based upon this disparity, the resident physician directed the physicist to stop the treatment. Both the physicist and the resident physician reviewed the chart and discovered that it did not belong to the patient being treated. The appropriate patient chart had been placed to the right of the console. The unit was reprogrammed with the correct information and the treatment progressed normally.

2.1.2 Consequences of the Misadministration. As a result of using the wrong treatment parameters, the licensee reported that the patient's lips received an unintended dose of 76 cGy. As of the date of the team visit, the licensee reported that the patient had not exhibited any adverse aftereffects as a result of the misadministration.

2.1.3 Mitigating Actions. The treatment was stopped by the medical physicist after someone inquired how long the treatment would take and the resident physician responded with a much shorter time than the medical physicist.

2.1.4 Direct Causes and Contributing Factors. There were several direct causes and contributing factors to this event:

Organizational Policy and Procedures

The licensee lacked a procedure requiring formal verification of the patient's identity against the treatment packet. During the required treatment parameter check, the physicist did verify the name on the HDR treatment programming card with the name on the treatment packet; however, this did not include verbal exchange between the physicist and the patient or the resident physician verifying the patient's identity against the treatment packet.

Training and Experience

The resident physician was not aware that the numbers on the printout represented source positions and dwell times. Had he known, he may have recognized that the information was not correct for his patient.

Interpretation Error

The physicist operating the unit was not acquainted with the patient. He assumed that the

nasal catheter represented an endobronchial treatment, as indicated on the treatment packet.

Changes and Unique Conditions

The medical physicist who operated the HDR unit for the patient's four previous treatments was not available. A part-time medical physicist unfamiliar with the patient responded to the page for a medical physicist and operated the HDR unit for this treatment.

The case constituted the first use of the HDR for this type of treatment. Gynecological treatments account for approximately 90% of the workload and endobronchial treatments account for most of the rest. Occasionally, a different type of treatment, such as the nasal septum case, occurred.

It was unusual for the licensee to give two fractions to two patients in the same week. In this case, two patients received two fractions on the same day. Charts of patients receiving fractionated treatments were not normally left at the console when no further treatment planning was needed. Therefore, the staff were not used to having two charts in use in the HDR console area at the same time.

2.1.5 Licensee Corrective Actions. As of December 11, 1991, the licensee had implemented, or was going to implement, the following corrective actions:

1. Patient's identity was to be verified prior to treatment by comparing a photograph, by asking the patient for his or her name, or by asking the physician who connects the catheter.

2. Photographs of the HDR patients were to be taken at the time of treatment planning.

3. A new check list was designed for nonstandard treatment protocols.

4. Treatments were to be delivered by one of the two primary physicists.

In addition, the radiation safety committee approved the formation of an ad hoc committee to review the radiation oncology's entire quality assurance program, which included the QMP.

2.1.6 Discussion of Corrective Actions. The corrective actions did not address the problem of the resident not knowing the parameters he was verifying. Having only one of the two physicists deliver the treatment will help, but it may not eliminate this problem. If the treatment packets were switched and an inexperienced person verified the treatment parameters, a similar misadministration might still occur. The corrective actions were also narrow in focus, and might not prevent other types of misadministrations.

2.2 Event B

Event B involved the cobalt-60 (Co-60) teletherapy treatment modality and was categorized as a misadministration involving delivery of a dose to the wrong site.

2.2.1 Description of the Event. The misadministration event in question involved a 75-year-old white male who was undergoing treatment for nonsmall-cell lung cancer. The radiation oncologist determined that palliative irradiation to the lung and right scapula was indicated for control of pain. The treatment to the right scapula was not delivered as prescribed and was the event that occasioned the investigation team site visit.

The prescription was for 3000 cGy in 10 fractions to be delivered to the right scapula at a tissue depth of 3 cm. The initial plan was to treat the patient with a direct oblique field with the patient in the prone position. Owing to discomfort, however, the patient was unable to cooperate in lying prone. An alternative treatment was sought so the patient could be treated lying supine. The technique chosen by the oncologist for treatment of the scapula was a posterior oblique, to be set up anteriorly with the patient in the supine position, the gantry rotated, and the patient treated from the posterior using source-to-skin-distance (SSD) geometry. This treatment technique was new to both the radiation oncologist and the simulation technologist.

The radiation oncologist directed the simulation, approved the planning x-ray, and marked the setup landmarks in the presence of the simulation technologist. The radiation oncologist intended the field center mark to be for the ceiling laser and central axis indicator. The technologist finished the markings and wrote setup instructions on the radiation therapy chart; however, the written instructions did not address the specifics of the setup. The instructions regarding the purpose of the field center mark were not written on the chart.

On January 13, 1992, the patient was treated with the Co-60 unit setup according to the instructions on the patient's chart. The radiation oncologist was not in attendance for the first treatment and did not review the portal film that day. It is the usual custom of the radiation therapy department to treat posterior oblique fields with an anterior SSD setup by setting the Co-60 unit backpointer laser to the field center when the gantry is rotated posteriorly. This is necessary when anterior posterior-posterior anterior (AP-PA) opposed oblique fields are used, as is usually the case. The backpointer was set to the field center also for this posterior-only oblique as well (at the direction of the department physicist, according to the treatment technologist), and the treatment was given.

The patient was treated again, the same way, in the morning of the following day, January 14, 1992. When the radiation oncologist reviewed the portal film in the afternoon of this second treatment day, he discovered that the treated area was significantly medial to the intended area, to the extent that most of the intended area was untreated and normal tissue had been given the two fractions of 300 cGy each.

The treatment parameters were adjusted, and the patient was treated with no further difficulties.

2.2.2 Consequences of the Misadministration. The licensee reported that the misadministered dose of 600 cGy in two treatments of 300 cGy each involved the following two critical anatomic structures not intended to be in the treatment field:

1. Spinal cord
2. Lung.

The dose was well below generally accepted tolerance levels for both of these critical organs, as well as for other noncritical tissue in the inadvertently treated field. The licensee reported that the dose administered to the unintended area should have less than one percent probability of short- or long-term complications to the patient.

2.2.3 Mitigating Actions. The error was discovered in the interval between the second and third treatment fractions. The attending radiation oncologist who discovered the error modified the remaining treatment fractions to include additional treatments for the originally intended treatment field. Although this was a systematic check to ensure the treatment was being performed to the correct site, it was not performed until after the second fraction.

2.2.4 Direct Causes and Contributing Factors. The direct causes and contributing factors of this incident were as follows:

Organizational Policy and Procedures

There were no formal procedures for handling unique treatment setups.

Communications

There were apparent miscommunications between the radiation oncologist and the simulation technologist.

There were no clear, instructions, vocal or written, from the radiation oncologist to the treatment technician.

Changes and Unique Conditions

The treatment setup was new and unique to the department.

The original treatment plan had to be modified because the patient could not lie prone, owing discomfort.

2.2.5 Licensee Corrective Actions. The licensee modified the quality management procedure, requiring the portal film to be reviewed after the first treatment.

2.2.6 Discussion of Corrective Actions. This corrective action will not prevent the licensee from giving one treatment to the wrong site before it is discovered by reviewing the portal film. A more positive means of preventing recurrence would be as follows:

1. Prior to administering the first treatment, have in place a procedure to ensure that the plan of treatment and related calculations are in accordance with the written directive.

2. Have in place a procedure that requires review of the portal film prior to the first treatment.

2.3 Event C

Event C involved the manual brachytherapy treatment modality and was categorized as a misadministration involving delivery of a dose to the wrong site.

Abbreviations Unique to this Event

RTA = new radiation technologist

RTB = radiation technologist

RTC = radiation therapy supervisor

ST = simulation technologist.

2.3.1 Description of the Event. This misadministration event involved a 53-year-old female with Stage IIB squamous cell carcinoma of the cervix who was undergoing definitive radiotherapy. The treatment plan for the patient entailed external beam irradiation to the pelvis and two intracavitary brachytherapy boosts.

From February 11 to 27, 1992, the patient received 2340 cGy in 13 daily fractions to the whole pelvis from a four-field external beam box technique, with all four fields treated daily. It was decided early in the course of external radiation to use two brachytherapy insertions using a Henschke afterloading applicator.

On February 28, 1992, the patient underwent placement of her first brachytherapy implant using the Henschke afterloading applicator. During this treatment, five 10-mg radium equivalent sources were implanted, three in the tandem and one in each ovoid. A total dose of 2500 cGy was delivered to point A over 72 hours based on hand-calculated dosimetry. The implant was removed without incident and the patient discharged on March 2, 1992.

From March 3 to 17, 1992, the patient received further external beam radiation using the above described technique, with the addition of a midline block in the anterior and posterior fields to protect central bladder and rectal volumes. An additional 2160 cGy was given in 12 fractions for a reported total external beam dose of 4500 cGy. The second implant was delayed for seven days to allow resolution of diarrhea and rectal tenesmus.

On March 24, 1992, the patient underwent her second planned Henschke applicator placement. That morning, the patient's physician (Physician A) was working with another physician (Physician B) at a clinic associated with the hospital. Since the patient's procedure had been delayed to a later start time, Physician A asked Physician B to perform the Henschke insertion. Physician B inserted the Henschke applicator at 3:00 p.m. When the straight intrauterine tandem did not fit optimally, Physician B exchanged it for a curved tandem. When the Henschke apparatus was assembled that morning, dummy sources had been placed in the straight tandem and the ovoids, but not the curved tandem. The dummy sources were not transferred to the curved tandem after insertion.

A new radiation technologist (RTA) was responsible for loading the cesium-137 (Cs-137) sources into the source carriers that were to be

placed within the Henschke applicator. RTA was being trained on active source loading procedures by another radiation technologist (RTB). The training of RTA had not progressed to the actual loading of Cs-137 sources into the Henschke applicator. RTB had left instructions with RTA that she would be available to assist and instruct when it was time to load the Cs-137 sources into the carriers. However, RTA began the loading process alone as she perceived RTB to be too busy with teletherapy patients. As RTA began, the radiation therapy supervisor (RTC) walked by the source storage room. RTA asked RTC for help. RTC was familiar with the active source loading process, but had not done it since 1984. The safe in the source storage room had four drawers. Three contained sources and one was empty. Either RTA or RTC (it is unclear who) opened the upper right drawer containing eight 10-mg sources and two 15-mg sources. With RTC's guidance, RTA loaded one 10-mg source into each ovoid carrier and three 10-mg sources into the tandem carrier. The sources loaded were like those used by RTC when she did this task in 1984. The safe was then closed and the carriers were placed in a pig for transport to the simulation room. RTA filled out the source control logbook, incorrectly using the inventory of the drawer containing the correct sources rather than the inventory that was actually loaded into the applicator.

After postanesthetic recovery, the patient was moved to the simulation room and positioned on the table. The simulation technologist (ST) took an x-ray film at approximately 5:00 p.m. and reviewed it. She noticed there were no dummy sources in the tandem, but knew that dosimetry could be done without them. The ST gave the film to Physician B for review. Physician B reviewed the film for proper placement of the applicator, but did not notice the lack of dummy sources in the tandem. Physician B then signed the film indicating her approval. The dummy sources were then removed and the Cs-137 sources loaded into the Henschke applicator. RTA also saw the film and noticed there were no dummy sources in the tandem. She questioned the ST about its acceptability. The ST indicated it was all right, saying that the dosimetry could be done without the dummy sources showing. The patient was then transported to a hospital room. An in-room radiation survey was completed after the patient entered the room.

On March 25, 1992, at 10:30 am, the hospital medical physicist set out to perform the dosimetry for the patient using the simulation film taken at 5:00 p.m. the previous day. The medical physicist saw there were no dummy sources in the tandem showing on the film. He also wanted to show another medical physicist, new to the staff, how to perform dosimetry for such an implant using standard localizing procedures. The medical physicist requested repeat simulation films with active sources in place, but could not get a time until 5:00 p.m. that day because of emergency cases using the facility. At 5:00 p.m. on March 25th, the patient was moved to the simulation room and a film was taken. The ST immediately noticed that the active sources were not where they should have been on the film, and that the ovoid sources appeared to be located below the ischial tuberosity landmarks. The ST gave the film to the medical physicist, who reviewed it. The medical physicist was initially concerned that the active sources may not have been placed in the patient. He conducted a radiation survey of the patient and found that radiation was present. The medical physicist and RTB went to the source room and checked the drawer where the active sources were kept and found they were all present. They then checked the other drawers and found that sources from the upper right drawer were missing. The medical physicist contacted Physician A, who immediately ordered the sources removed. The "old" sources were placed back in the upper right drawer and logged in.

Based on simulation films that first indicated the misplaced old Cs-137 sources, the licensee assumed that the source slippage from the intended locations had occurred soon after placement, indicating that the sources were incorrect positioned for approximately 24 hours before discovery of the error. The two ovoid sources were located at the same transverse level, at the bend of the colpostat holders, approximately 2 cm outside the vaginal introitus, but within the labial folds. These two ovoid sources were seen on the

simulation films. The other three tandem sources could not be seen within the exposed portions of the film, and were, therefore, inferior to the inferior collimated edge of the film. When the tandem source carrier was removed, the sources were confirmed to be misplaced in the lower portion of the carrier.

The licensee assumed that the sources were misplaced early and then fixed, which was the conservative assumption (substantiated later by the patient's symptoms, see below). The licensee also assumed that the tumor volume had received no effective dose, and Physician A decided to proceed with definitive brachytherapy using the correct 10-mg sources in the proper locations. This corrected placement delivered 2000 cGy in 42.5 hours to point A.

The patient was informed that the source change was done because Physician A was "not satisfied" with the initial sources used. The rest of the implant duration for the additional 42.5 hours was without incident. At discharge, the patient was told that there may be some vulva and skin reaction, secondary to the treatment, and to inform the doctors of such. No specific mention of incorrect source selection or placement was made to the patient. The implant was removed and the patient discharged on March 27, 1992.

The hospital determined that the old Cs-137 sources had not been used since 1984. This was approximately the last time RTC had loaded the sources into an applicator. The old sources slipped within the source carrier because they were smaller in diameter than the correct sources, allowing migration through the end of the helical spring that was supposed to keep them at the end of the source carrier. The old sources were 1.5 mm in diameter; the correct sources were 3.0 mm in diameter.

About a week later, the patient called and complained of burning and pain in the perineal area. The patient was seen on April 13, 1992. Physician A noted a bilateral, posterior medial labial superficial skin erosion measuring approximately 1.8 cm in diameter located 2-cm outside the introitus, corresponding to the simulation film locations of the misplaced ovoid sources. No intravaginal lesions were noted. The patient was treated on an outpatient basis, with the affected area treated using saline rinses and cortisone. Symptoms reportedly resolved in two weeks. The hospital informed the NRC of the misadministration in writing on April 8, 1992.

2.3.2 Consequences of the Misadministration. All five misplaced, or old, Cs-137 sources within the Henschke applicator were found inferior to their intended locations. Based on simulation film findings and subsequent patient symptomology, the licensee made the conservative assumption that all five sources were fixed in their incorrect positions during the 24-hour period that the sources were implanted.

The two ovoid sources were located at the same level, approximately 2 cm outside the vaginal introitus and 1 cm inferior to the inferior borders of the external beam radiation fields. The calculated dose 0.5-cm lateral to each source, which would correspond approximately to the skin dose, was 3500 cGy, delivered over 24 hours. The dose at 1 cm was 1307 cGy. The misplaced ovoid sources were fully 1 cm inferior to the inferior borders of the external beam radiation fields. The labial skin dose received caused acute local moist desquamation, noted approximately 10 days after removal of the implant. This desquamation was treated with saline flushes and cortisone.

The three tandem sources were not seen on the simulation film and were inferred to be below the collimated field exposure or at least 2.5 cm further inferior to the ovoid sources. Their dose contribution to the labial skin is minimal, and would have added no more than 100 cGy to the overall exposure to labial skin. Because of protective packing and padding placed around the external portion of the Henschke apparatus, it is assumed that the tandem sources were at least 2.5 cm away from the skin of the medial thighs, and maximum dose delivered would be 450 cGy.

2.3.3 Mitigating Actions. The medical physicist, upon examining the films the morning of March 25, 1992, noticed that no dummy sources

had been loaded in the tandem. He requested a second set of films be taken with the active sources in place so he could perform accurate calculations of the dose to point A. Because the simulator was fully scheduled during the day, the films were not taken until 5:00 p.m. When he saw the films, he initially saw no apparent active sources. He then surveyed the patient and found radiation present. He did a source inventory and found that incorrect sources had been loaded into the patient. He verified that two of the incorrect sources could be seen on the simulation film, but in the wrong location. The medical physicist notified Physician A, who ordered the sources removed. This action limited the exposure the patient received from the improperly placed sources. After the incorrect sources were removed, the correct sources were placed in the applicator, the original treatment plan was executed, and the intended dose of 2000 cGy to point A was delivered.

2.3.4 Direct Causes and Contributing Factors. The direct causes and causal factors that led to this misadministration were as follows:

Organizational Policy and Procedures

The licensee did not require the technologists to have periodic refresher training on the current practices in the department.

The licensee allowed old sources to be stored in the same safe as the sources in use without proper safeguards in place.

Radiation Safety Officer and Authorized User Oversight

The RSO did not ensure the source control log book was being used correctly. Had the source control log book truly been used correctly, the technologist might have detected the mismatch between the number of sources in the drawer and what was supposed to be there.

Training and Experience

The RTA was not adequately trained to perform the task.

The RTC was not adequately trained to be able to direct the RTA to perform the task correctly.

Supervision

There was lack of supervision of the RTA. The RTA began the source loading process without RTB being present.

Changes and Unique Conditions

The RTA was a new employee in training. The RTB who was training RTA was busy that morning, but had told RTA not to start loading the sources until she was available. However, RTA began the process and was then aided by RTC who happened by the source storage room.

Labeling

The source safe was not adequately labeled as to which drawers contained the sources to be used.

Hardware Incompatibilities

The sources selected and loaded in the source carriers were smaller in diameter than the correct sources and slipped through the opening in the end of the helical spring.

2.3.5 Licensee Corrective Actions. The following are the corrective actions the licensee took to prevent recurrence:

1. The drawer containing the incorrect sources was retaped and clearly labeled with a warning not to use the contents.

2. A diagram of the source safe was posted in the storage room. The diagram has front and top views of each of the drawers in the safe indicating what they contain.

3. Descriptions and specifications of the sources were also posted in the storage room. All technical personnel were made fully aware of which sources should be used for each brachytherapy procedure.

4. Personnel were instructed concerning 1, 2, and 3 above.

5. Pertinent brachytherapy procedures were revised.

6. A check list was to be developed to aid in performing brachytherapy procedures.

7. Educational opportunities on various radiation safety topics were offered to the employees.

2.3.6 Discussion of Corrective Actions. The corrective actions the licensee took did not adequately address all of the findings from the investigation concerning the safe. Comments from the staff indicated that they would like to see the drawer containing the old sources sealed with solder, or the old sources removed to some other location, rather than the drawer simply taped. The INEL team believes that the only way to ensure the old sources are not used is to remove them from the safe and place them in another storage area.

2.4 Event D, Iodine-131

Event D involved an iodine-131 (I-131) diagnostic study. The event was categorized as a misadministration involving the wrong dosage because it resulted in a dose of greater than 50 rem to an organ and because it occurred after 1/27/92.

Abbreviations Unique to this Event

HCS	=	hospital's computer system
MS3	=	third-year medical student
NMR	=	Nuclear Medicine Department receptionist
NMT	=	nuclear medicine technologist
NMTS	=	nuclear medicine technologist supervisor
OPN	=	outpatient nurse
PGI	=	first-year resident
T4	=	serum thyroxin
TSH	=	thyroid stimulating hormone
TS+U	=	thyroid scan and thyroid I-131 uptake
TWBS	=	thyroid whole body scan.

2.4.1 Description of the Event. The misadministration event involved a 50-year-old female undergoing evaluation of an enlarged thyroid. The patient was referred to the hospital's nuclear medicine department for evaluation. The patient was seen in the outpatient clinic by a third-year medical student (MS3) and the endocrinology attending physician (Physician A). After obtaining a medical history, examining the patient, and reviewing the laboratory data, they felt that the patient's enlarged nodular thyroid gland, elevated serum thyroxin (T4), and decreased thyroid stimulating hormone (TSH) were the result of diagnosed Grave's Disease. They proceeded to order a thyroid scan and thyroid I-131 uptake (TS+U) study.

The order for the TS+U study was written on the order sheet in the patient's chart by MS3 and co-signed by Physician A. This order said "thyroid scan and thyroid I-131 uptake." MS3 completed the nuclear medicine requisition card and asked the patient's primary physician, a first-year resident (PGI), to co-sign it. This card requested a "thyroid scan" without indicating a thyroid I-131 uptake and contained the diagnosis "diffusely enlarged thyroid-?R nodule-lower."

The outpatient nurse (OPN) called the order into the hospital's diagnostic scheduling center. The OPN read the order from the order sheet to a scheduling clerk via the telephone. The scheduling clerk in the hospital's diagnostic scheduling center understood the order as a thyroid whole body scan (TWBS). The clerk completed coding the TWBS order into the hospital's computer system (HCS).

The OPN incorrectly told the scheduling clerk that Physician B was the patient's physician, whereas the OPN should have said Physician A.

Physician B had not seen the patient, but his name was associated with the patient because he was on the clinic receptionist's roster as being the attending physician for that day when, in fact, the schedule had been changed. Physician A was actually the attending physician on that day. Physician B had the hospital authorization to order a TWBS, whereas Physician A did not. Upon selecting the TWBS on the HCS, a note appeared on the screen that stated that only Physician B and one other physician could order the study. Physician A was not on that list. The OPN then read the diagnosis of enlarged thyroid to the clerk. The clerk twice questioned the OPN on this diagnosis since it appeared to the scheduler that there was a mismatch between the study requested and the diagnosis. The clerk said she did not directly ask the OPN to repeat the name of the study being ordered, but asked only if the OPN was sure of the correctness of the study. The clerk placed the OPN on hold and called the Nuclear Medicine Department's receptionist (NMR). The clerk asked the NMR whether this was an appropriate study for this diagnosis. The NMR then told the clerk that if Physician B (who could authorize this study) ordered the study, then it was correct. The patient was then scheduled for the TWBS on May 18, 1992, at 11:30 a.m. and a patient information packet was sent to her home. The scheduling clerk returned to the OPN and confirmed the scheduling of the study. The OPN mailed the nuclear medicine requisition to the diagnostic scheduling center in the interoffice mail.

On Friday, May 15, 1992, as the NMR was transcribing the information from the computer-generated service roster to the Nuclear Medicine Department's working cards, she noticed a mismatch between the diagnosis and the study that was to be conducted for the patient. NMR called the scheduling clerk and asked her if the study was correct. The clerk told the NMR she had verified the request three times and that it was correct. Then NMR completed the working card and transferred it to the nuclear medicine technologists.

Also, on May 15, 1992, the nuclear medicine technologist supervisor (NMTS) reviewed the service roster to determine the amount of I-131 needed for the next working day, which was Monday, May 18, 1992. The NMTS determined that she needed to place an order because of the TWBS to be conducted on Monday. NMTS ordered a unit dose of 4.0 mCi of I-131 for the patient.

At approximately 11:15 a.m. on May 18, 1992, the patient checked in with the NMR for her appointment. Upon hearing that the patient was in the office, the nuclear medicine technologist (NMT) began making preparations for delivering the dose. The NMT obtained the working card and noticed the mismatch between the study and the diagnosis. The NMT then began looking for the nuclear medicine requisition and, when she couldn't find it, she went to talk to the NMR. The NMT asked the NMR where the requisition was and the NMR said they had not received it yet, which was not unusual for requisitions coming from outpatient clinics. The NMR said she had verified the study with the scheduling clerk who had verified it with the clinic. The NMT then tried to call Physician B's office, but the line was busy. After trying for approximately 30 minutes, the NMT finally talked with Physician B's receptionist who said that Physician B was out of the office until 3:15 p.m. that day. The NMT could not contact a Nuclear Medicine Departmental physician or the NMTS because they were out of the office. The NMT knew that, according to standard departmental procedures, she could give a 4.0 millicurie dose of I-131 for diagnostic purposes without approval from a nuclear medicine physician.

The NMT decided to proceed in dosing the patient because

1. The NMTS had reviewed the requested study and diagnosis and had ordered the I-131 dose

2. The NMR had verified with the scheduling clerk that the study was correct

3. Physician B who was one of the two physicians authorized to order the study and frequently did so, was the requesting physician

listed on the working card and service roster.

The NMT then prepared a written directive, as directed by departmental procedure. The NMT then went to the hot laboratory, found the dose of I-131 ordered for the patient, measured the dose in the dose calibrator, administered the dose under a fume hood, and counted the empty vial. The NMT did not discuss the apparent mismatch between the diagnosis and the study to be conducted with the patient. The patient was scheduled to return 24 hours later for scanning and was dismissed by the NMT.

At 1:30 p.m., 45 minutes after the patient left the hospital Nuclear Medicine Department, the NMR located the nuclear medicine requisition in the afternoon interoffice mail. The NMR immediately gave the requisition to the NMT, who noted the order for a thyroid scan rather than the TWBS for which the patient had just been dosed. The NMT notified the RSO, the Nuclear Medicine Department physician, and the NMTS. The NMT again called Physician B, but was unable to reach him until the next morning, May 19, 1992. Physician B stated that he had not seen the patient. Physician B determined the patient had been under the care of Physician A and called Physician A to explain the apparent misadministration. Physician A confirmed that a TS+U had been ordered and not a TWBS.

The Nuclear Medicine Department physician decided to proceed with the whole body scanning (including the thyroid) and a 24-hour I-131 thyroid uptake measurement, which was done on May 19, 1992. These studies showed I-131 thyroid uptake only in the thyroid gland with a 66% uptake at 24 hours. The licensee's RSO calculated the radiation dose to the thyroid to be 14,350 cGy, based on a linear interpolation from information in the administered I-131 package insert. The insert indicated a dose of 35,000 cGy to the thyroid in a normal man given a 10-mCi dose of I-131. The RSO calculation multiplied the 35,000 cGy by 41%, which was the percentage of the 10-mCi dose that the patient received (i.e., 4.1 mCi). This calculation did not take into account the patient's enlarged thyroid gland or abnormal uptake. This method was also used to calculate the whole body dose of 6.56 Gy.

2.4.2 Consequences of the Misadministration. The INEL medical consultant estimated the radiation dose to the patient's thyroid was 4,572 cGy. This was calculated using the 4.1-mCi I-131 dosage, a 45-gram thyroid gland, a 66% uptake at 24 hours, a 5-day effective T1/2 in the thyroid, and Medical Internal Radiation Dose (MIRD) tables for the S value. The usual dose range using I-131 to treat Grave's disease would be 6,000 to 10,000 cGy to the thyroid. Generally, this requires a dose of 5 to 10 mCi I-131 for therapy. The diagnostic imaging dosages of I-131 for TWBS for thyroid carcinoma given to patients following partial or total thyroidectomy is 1 to 10 mCi.

The patient's exposure to I-131 will have a greater than 50% chance of causing her to become hypothyroid over the next 10 years. This risk is lower than if she had been treated with the usual higher dose given for Grave's disease, which has a 75 to 100% likelihood of causing hypothyroidism.

During the interview, Physician A stated that prior to the misadministration, he had anticipated treating the patient in 4 to 6 weeks with I-131 for Grave's disease after reviewing the treatment options with the patient. The options would have included I-131, a trial period of propthiouracil (PTU), or surgical resection of the thyroid. Physician A stated that almost 100% of the time he would have recommended I-131 therapy for a patient of similar age and similar symptoms. The dose of I-131 used would probably have been approximately 10 mCi. Both Physicians A and B predicted that this patient will eventually become hypothyroid from this dose or after a second dose of I-131 and will require thyroid hormone administration, as do nearly all patients treated with I-131 for Grave's disease. Both felt that the only adverse impact on the patient was the loss of her right of informed consent before being treated and the loss of the option to decline the recommended I-131 therapy.

2.4.3 Mitigating Actions. No mitigating actions were taken prior to the event investigation.

2.4.4 Direct Causes and Contributing Factors. The following are the direct causes and causal factors that led to the misadministration:

Organizational Policy and Procedures

The facility's QM plan was not in accordance with 10 CFR 35.32. Specifically, the facility allowed a non-authorized user to administer doses of I-131 greater than 30 uCi without a written directive.

Error of Judgment

The technologist delivered the dose of I-131 even though she had doubts regarding whether or not it was the correct dose or diagnostic procedure.

Communications

A communications error occurred when MS3 completed the nuclear medicine requisition card without a full description of the study. The card read "thyroid scan" instead of "thyroid scan and thyroid I-131 uptake."

A communications error occurred between the out-patient clinic nurse and the scheduling clerk when the study was originally called into the clinic. It was not determined whether the nurse or the clerk made the error.

The facility did not have a central source for patient and procedure information. Employees relied on each other for information about patients instead of contacting a physician or other better source. Along with this, employees were not trained in how to verify vocal communications.

The note that came up on the hospital computer system when the scheduling clerk entered the study, indicating Physician B was approved to perform the study, gave the hospital staff a sense that the study was appropriate.

MS 3 did not fully describe the procedure on the order sheet.

Changes and Unique Conditions

The wrong physician's name became associated with the patient because the scheduling clerk's roster listed him as the attending physician for the day.

All the nuclear medicine physicians were out during the time the technologist tried to verify the diagnostic study order.

2.4.5 Licensee Corrective Actions. The following were the licensee's corrective actions:

1. All future Radiology Department requisitions will be sent from each outpatient clinic (i.e., endocrinology) to the Radiology Diagnostic Imaging Department in a designated colored envelope. These will be delivered directly to the respective section in the hospital Radiology Department.

2. Fall of 1992 was the projected date for satellite clinics to be added or integrated into the preexisting computerized hospital Patient Services Ordering System, which all Diagnostic Imaging Scheduling was already using. This will eliminate the vocal scheduling between the clinics and the hospital.

3. A written directive will be completed by the authorized user before any dose of >30 uCi of I-131 is administered for either therapy or diagnostic purposes.

4. Any requests for nuclear medicine procedures that are not written will be verified by phone with the ordering physician or nurse, will include the name of the person verifying from the referring office, and will be countersigned by the hospital nuclear medicine physician.

5. The staff will receive an in-service every 6 months to review the details of the QM plan.

2.4.6 Discussion of Corrective Actions. The licensee's corrective actions appear to be

adequate for preventing recurrence of similar misadministrations, but may not be broad enough to eliminate other types of misadministrations.

2.5 Event E

Event E involved the manual brachytherapy treatment modality and was categorized as a misadministration involving delivery of a dose to the wrong site.

2.5.1 Description of the Event. The patient was a 69-year-old male with jaundice. An abdominal computerized tomography (CT) scan showed a 3-cm lesion obstructing the common bile duct. They bypassed the obstruction with percutaneous catheters. It was decided to give palliative brachytherapy through an existing catheter with iridium-192 (Ir-192). The initial plan was to give between 1500 and 2000 cGy to the tumor over 17 to 24 hours.

The radiation oncologist originally wanted to perform the procedure in Hospital B, but the patient wanted to have the procedure performed in Hospital A, which was closer to his house. The radiation oncologist agreed to do the procedure in Hospital A because she had done brachytherapy at Hospital A, though it was several years earlier (November 1989). The radiation oncologist contacted Hospital A's RSO and explained what she wanted to do. The radiation oncologist explained that she would handle all the details and use her medical physicist. The RSO then agreed to having the procedure done at Hospital A.

The nursing staff were made aware that the patient was coming and enacted the standard hospital procedure for handling radiation patients. The nurses were to read and sign an information sheet as they came on duty and before they cared for the patient. Also, the radiation detection badges were sent up to the nursing floor along with the badge log book.

October 1, 1992, 1400—Fluoroscopy was used to insert two plastic catheters into the patient in the existing metal stints in the common bile duct. The plastic catheters were sutured to the skin. Two ribbons containing dummy sources were then placed in the catheters and a simulation film taken. The dummy ribbons were then removed from the catheters. The patient was moved to recovery, and then later to the hospital room normally used for radiation treatment. The medical physicist performed the dosimetry from this film.

1430—The radiation oncologist placed a ribbon containing six Ir-192 seeds into each catheter, then tried to use a hemoclip to lock the ribbons in place. Because the plastic catheter would not crimp properly, he used surgical tape to fasten the ribbon to the catheter to keep it in place.

The physicist then performed a radiation survey and placed signs on the patient's door. A ribbon containing dummy sources was then attached to the patient's door with a note stating it was an inactive sample. The radiation oncologist then contacted the day charge nurse and explained the procedure. The radiation oncologist told the nurse that the ribbons and catheters were not to be disturbed. The radiation oncologist also said that if any problems arose the nursing staff were to call her.

1500—The day charge nurse explained the information about the brachytherapy to the evening charge nurse during shift change. She also showed her the inactive sample source ribbon attached to the patient's door.

2200—That evening, copious bile drainage was noted on the dressings. The evening nurse changed the dressing and notified the radiation oncologist of this by telephone. During this telephone conversation the radiation oncologist told the nurse not to change the dressings anymore, but to reinforce them only. The radiation oncologist then asked the evening nurse to go back in the room and check to see if the ribbons were still going into the catheters. The radiation oncologist called back in 10 minutes and the nurse informed her that the ribbons were still in place.

2300—During shift change the evening nurse discussed the patient with the night charge nurse and the LPN who would be caring for the patient. The LPN did not hear the complete discussion,

however, because she was called away to care for other patients. The evening nurse mentioned the problems she had with the patient's bile drainage and that she had called the radiation oncologist. The verbal order from the radiation oncologist to reinforce, but not change, the dressing was apparently not communicated. During the night, the LPN changed the dressing several times and even taped a urostomy bag over the ends of the catheters to help collect the bile.

0400, October 2, 1992—The LPN changed the dressing and noted that the Ir-192 source ribbons were both out of their catheters. The LPN handled the ribbons briefly and then went to find the night charge nurse. The night charge nurse and the LPN entered the room and they both looked at the coils laying on the patient's abdomen. The LPN then lifted each ribbon off the patient, coiled it around her hand, and taped the coil to the patient's lateral abdominal wall. The night charge nurse tore off pieces of tape and handed them to the LPN. They thought the seeds were in the catheters and were independent of the guide wires. It was not determined why they thought this. They also thought the Ir-192 sources would look like seeds. Both knew that radiation was present and that they needed to minimize their time in the room. The LPN handled the ribbons for between 30 and 120 seconds. Neither the LPN nor the night charge nurse knew the ribbons contained the source seeds. Since the LPN had been in the room for a relatively long period of time, the night charge nurse told the LPN that she would care for the patient for the rest of the shift.

0900—The patient was given a scheduled portable abdominal x-ray. Initial reading by the radiologist suggested that all the Ir-192 sources had been removed.

1000—The radiology special procedures nurse checked the patient and saw the ribbons taped to the patient's side. Further review of the portable abdominal film by the radiologist showed the ribbons on the patient's lateral abdominal wall, in an overexposed area of the film.

About this time, the day LPN checked on the patient and noticed the wires taped to the patient's abdomen. She contacted the day nurse who looked at the wires and saw the seeds in the end of the ribbon. The day nurse then contacted the day charge nurse who contacted the Radiology Department. The Radiology Department indicated they were already aware of the problem.

1100—The radiation oncologist was notified of the problem and arrived at the hospital at noon on October 2, 1992, and removed the ribbons from the patient. The sources had remained on the patient's abdomen while the hospital awaited the arrival of the radiation oncologist.

1600—The patient and the patient's primary physician were notified of the misadministration.

October 3 and 6, 1992—The patient was examined by the radiation oncologist who noted no skin erythema.

Dose Assessments

Physics calculations done by Hospital A gave the following exposure data:

Patient	1032 cGy to patient's skin
Evening Nurse	0.03 cGy whole body personnel exposure
LPN's Hands	7.6 cGy to the LPN's hands.

Calculations done by the NRC site visit team gave the following exposure data:

Patient	a. 3400-cGy point dose, given the source was 2 mm from the skin for 8 hours
	b. 600 cGy for a 1-cm region, given the source was 2 mm from the skin for 8 hours
Evening Nurse	0.028-cGy whole body dose, given the body was within 50 cm from all 12 sources for 20 minutes

LPN	0.039-cGy whole body dose, given the body was within 30 cm from all 12 sources for 10 minutes
LPN's Hands	14.4-cGy maximum dose, given a source was within 1 mm of the skin for 30 seconds
	1.5-cGy whole finger dose, estimated at a depth of 0.5 cm, assuming 30 seconds.

2.5.2 Consequences of the Misadministration. The patient received a possible dose of 600 cGy to a 1-cm^2 region near where the sources were taped to the skin. The patient may also have experienced a point dose of 3400 cGy. However, it was not determined exactly where the sources were on the body. The licensee reported that the patient did not experience any erythemia or other noticeable effects upon examination on October 3 or 6, 1992. The licensee also reported that the patient should not have any adverse long-term effects from the exposure.

The licensee reported that the LPN who handled the sources received a dose of 7.6 cGy, which was within occupational limits. However, the LPN had the potential for receiving an overexposure.

2.5.3 Mitigating Actions. The radiologist, upon reviewing the x-ray film taken on October 2, 1992, could not see the sources in place and had the special procedures nurse (SPN) investigate to see if the sources had been removed. The SPN saw the patient, noticed the ribbons out of the catheter, and talked with the nursing staff who indicated the sources should still be in. She plugged the catheters so more bile would not leak out and reported back to the radiologist, who again reviewed the film. Upon this review he noticed the ribbons in an overexposed part of the film and then contacted the radiation oncologist. The radiation oncologist then went to the hospital and removed the sources. However, the sources remained on the patient's abdomen until the radiation oncologist arrived at the hospital to remove them. This was approximately one hour.

The day LPN and nurse also saw the dislodged sources and reported to the day charge nurse who called the Radiology Department, but by this time the radiation oncologist had already been notified of the problem.

2.5.4 Direct Causes and Contributing Factors. The following are the direct causes and contributing factors:

Organizational Policy and Procedures

The licensee allowed a procedure to be performed in which the nursing staff were not experienced.

Radiation Safety Officer and Authorized User Oversight

The RSO did not ensure the nursing staff were adequately trained to care for a patient with a brachytherapy implant.

Training and Experience

The nursing staff were not adequately trained to care for patients with brachytherapy implants.

Errors of Judgment

The radiation oncologist used tape to fasten the source ribbon to the catheter. This was not a positive means of fastening the ribbon in place and, once the tape became soaked with bile, the adhesive began to fail and the ribbon could be more easily removed from the catheter. The radiation oncologist indicated that she could not hemoclip the catheter because it was made out of a different material than she was used to working with at Hospital B.

The radiation oncologist did not go to the hospital upon learning that the patient's bile duct had opened up and was soaking the patient's dressings with bile.

Communications

Communications at shift change did not supply the nursing staff coming on shift with the

necessary information to properly care for a patient with brachytherapy sources in place.

The radiation oncologist told the day nurse that the dressing and sources were not to be disturbed. However, the evening nurse changed the dressing and then called the radiation oncologist. During this conversation, the radiation oncologist informed the night nurse that the dressing was not to be disturbed, only reinforced. This information was not passed along.

The primary reason the dislodged ribbons were not discovered earlier was that the nursing staff were not trained to recognize the ribbons. Most of the nursing staff on the night shift thought the Ir-192 sources should look like seeds and were not part of the nylon ribbon. In fact, the nursing staff thought the ribbon was a guide wire of sorts. The evening and day shifts nursing staff were more aware of what the radioactive sources should look like.

Changes and Unique Conditions

The patient wanted to be treated in the hospital close to his home, rather than the hospital where the physician normally treated her patients.

2.5.5 Licensee Corrective Actions. Hospital A committed to the following corrective actions:

1. Replacing their current RSO with a person who could oversee the hospital's radiation activities more closely.

2. Developing a nurse's procedural manual that includes photographs of the equipment, as well as specific cautions with the stated emergency actions.

3. Conducting formal in-service training in radiation safety for all the unit workers who cared for patients requiring radiation.

4. Requiring that the written directive be initiated using radioactive material, before ordering.

2.5.6 Discussion of Corrective Actions. The corrective actions to which the licensee committed to implementing dealt primarily with nursing care of the patient. These corrective actions, however, appear to address only some of the issues concerning nursing care of the patient. It is not clear whether the manual the licensee was to develop would include procedures to ensure that special patient care instructions would be communicated to the appropriate staff at shift changes. If this is not done, then a similar misadministration might occur.

The direct cause that initiated the event was not addressed by these corrective actions (i.e., the failure of the physician to properly secure the sources in place).

Sources loaded and secured in a patient in a similar fashion could still become dislodged and expose the patient to radiation at an unintended site. The loose sources would not be detected until the next scheduled nursing check. If bandages obscured the treatment site, then the loose sources might not be detected for a long time.

2.6 Event F

Event F involved the manual brachytherapy treatment modality and was categorized as a misadministration involving delivery of a wrong dose.

2.6.1 Description of the Event. The patient was an 85-year-old male who had been diagnosed with cancer of the prostate. The radiation oncologist prescribed brachytherapy treatments with Ir-192. The prescribed dose was 3258 cGy. The brachytherapy treatment was completed as planned, and the radiation oncologist believed that the prescribed dose of 3258 cGy had, in fact, been administered. During preparation for a later brachytherapy procedure, however, it was discovered that the actual dose to this patient was approximately 5669 cGy.

The dosimetrist, while preparing an order of Ir-192 seeds for an upcoming prostate implant, reviewed previous prostate implant cases to estimate the amount of Ir-192 required for the

upcoming case. She noticed from the previous Ir-192 shipping records that the most recent patient was implanted with significantly greater activity than prior patients. Upon further review, she realized that an incorrect source strength had been entered into the treatment planning computer. This incorrect entry occurred because the dosimetrist had ordered the seeds in units of mCi (0.79 mCi per ribbon) but the shipping document that accompanied the seeds reported the source strength in units of mgRaeq (0.79 mgRaeq per ribbon). In logging in the shipment, the dosimetrist confirmed that the source strength number ordered matched the source strength number received (0.79) but failed to notice that the units were different.

Believing that the source strength was 0.79 mCi per ribbon, that value was entered into the treatment planning computer. As the source strength was actually stated in mgRaeq, the dose delivered was higher than calculated by the ratio of the exposure rate constants (8.25/4.66 = 1.77). The patient, thus, received a dose 77% higher than intended.

2.6.2 Consequences of the Misadministration. The patient received a dose of 5,669 cGy rather than the intended dose of 3,258 cGy. The licensee reported no observed effects.

2.6.3 Mitigating Actions. No mitigating actions were taken.

2.6.4 Direct Causes and Contributing Factors. The dosimetrist had normally ordered Ir-192 seeds from Supplier A in units of mCi. Supplier A's shipping document specifies the source strength in units of mgRaeq. The dosimetrist then converts the strength in mgRaeq back into mCi and enters this amount into the treatment planning computer. On this occasion, in an attempt to save money and procure a more easily handled source, the dosimetrist ordered the sources from a new supplier, Supplier B. As usual, the sources were ordered in units of mCi. The new supplier shipped the quantity ordered in units of mgRaeq. Supplier B's shipping document, like that of Supplier A, lists source strengths in units of mgRaeq. In this instance, however, the dosimetrist saw that the number of the source strength matched what had been ordered in mCi, failed to notice that the strength was expressed in mgRaeq, and entered that 0.79-mCi value into the treatment planning computer. One of the hospital's temporary part-time medical physicists checked the treatment plan for accurate digitization of the sources, verified that the computer reconstruction of the needles agreed with the localization x-rays, checked that the activities had been correctly decayed from the assay date, and checked that the correct ribbon strength was in the correct position. He did not, however, verify source strength from the original shipping document.

The investigation of this event revealed one primary cause and several contributing factors which served to predispose the error or make its prevention less likely. Each of these causal elements is discussed below.

Organizational Policy and Procedures

The major factor that allowed the error to occur was a lack of any formal procedure for verifying the source strengths. Although the licensee's QMP requires verifying source strength prior to treatment, the staff were unfamiliar with the provisions of the QMP and no specific procedure for source strength verification had been developed. A procedure that ensured either direct verification (assay) or indirect verification (a checklist that required verification and sign-off on source strength, including the units in which the strength were expressed) would have made the likelihood of this type of error much lower.

Radiation Safety Officer and Authorized User Oversight

The investigation revealed that the facility's QMP was not fully implemented. In fact, the part-time medical physicists had never seen the plan. The facility's RSO and the director of radiology both reported that formal training regarding the QMP had not been developed.

Training and Experience

The dosimetrist who failed to notice that the units of the source strength differed from that which had been ordered was relatively inexperienced in ordering and receiving the sources. The order, which is the subject of this misadministration, was the third order that the dosimetrist had processed. Earlier orders were processed by the facility's full time medical physicist. Prior to leaving the facility, the physicist trained the dosimetrist in how to process orders of sources.

Interpretation Error

The primary cause of the misadministration was a wrong interpretation of the source strength units. The dosimetrist apparently verified only the number, not the units. This error represents a simple lack of attention to detail. While, ideally, such an error should not occur, such errors will occur from time to time. They become even more likely when the facility's procedures and practices do little to prevent them.

Changes and Unique Conditions

The use of a new supplier of the sources may have contributed to this misadministration in that the dosimetrist may have assumed (based on the fact that the number of mgRaeq received matched the number of mCi ordered) that the units received were the units ordered. It was noted during the investigation, however, that the shipping label that accompanied the order received from the new supplier was very similar to the labels sent by the previous supplier. The dosimetrist may have unconsciously believed they expressed the source strengths in different units based on the change of suppliers and the fact that the numbers ordered matched the numbers received.

Organizational Factors

During the investigation, it was learned that the facility was relying on the services of two part-time temporary medical physicists and had been unsuccessful in hiring a full-time permanent medical physicist. Because of their part-time status, the physicists had been reluctant to make significant changes in the practices and procedures used by the Radiology Department. Both noted, however, that the procedures used in their home facilities were much more formal and rigorous. Both reported, for example, that they routinely assayed sources to verify source strength. The transitional status of the Radiology Department with respect to the duties of the medical physicist position very likely contributed to this misadministration.

2.6.5 Licensee Corrective Actions. The facility has implemented two corrective actions intended to prevent recurrence of this type of event.

1. A new brachytherapy implant checklist has been developed. The checklist requires, among other things, positive verification of source strengths (including specification of mCi or mgRaeq) and independent checking by the medical physicist.

2. The facility has developed a policy and a procedure to assay the source activities in the dose calibrator, thus providing an additional independent check.

2.6.6 Discussion of Corrective Actions. The two corrective actions implemented by the licensee addressed some of the direct causes of the misadministration. Broader corrective actions, however, focusing on staff training and implementation of the QMP, would result in improved patiert and staff safety.

2.7 Event G

An abbreviated description of Event G is presented here. The event is described thoroughly in NUREG 1480 (1993). Only the events that occurred in the treatment facility itself are discussed below.

2.7.1 Description of the Event. On November 16, 1992, an 82-year-old female patient was undergoing radiation therapy for an anal carcinoma. The radiation therapy was to be administered by a HDR afterloader with five connecting catheters. For that day's treatment, a dose of 6 Gy (600 rad) was to be administered through five

catheters implanted as a single-plane perineal (rectal) implant encompassing the tumor. After a trial run through the five catheters with a dummy source, the Ir-192 source was easily placed in four of the five catheters. After several unsuccessful attempts to insert the source into the fifth catheter, the physician directed termination of the treatment. An area radiation monitor in the treatment room was observed in an alarm condition—flashing red light—at some point during the unsuccessful attempts to insert the source into the fifth catheter. Although three technologists and the physician were aware of the alarm, no one used the available portable survey meter to detect whether radioactivity was present. Believing that the area radiation monitor was malfunctioning, they reset the area radiation monitor and returned the patient to a local nursing home without performing any radiological surveys. The staff were unaware that the Ir-192 source had remained in the patient.

The patient was returned to the nursing home where she resided with four of the original five treatment catheters, one containing the Ir-192 source, in place. One loose catheter had been removed at the clinic. The source remained in the patient's body for almost four days. On the fourth day, the catheter with the source came loose, and early on the morning of November 20, 1992 the catheter fell out. The patient died on November 21, 1992.

On December 1, 1992, the Licensee's medical physicist notified NRC Region I that a 1.37 E+11 Bq (3.7-Ci) Ir-192 sealed source was missing from the licensee's HDR afterloader. The medical physicist believes that a radioactive source discovered by Browning-Ferris Industries (BFI) at their nonradioactive medical waste incinerator facility in Warren, OH, and later returned to another BFI facility in Carnegie, PA (BFI-Carnegie), could be the same source that was missing from the HDR afterloader at the licensee's facility.

2.7.2 Consequences of the Misadministration. The NRC's medical consultant determined that the radiation the patient received from the Ir-192 source was a probable contributing cause of her death.

2.7.3 Mitigating Actions. The licensee did not perform any actions in the treatment facility to lessen the effect on the patient.

2.7.4 Direct Causes and Contributing Factors. The direct causes and contributing factors are listed below:

Organizational Policy and Procedures

The licensee allowed a technologist to operate the HDR unit without adequate training.

The clinic had a set of emergency operating procedures, but they did not specifically address the event, and the staff had not been trained on them.

Radiation Safety Officer and authorized user Oversight

The RSO did not ensure that the authorized user and technologists at the facility were adequately trained.

Training and Experience

The technologists had not been given radiation safety training since they began their employment at the facility. In some cases, this was several years.

The technologists had not received formal training on how to use a radiation survey instrument. The medical physicist had only given them informal training on its use.

The technologist had not been trained on what constituted an emergency nor what to do in emergencies.

The clinic's authorized user had not ensured that the staff were adequately trained. In fact, the RSO did not ensure that the authorized user was properly trained.

Supervision

The physician did not take an adequate supervisory role when informed of problems encountered

during the patient's treatment. The physician tried to help the technologists complete the treatment, but he did not try to find the cause of the problem, nor did he direct the technologists to find the cause of the problem. Instead, he curtailed the treatment without conducting any sort of investigation or radiation survey to ensure that the sources had returned to their shielded position prior to removing the patient from the treatment room.

Interpretation Error

The technologists thought the radiation alarm was giving a false positive alarm, rather than actually detecting radiation in the room.

Hardware Failure

The wire containing the source broke. At the conclusion of the investigation it was determined that the likely cause of the wire breaking was hydrogen fluoride attack caused by the breakdown of Teflon in the presence of moisture and a high radiation field.

Organizational Factors

The licensee relied on a part-time medical physicist who was not readily available to perform the functions normally delegated to them, such as providing radiation safety information and performing daily quality assurance checks. The RSO was not readily available either.

The technologists, physician, and medical physicist assumed the source wire would not break. This assumption was instilled in them by the HDR device manufacturer. This displayed a poor safety culture because the individuals did not have a questioning attitude. They assumed that everything was fine when a radiation alarm sounded, thinking that it was the alarm that failed and not the source wire. This assumption was reinforced by the HDR device's display that showed the source being safely parked.

Workplace Design

The workplace design prevented the HDR operator from watching the closed circuit TV patient monitor and the HDR computer monitor at the same time. Therefore, while watching the patient, the HDR operator may not have seen some of the important error messages presented on the HDR computer monitor.

2.7.5 Licensee Corrective Actions. The licensee committed to implement the following corrective actions:

1. Physician A directed the staff to follow additional precautions for HDR brachytherapy treatments. These proposed precautions included performing additional radiological measurements during HDR patient treatment by placing a diode detector probe near or over the center of the treatment location. This detector will be used to verify that no radioactive material remains in the patient.

2. Personnel involved in HDR brachytherapy treatments will be trained on radiation safety practices. Additional training will be given semiannually.

3. The documentation of radiological surveys, quality control verifications, and training will be improved.

4. The RSO stated that an independent outside contractor will perform an audit of practices in the department. The RSO will also conduct an internal audit.

2.7.6 Discussion of Corrective Actions. This was the only event in which the licensee committed to broader corrective actions than those limited to preventing a recurrence of a similar misadministration. The actual implementation of these corrective actions was not assessed and, therefore, it is difficult to determine whether the corrective actions would be adequate to prevent a similar misadministration or other types of misadministrations.

3. SUMMARY OF EVENT CONSEQUENCES, DIRECT CAUSES, AND CONTRIBUTING FACTORS

This section summarizes the consequences, direct causes, and contributing factors associated with the seven misadministration events investigated in this project. In addition, it presents definitions and explanations of the direct causes and contributing factors identified.

3.1 Observed Consequences of Misadministrations

The consequences of the misadministration events investigated range from no effect on the patient to the probable contributing cause of death. The specific consequences of each of the events which were investigated are summarized in Table 3-1.

Table 3-1 shows the wide range of consequences of the misadministration events investigated for this project. Some of the misadministrations had minor or no immediately observed adverse effects. One event caused an immediate, acute skin reaction (Event C). One event (Event D) has the potential for causing the patient a physical disability, namely the impairment of the thyroid gland, at some point in the future. It is evident that misadministrations can also result in very grave consequences, as illustrated by Event G in which the misadministration was a probable contributing cause of the patient's death. The actual long-term consequences of the misadministrations were not determined as a part of this study.

3.2 Direct Causes and Contributing Factors

The principal product of the analyses of each of the events is an identification of the direct causes and the contributing factors that predisposed the direct causes. For the purposes of this project, a direct cause is a fundamental condition or error that directly results in the occurrence of a misadministration. A direct cause is the absence, inadequacy, or improper implementation of a policy, procedure, action, or decision that directly initiates or propagates the misadministration event. Contributing factors are conditions, often environmental or contextual, which do not directly cause a misadministration. Rather, these conditions serve to increase the likelihood that a direct cause will manifest itself, resulting in a misadministration.

Table 3-2 presents a matrix that summarizes the direct causes of the events. Table 3-3 presents a matrix of contributing factors for the events. The direct causes and contributing factors associated with the misadministrations analyzed in this project are defined below.

3.2.1 Direct Causes. In looking at the direct causes of the misadministrations analyzed for this project, it is interesting that each of the events involved more than one direct cause. This finding suggests that any steps taken to prevent misadministrations in the future should be systematic in nature and should not address only specific direct causes.

One direct cause found in every misadministration investigated involved organizational policy and procedures. The licensees at these facilities either (a) lacked the policies or organizational procedures needed to adequately direct and control the treatment processes, or (b) failed to follow such procedures.

Another significant direct cause was lack of oversight of program activities by the RSO. RSO actions or lack of actions affected five of the events. Similarly, a lack of direct involvement on the part of authorized users was a direct cause in two of the events and may have played a role in others as well. The direct causes are discussed by type below.

Policy and Procedures. The policies and procedures implemented, both explicitly and implicitly, by licensees appear to be the primary factors in determining the success or failure of the radiation safety programs. A procedure that is

Table 3-1. Consequences of misadministrations. (The radiation doses listed in this table are approximate.)

Event	Treatment modality and reason for treatment	Type of event	Doses and observed consequences[a]
A	High dose rate brachytherapy for a tumorin the nasal septum.	Wrong site	The patient received an unintended dose of 76 cGy to the lips. The licensee reported no observed effects.
B	Teletherapy for non-small-cell lung cancer that had metastasized to the right scapula.	Wrong site	The patient received an unintended dose of 600 cGy to the lung and spinal cord. The licensee reported no observed effects.
C	Manual brachytherapy for cervical cancer.	Wrong site	The patient received an unintended dose of 3500 cGy to the labial skin. The licensee reported the patient experienced local, moist desquamation in this area. The patient also received an unintended dose of 450 cGy to the inner aspects of the thighs. No effects in this area were observed.
D	Diagnostic iodine-131 for the diagnosis of an enlarged thyroid gland.	Wrong dose	The patient received a total dose of 4,572 cGy to the thyroid, rather than the intended diagnostic dose.[b] The licensee reported no immediate observed effects.
E	Manual brachytherapy for a tumor obstructing the common bile duct.	Wrong site	The patient received an unintended dose of 1,032 cGy to a 1-cm^2 area of the abdominal skin. There were no observed effects. An LPN received an unintended dose of 7.6 cGy to a hand. The LPN experienced no observed effects.
F	Manual brachytherapy for prostate cancer.	Wrong dose	The patient received an unintended dose of 5,669 cGy rather than the intended dose of 3,258 cGy. The licensee reported no observed effects.
G	High dose rate brachytherapy for an anal carcinoma.	Wrong dose	Probable contributing cause of death.

a. The doses of radiation that the patients and hospital staff received and the observed effects contained in this table were reported by the licensee. The observed effects reported in this table were those that were apparent at the time of the team investigations. Section 4 discusses the doses and observed consequences in more detail.

b. The INEL medical consultant calculated this dose based on information collected during the investigation. The licensee's RSO calculated the dose as 14,350 cGy, but did not consider all the parameters (such as percent I-131 uptake) necessary to estimate the dose to the thyroid.

Table 3-2. Matrix of direct causes.

Direct cause	Event						
	A_{HB}	B_T	C_{MB}	$D_{I\text{-}131}$	E_{MB}	F_{MB}	G_{HB}
Organizational policy and procedures	X_I	X	X	X	X	XI	X
Radiation safety officer oversight	—	—	X	—	X	X	X
Training and experience	X	—	X	—	X	X	X
Supervision	—	—	X_I	—	—	—	X
Decision errors: errors of judgment	—	—	—	X	X_I	—	—
Decision errors: interpretation errors	X	—	—	—	—	X	X
Communications	—	X_I	—	X_I	X	—	—
Hardware failures	—	—	—	—	—	—	X_I

HB = high dose rate brachytherapy

MB = manual brachytherapy

T = cobalt-60 teletherapy

I-131 = diagnostic I-131

XI = initiating direct cause. This is the direct cause of the event.

well conceived and implemented serves to decrease the likelihood or severity of misadministration events by (a) anticipating potential errors or failures, (b) eliminating conditions that could contribute to the occurrence of misadministrations, (c) imposing independent verification and monitoring to ensure that errors or failures are detected and corrected, and (d) clearly delineating the authority and responsibilities of all persons involved.

Radiation Safety Officer and Authorized User Oversight. The RSO is required by the NRC to implement the licensee's radiation safety program. Key responsibilities of the RSO include developing and implementing procedures for byproduct material inventory management, safe use of byproduct materials, personnel training, and implementing corrective actions. A lack of sufficient RSO oversight is defined as a failure on the part of the RSO to exercise adequate supervision or personal involvement in the radiation safety program to prevent misadministration events.

Authorized users are physicians who have received special training and experience in the clinical use of byproduct material. They are the persons authorized to prepare the written directives that define the treatments or procedures administered to patients. A lack of sufficient authorized user oversight is manifest as a failure to prepare a written procedure or directive, or a lack of sufficient involvement with the patient to

Table 3-3. Matrix of contributing factors.

Contribution cause	Event						
	A_{HB}	B_T	C_{MB}	$D_{I\text{-}131}$	E_{MB}	F_{MB}	G_{HB}
Changes and unique conditions	X	X	X	X	X	X	—
Organizational factors	—	—	—	—	X	—	X
Labeling	—	—	X	—	—	—	—
Hardware incompatibilities	—	—	X	—	—	—	—
Workplace design	—	—	—	—	—	—	X

HB = high dose rate brachytherapy

MB = manual brachytherapy

T = cobalt-60 teletherapy

I-131 = diagnostic I-131.

ensure that the right patient receives the right treatment.

It is difficult to separate problems with RSO oversight from problems of organizational policy and procedures because the RSO has, to a certain degree, control of the policies and procedures. However, for the purposes of this report, we use a separate category to capture what we believe were significant problems with a licensee's RSO oversight.

Likewise, it is difficult to define precisely what level of involvement constitutes sufficient involvement on the part of the authorized user. At a minimum, preparation of a written directive (in accordance with 10 CFR 35.32) based on direct knowledge of the patient's condition, and a hands-on approach to ensuring that those written instructions are in fact carried out as ordered, should be expected. For the purposes of this report, a lack of a written directive or a lack of direct personal involvement on the part of the authorized user is defined as lack of authorized user oversight.

Communications. Clear communication, both written and vocal, is vital to the prevention of misadministrations. Lack of or ambiguous written directives, inadequate treatment or care instructions, and inadequate definition of staff responsibilities are all examples of communications problems that have the potential of leading to misadministrations. Several of the events investigated as part of this program were caused, at least in part, by poor communication. Problems with communication set in motion Events B and D and significantly contributed to Event E.

Training and Experience. Although a licensee's policies and procedures should prevent inadequate training and experience from leading to a misadministration, several of the events investigated involved both inadequate procedures and a lack of sufficient training and experience. For the purposes of this report, adequate training and experience is defined as formal education, on-the-job training, and general work experience that is sufficient to develop the knowledge and skills required to perform tasks. None of the misadministration events investigated were initiated by a lack of training or experience. They did,

however, have direct effects on Events A, C, E, F, and G.

Supervision. Closely related to the issue of training and experience is the issue of supervision. Indeed, one of the roles of supervision is to provide guidance and oversight for persons who may not have adequate experience and training to perform independently. When combined with a lack of adequate procedures, lack of training and experience, or other factors, inadequate supervision can be a direct cause of misadministrations. Although lack of supervision could manifest itself in a number of ways in medical misadministrations, the most obvious would include a lack of involvement on the part of RSOs, authorized users, chief technologists, or department managers. Medical physicists, nurse supervisors, and other personnel may also be assigned supervisory duties that are important to patient safety. A failure to perform these duties constitutes a lack of adequate supervision.

Decision Errors. Decision errors are cognitive in nature. A decision error occurs when a person makes an erroneous or ill-advised decision based on available information and situational factors. It should be pointed out that the identification of decision errors can sometimes be quite subjective and, in some cases, decision errors are positively identified only after some undesired outcome has been experienced or observed. For the purposes of this project, two different types of decision errors are defined. Errors of judgment are defined as decisions to perform some action, or to perform it in a particular way, when the action is clearly contraindicated or when the potentially negative outcome of performing a task in a particular way should be reasonably foreseen. Interpretation errors are defined as failures to properly recognize or interpret indications, signs, alarms, or other cues. Both types of decision errors were identified as direct causes of events examined in this project.

Hardware Failures. Physical failures of the equipment used in the administration of medical radioisotopes represent potential direct causes of misadministrations. Only Event G involved a hardware failure. During this event, the source wire broke while in the patient. At the conclusion of the investigation into this event, it was determined that the likely cause of the wire breaking was hydrogen fluoride attack of the wire caused by Teflon breakdown in the presence of moisture and a high radiation field.

In many postulated scenarios, prompt detection of hardware failures will serve to prevent a misadministration from occurring or reduce the severity of any misadministration that might occur. Because of the potential severity of hardware failures, training and procedures designed to detect and correct hardware failures become very important.

3.2.2 Contributing Factors. The contributing factors identified during the misadministration event investigations are shown in Table 3-3. The most common contributing factor is labeled Changes and Unique Conditions. This contributing factor was identified in six of the seven events. Other contributing factors were also identified. Definitions and summaries of each of these contributing factors in the events investigated are discussed below.

Changes and Unique Conditions. All but one of the events involved a recent change or something about the procedure that was unique. The most common change was that the medical specialist who was to perform, monitor, or contribute to the treatment of the patient was busy or not available. As a result, another person, often less familiar with the patient's identity or condition, the treatment process, or other issues, became involved in the process. Another common finding was that the treatment performed was new to the staff or had been modified from the way it was normally performed. These treatment modifications were not always fully or accurately communicated to the persons who actually performed the treatment.

One of the events investigated involved unique factors associated with the patient. In this event, the patient was physically unable to

assume the customary position for the treatment to be administered.

Labeling. Aadequate or ambiguous labeling of materials or material storage areas used in radiation oncology and nuclear medicine procedures are potential contributors to misadministrations. One of the events investigated in this project involved this contributor. Inadequate or ambiguous labeling of materials or materials storage areas constitutes one form of potential labeling problems; other forms of this contributor could include labels on equipment, equipment controls, gauges, and other indicators. Information collected in this project suggests that error codes generated by devices used in treatments may sometimes be inadequate or difficult to understand.

Organizational Factors. The category of organizational factors concerns the structure of the organization, roles of the persons within the structure, the relationships among the individuals, and the organization's culture. Safety culture is a subset of the organization's culture and includes the knowledge, beliefs, values, and attitudes of the staff concerning patient and personnel safety.

It is, again, difficult to break out organizational factors as a separate category because all aspects of the organization, from organizational policy and procedures to decision errors, can be considered organizational in nature. However, for the purposes of this report, issues related to interpersonal relations, organizational structure, and corporate culture that appear to be directly related to the occurrence of a misadministration event are defined as organizational factors. Examples of organizational factors that contributed to the occurrence of misadministrations include interpersonal difficulties that may have resulted in poor communication, the use of part-time temporary employees in key positions, and a work environment that did not promote a questioning attitude on the part of the staff.

Hardware Incompatibilities. Hardware incompatibilities occur when persons combine and use pieces of equipment that are not designed to be used together. For example, use of an incorrect combination of a source and an applicator may result in the source not being properly placed for the treatment. Only one of the events analyzed for this project involved hardware incompatibility.

Work Place Design. Work place design is a contributing factor that deals with the way in which the work area is arranged, whether there is adequate lighting, what the ambient noise level is, whether there are physical impediments to persons performing tasks, and similar issues.

4. LESSONS LEARNED

The general lesson learned from this project is that licensees who have experienced misadministration events often lack a comprehensive radiation safety culture, which shapes all aspects of daily operations and which regards patient and staff safety as the primary objective of all activities. This general conclusion is borne out by the results of the on-site team investigations and the review of misadministrations reported to the NRC between 1987 and 1992 and documented in NUREG reports. More specific lessons learned in this project are detailed in the remainder of this section. These lessons are based on thorough analyses and can provide valid and useful insights into the apparent causes of medical misadministrations. Careful consideration of these lessons thus provides a means by which the frequency and severity of these events may be further reduced.

The following subsections report the lessons learned in this program regarding the direct causes and contributing factors, consequences, mitigating factors, and licensee corrective actions associated with misadministration events.

4.1 Direct Causes and Contributing Factors

The direct causes and contributing factors associated with misadministrations are the reasons for, or conditions which contribute to, the occurrence of these events. While it is recognized that the frequency of misadministration events cannot realistically be reduced to zero, correction or elimination of direct causes is, hypothetically, the means by which misadministrations can be eliminated. By addressing contributing factors, the likelihood of direct causes producing misadministration events can be reduced.

4.1.1 Many Misadministrations Occurred Primarily from a Lack of Rigorous Procedures or a Failure to Follow Procedures.

Medical misadministrations are, in effect, operational errors and, like operational errors in any other setting, occur from what is often regarded as human error. It is well recognized that human error can never be eliminated. This recognition is reflected in such common observations as "to err is human" and "we all make mistakes." Recognizing the susceptibility of even highly educated and well-intentioned people to the possibility of human error, a number of potentially high risk technologies have adopted a highly proceduralized formal approach to their day-to-day operations. Examples of technologies that have benefited from this kind of formalism include commercial aviation, nuclear power plant operations, manned spacecraft flights, nuclear weapons launch control, and some types of chemical processing. In each of these settings, the potential consequences of human errors are clearly recognized and, based on this recognition, rigorous procedures have been developed that result in the creation of systems that are more error tolerant and in which the probability of human error is substantially reduced. Data collected in this program suggest that many misadministrations occur because there is no formally proceduralized environment for administering medical radioisotopes.

Effective procedures provide step-by-step instructions in a clear, concise manner for the completion of all tasks. They anticipate potential problems and provide a means for detecting, avoiding, or correcting these problems. As such, they help to address other potential direct causes of misadministrations such as a lack of training, ineffective communication, or decision errors. They ensure that independent, positive, and sometimes redundant verification of certain questions or issues is obtained prior to proceeding with critical tasks or steps. They ensure that appropriate personnel are assigned specific responsibilities and that any deviations from the procedure can only occur when an authorized individual orders such a deviation.

Note that merely developing good procedures will not prove effective unless those procedures are fully implemented. Proper implementation means that staff members are aware of the procedures, understand them, have received training regarding the intent and provisions of the procedures, and that the procedures are unfail-

ingly used and adhered to. Even the best procedures are useless if they are not understood or used by the staff.

Contrary to some perceptions, formal procedures effectively implemented need not add to administrative burden or inhibit the exercise of professional judgment. A great deal of flexibility can be retained in using effective procedures with the proviso that this flexibility can be exercised or authorized only by staff members who have the knowledge, training, experience, and responsibility (both legal and administrative) to deviate from the standard procedure. A well-implemented procedure can free professionals to concentrate on issues that most require their attention by diminishing the ad hoc nature of many aspects of the daily routine.

Each of the misadministrations analyzed in the team investigations involved a lack of procedures, inadequate procedures, or a failure to follow procedures. Procedures that require the positive verification of patient identity, isotope source strength, location of the source, or the intended medical procedure (through the use of a written directive) would have prevented four of the seven misadministrations. Procedures that provide for adequate staff training and proper identification and storage of sources would very likely have prevented or reduced the severity of the remaining three misadministrations.

Inadequate procedures or a failure to follow procedures can also be considered to be the source of several of the other direct causes of misadministrations investigated in this program. These other direct causes include a lack of adequate training programs, poor communications, and some kinds of decision errors. Generally, these are considered *human factors* issues.

4.1.2 Significant Impact on the Substantial RSO and Authorized User Involvement Has a Risk of Misadministrations.

10 CFR 35.21 states

A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

Specific duties of the RSO, defined in NRC regulations, include investigation of accidents, spills, losses, thefts, misadministrations, or other deviations from approved radiation safety practices; byproduct material inventory management; training personnel who work with or around byproduct material; and a variety of record-keeping tasks. Authorized users are physicians who have received special training and experience in the clinical use of byproduct material and are authorized to prepare written directives ordering nuclear medicine and radiation oncology procedures.

In an ideal implementation of the responsibilities set forth for the RSO and authorized users in 10 CFR 35, the RSO would exercise direct oversight to ensure effective implementation of a comprehensive and proactive radiation safety program, including implementation of the QMP. Authorized users would be directly responsible for ensuring that the instructions they issue for the use of byproduct material are carried out as directed. In short, RSOs and authorized users would assume hands-on responsibility for ensuring that the right patient receives the right treatment, and that the safety of the patient and the licensee's staff is not compromised. The results of the investigations suggest, however, that some designated RSOs and authorized users may have very little direct knowledge or control over many aspects of the day-to-day operation of the nuclear medicine and radiation oncology (therapy) departments in licensee facilities.

The investigations suggest that, in some cases, the RSO may function minimally, in a purely administrative capacity. The duties of the RSO may be regarded as peripheral to, or of little significance relative to his or her *real job* (i.e., the RSO function has been added to his or her main job responsibilities). In these cases, the RSO may exist only on paper in so far as actually carrying

out the defined role. Based on findings of the investigations conducted during this study, it appears that some authorized users confine their role to ordering diagnostic and therapeutic procedures without assuming direct responsibility for ensuring that their orders are carried out as directed. In one case, the licensee's authorized users had no direct involvement with the patient, and they did not sign a written directive for the diagnostic procedure before the dose was given to the patient. The authorized users involved in the misadministrations investigated by the teams did not always understand the role of the RSO, nor the provisions of the QMP. In one case, the authorized user did not even know who the licensee's RSO was.

4.1.3 The Contribution of Hardware Failures to the Overall Risk of Misadministrations Is Uncertain. Only one of the team investigations involved a misadministration that was directly caused by an equipment failure. Based on the analysis of this event and the other misadministrations reported between 1987 and 1992, it would appear that the frequency of hardware failures resulting in misadministrations is extremely low. The consequences of these hardware failures are, however, potentially very severe. The misadministration investigated in this program that occurred because of a hardware failure, apparently contributed to the death of the patient being treated. Because overall risk is often defined as the product of frequency and consequences, this risk contributor of potential hardware failures may not be as insignificant as is often believed. It seems likely that the evolution of a more rigorous safety philosophy through the implementation of disciplined procedures could result in the creation of *fault tolerant* systems in which hardware failures, should they occur, could be quickly detected and corrected. Thus, by implementing systematic mechanisms to detect and mitigate hardware failures, the overall impact of these failures might become negligible.

4.1.4 Changes in Routine and Unique Conditions Often Predisposed Misadministration. Unique conditions and changes in routine were identified as highly significant contributors to the misadministrations investigated in this project. These changes or unique conditions might include such things as a personnel change, change supplier of equipment or materials, performing a treatment in a new location, or treating with a patient who cannot assume the usual position for the prescribed treatment. These changes or unique conditions serve to introduce unfamiliar and possibly difficult circumstances, which tend to increase the likelihood of errors. By themselves, changes or unique conditions probably would not lead to a misadministration. Rather, they serve to increase the likelihood that a direct cause will manifest itself in such a way as to result in a misadministration. There were two ways licensees responded to changes and unique conditions within the cases examined:

1. Licensees were insensitive to these factors. For example, certain licensees failed to take additional precautions when they knew a procedure was new or unique because they did not recognize the need to do so.

2. Licensees were sensitive to the issue, but were ineffective in implementing additional safety measures or failed to do so at all. For instance, a licensee knew that they were performing a unique procedure and took steps to ensure problems did not occur, but these steps failed to prevent a misadministration.

These findings suggest that it would be beneficial for the licensees to establish mechanisms that help them anticipate problems associated with changes and unique conditions. One such mechanism is to design procedures using human factors principles. The formalism of clear, concise, disciplined procedures can lessen the need to rely on improvisation in dealing with unfamiliar situations. Additionally, such procedures may have the positive effect of causing the staff to slow down, seek further guidance, verify critical information, or to involve other appropriate personnel.

4.1.5 Misadministrations Often Resulted from the Interaction of Multiple Causes. Each of the misadministrations that were the focus of the team investigations involved more than one cause. Beyond the obvious difficulties of pinpointing a single root cause of each event, this finding suggests that simple fixes that focus on

only a single cause may not have the desired effect. Rather, initiatives are called for that will address multiple direct causes of misadministrations. This again indicates the need for an integrated, comprehensive, and systematic approach to ensuring that patient and staff safety are paramount to every other aspect of the licensee's operations.

4.2 Lack of Effective Implementation of Quality Management Programs

10 CFR 35.32 requires that each licensee shall establish and maintain a written QMP to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. Among other things, the QMP requires the use of written directives prior to the administration of the prescribed dose, positive and redundant identification of the patient, and treatments planned and delivered in accordance with the written directive. Provisions are made for oral directives in the event of emergencies. Data collected in this program indicate that some licensees have not effectively implemented QMPs.

Some of the licensees involved in misadministrations investigated in this project viewed the QMP requirement as merely a paper requirement that is largely irrelevant to them, and, consequently, approached compliance with the requirement as a pro forma exercise. Although they may have developed a QMP, they did not achieve true implementation of the intent of 10 CFR 35.32 in that the plans were not known or used by licensee staff. It was observed that, in several instances, the licensee's staff were unaware of the existence or applicability of the licensee's QMP. In one case, the licensee's RSO had signed the QMP but could not remember what it contained. In another case, the QMP did not meet the requirements of 10 CFR 35.32. At least one of the team investigations revealed that the licensee's QMP had been prepared by a consultant and that the licensee had little or no direct involvement in preparing or implementing it. All of this suggests that some licensees may not understand the requirements and intent of 10 CFR 35.32.

4.3 Mitigating Actions

Four of the seven misadministration events investigated were mitigated during the course of the patient's treatment. Two of these events, however, were only detected and mitigated because of fortuitous circumstances (luck) and not because some systematic procedure or check was designed to detect errors. Thus, only two of the seven misadministrations were discovered as the result of systematic checks for problems. In one of these cases, however, the problems were not detected until after the second fraction was delivered. In the other event, which was detected by systematic means, the error was not corrected until Ir-192 sources had remained taped to the patient's abdomen for almost three hours.

These findings suggest that a fully adequate means of detecting and mitigating problems did not exist in the seven events studied. To the extent that the facilities and processes examined in this project represent other licensees, this implies that there is great opportunity for the imposition of positive checks and controls to improve the procedures, allowing timely correction of problems that may develop in the course of these treatments.

4.4 Consequences

The consequences of the misadministration events investigated ranged from little apparent adverse effects on the patient to the probable contributing cause of a death. The primary lesson regarding consequences from these investigations is that, even though some of the misadministrations investigated had minor or no immediate observed adverse effects, unless prevented or, at worst, promptly detected and mitigated, there is the potential for a misadministration to cause acute physical symptoms, physical impairment, or even death. Also, generally, the consequences of treatment and diagnostic modalities are relative to the dose delivery rate and whether the dose is fractionated. There is more time to intervene when dealing with a manual brachytherapy treatment that might take up to 48 hours to complete.

During a 10 fraction teletherapy treatment there are scheduled stop points of up to several days at which time reviews can be performed. Conversely, for HDR brachytherapy and I-131, there is less time to intervene since an HDR brachytherapy may only last a few hundred seconds and, once the I-131 dose is swallowed, few options exist for mitigation.

4.5 Corrective Actions

As discussed, the INEL team arrived at a licensee facility shortly after a misadministration was discovered and reported to the NRC. For the majority of the events investigated, the licensee had already developed a set of corrective actions to prevent a recurrence of the misadministration. A subset of these licensees had begun to implement the corrective actions. In a few cases, the licensees had not developed corrective actions. In no cases had the corrective actions been in place long enough to unequivocally determine whether, in the long term, they would effectively prevent recurrence of a similar misadministration. Also, the INEL could not determine the degree to which the licensees had implemented the corrective actions. The INEL team did, however, review the corrective actions developed by the licensees. Based on this review, the INEL Team formulated an opinion on the effectiveness of the licensees' corrective actions. Because of the difficulty in making generalizations concerning their effectiveness, the licensee corrective actions for each event were discussed in Section 2. Most of the corrective actions were narrow in focus. In general, the corrective actions addressed only those issues associated with the misadministration event being investigated and not the system as a whole. Therefore, it appears that even if the licensees' corrective actions were effective, they might not prevent a misadministration involving other direct causes, contributing factors, treatment modality, or other characteristics not present in the event being investigated.

5. REVIEW OF CAUSES, SEVERITIES, AND CORRECTIVE ACTIONS OF PAST MISADMINISTRATIONS

In order to learn more about selected aspects of misadministration events, the INEL compiled and analyzed an extensive data base dealing with past misadministrations. Four specific issues are addressed in this analysis. These issues are

1. Common causes of misadministrations
2. Correlations between direct causes and severities of misadministrations
3. Preventability of misadministrations through proper implementation of licensee Quality Management Plans
4. Causes of multiple misadministrations and adequacy of licensee corrective actions to prevent multiple misadministrations.

This section describes the INEL's approach to analyzing these issues and presents the findings of these analyses.

5.1 Data Collection and Data Base Development

To facilitate analysis of the issues identified above, an extensive data base containing information about past misadministration events was developed. The data base consists of Abnormal Occurrence events reported in the NRC's quarterly reports to Congress (NUREG-0090 documents) issued from 1987 through 1991 as well as misadministration events contained in the NRC's Office of Analysis and Evaluation of Operating Data (AEOD) data base for 1992. The format and content of the AEOD data base changed in 1992 to include narrative descriptions of all events. Based on this change, the AEOD data base became very useful for the purposes of this project. For years prior to 1992, however, the best source of readily available information was the NUREG-0090 reports. Consequently, the INEL data base consists (a) of only the more serious misadministrations which meet the definition of Abnormal Occurrences for the period 1987 through 1991 and (b) of all misadministrations reported in 1992. Coincidentally, changes in the definition of misadministration events, which took effect in 1992 (increasing the reporting threshold for deviations from 10% to 20% of the intended dose), make all the data in the INEL data base quite consistent despite the changing regulatory definitions.

The INEL data base was developed by interpreting and extracting information from the data sources regarding event causes, dose information, treatment modality, and other parameters. All records in the data base represent misadministration events reported between 1987 and 1992. The data base contains 104 records and, because some records pertain to multiple patients, represents misadministrations to 216 patients. For reasons of confidentiality, none of the licensees or patients involved in the misadministrations represented in the data base are identified in this report.

5.2 Common Cause Issues Associated With Misadministrations

In the fields of safety and risk analysis, common cause failure mechanisms are typically defined as conditions or phenomena that can lead to the failure of more than one component, subsystem, or system as the result of the same physical cause. Common cause failures are of special safety significance because they have the potential to defeat redundancy or diversity in systems. A related consideration is the fact that the probability of two failures occurring from a single common cause is often much higher than the probability of the two failures occurring from random independent causes. Although the concept of common cause failures is relatively easy to define for failures involving interrelated hardware components, the concept is harder to define for medical misadministrations. In the case of failures of two different pieces of hardware, nearness in physical location of the hardware and nearness in time of failure both tend to suggest

that the failures are due to common causes. In the case of medical misadministrations, groups of events very seldom occur closely in time and space. In an effort to deal with the issue of common causes of misadministrations, two different types of common causes are defined.

First, common cause misadministrations are defined as multiple misadministrations that occurred at the same facility, involved more than one patient over a relatively short period of time, and were attributable to the same direct causes. Such events most closely fit the usual definition of *common cause* by virtue of nearness in time and space. While it is, of course, theoretically possible that these multiple misadministrations may have resulted from random independent factors only, conservatism and probability both suggest that all events that meet these criteria should be classed as common cause failures. These events are termed *Type I* common cause failures for the purposes of this task. Most of the events that fall into this category had been previously identified as *multiple misadministrations* in the NUREG-0090 documents. Several of these events, however, had apparently not initially been classified as multiple misadministrations, but, upon more detailed analysis, met the definition of Type I common cause failures as defined for this task.

In an effort to identify the relative impact of various direct causes of misadministrations, the percentages of events in the data base that involved each of the defined direct causes were also calculated. Although this way of measuring the relative frequencies of specific direct causes of misadministrations probably cannot be used to draw any insights about true physical common causes, the measure does provide valid insight into the degree to which specific causes are *common* to the sample of misadministrations included in the data base. Thus, these causes were termed *Type II* common causes. Figures 5-1 and 5-2 present the relative frequencies of specific causes of misadministration events. Figure 5-1 pertains only to primary direct causes of misadministrations while Figure 5-2 pertains to both primary and secondary causes.

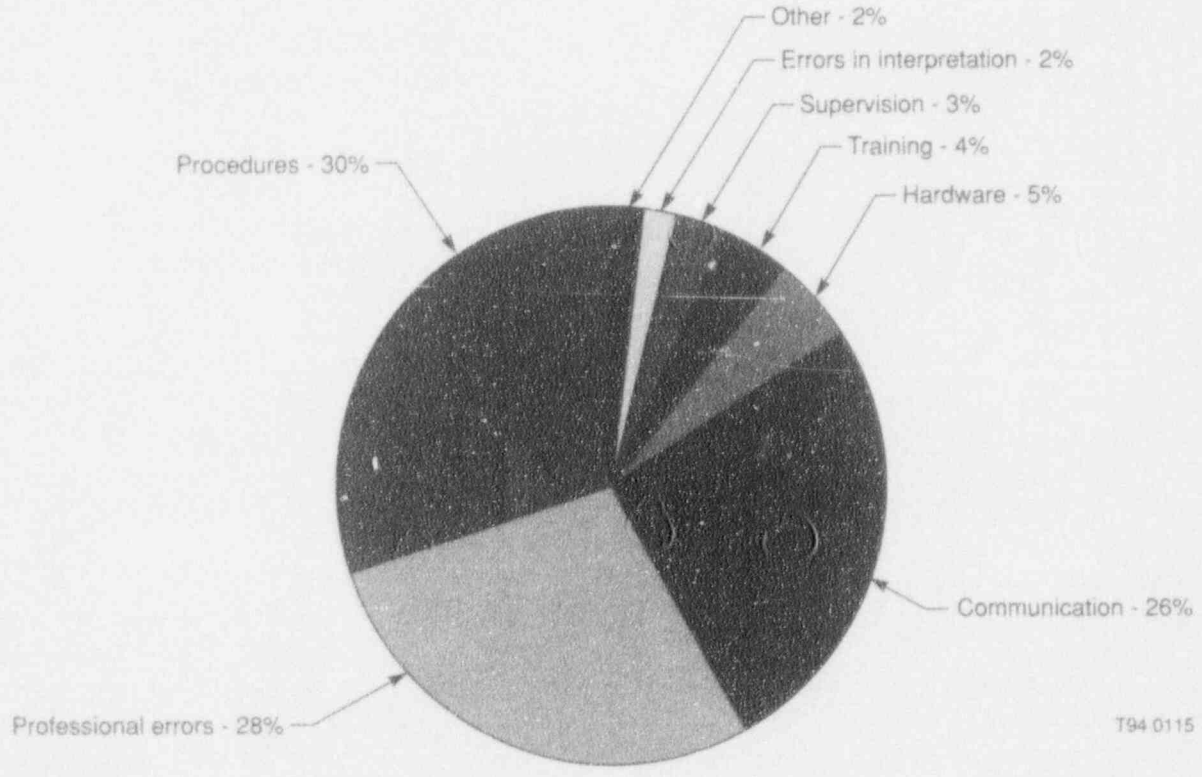

Figure 5-1. Relative frequencies of primary direct causes for single misadministration events.

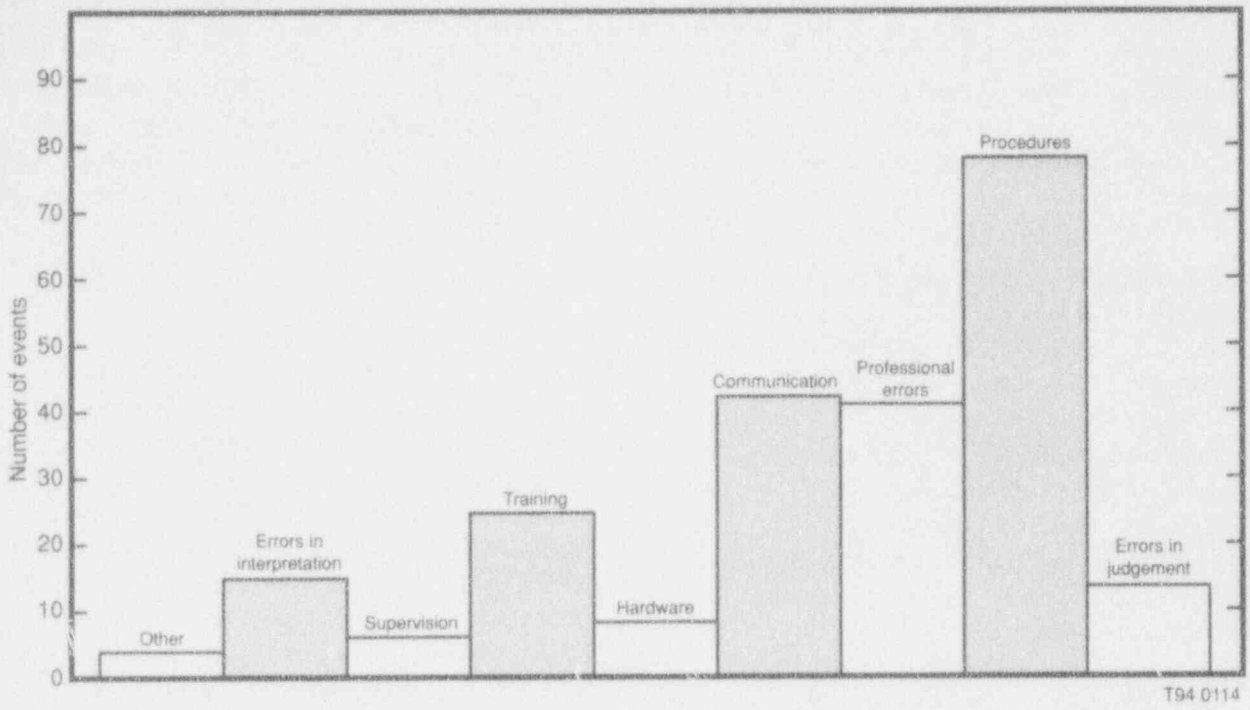

Figure 5-2. Absolute frequencies of primary and secondary direct causes.

Analysis of the data base shows that eleven licensees experienced Type I common cause events. Interestingly, while only 10.5% of the records in the data base represent Type I common cause events, these misadministrations involved 128 out of the 216 patients (59%) included in the data base. Further, 110 out of the 128 (85.9%) patient misadministrations, which occurred, in part, owing to Type I common cause events, involved errors in either data input to computers or in a computer program itself. One multiple misadministration (involving 21 patients) occurred from a computer program error. All other computer-related common cause events (seven events involving 89 patients) occurred from errors in entering data into computer programs. Thirteen patients were affected by a multiple misadministration caused by the use of erroneous time charts used for treatment planning. In terms of primary direct causes, available information indicates that, of the patients involved in Type I common cause misadministrations, 44% were primarily caused by inadequate procedures or a failure to follow procedures, 27% by professional errors, 12% by communication errors, 11% by a lack of adequate supervision, and 4% by errors in interpretation.

Based on the above information, it appears that data input errors and computer program errors have a rather large potential to manifest themselves as common cause failures that can result in multiple misadministrations. Although any conclusions regarding the reason for this are largely based on speculation, it seems likely that these multiple misadministrations resulted from a lack of independent checking of the software and inputs, and from a tendency to accept values and information that comes out of a computer. Procedures which may have been required by independent verification and validation eliminated these common cause failures.

The frequencies of direct causes of misadministrations are presented in Figures 5-1 and 5-2. Figure 5-1 reveals that the three most significant primary direct causes of misadministrations were inadequate procedures or failure to follow procedures (30%), professional errors (28%), and communication problems (26%). Collectively, these primary direct causes accounted for 84% of all the misadministrations represented in the data base. No other single primary direct cause accounted for more than 5%. Note that Figure 5-1 is based only on the *single* misadministration events and does not include multiple

misadministrations. A primary direct cause is defined as the causal factor that most fundamentally resulted in the misadministration. Each of these primary direct causes is defined and discussed below.

Inadequate procedures or failure to follow procedures. This direct cause represents procedures that are (a) erroneous, ambiguous, or incomplete, (b) unavailable, (c) not used. Of the 28 events (30% of the total number of single misadministrations) primarily caused by these factors, 17 were the result of a failure to follow procedures. Examples include failures to verify dose information, failure to properly identify the patient or patient chart, and failure to verify treatment location. Ten events primarily resulted from a lack of adequate procedures. Examples include no procedure to verify dose, no procedure to check labels, and inadequate procedures to govern administration of radioisotopes. One event was primarily caused by following an erroneous procedure. In addition to its role as the dominant primary direct cause, inadequate procedures or a failure to follow procedures also appeared as the most significant secondary direct cause. As shown in Figure 5-2, this cause was a factor in 74 events; nearly twice the number of the next most dominant cause. From this information, it can be concluded that 77% of the single misadministration events in the data base (for which causes can be determined from available information) involved inadequate procedures or a failure to follow procedures as a cause.

Professional errors. This direct cause represents what can best be thought of as human errors, sometimes referred to as slips or lapses. Errors in which licensee personnel properly identified the patient, correctly understood the intended treatment and dose, knew how to properly administer the treatment, but still made some kind of mental or physical mistake fall into this category. Of the 25 events determined to be primarily caused by professional errors, 14 were caused by arithmetic errors in calculating doses prior to administration and 12 were caused by improper administration of the dose. In total, professional errors were the primary direct cause of 28% of the single misadministrations in the data base. Approximately 41% of the events involved professional errors as either primary or secondary direct causes. Although it could be argued that more stringent procedures, closer supervision, or more independent verification could have eliminated many of these errors (and that perhaps another direct cause would be more applicable), the events to which this primary direct cause were assigned appeared to be most directly caused by the kinds of slips and lapses that would likely have occurred regardless of the sophistication of procedures, the degree of training, or the amount of oversight that might be present. Thus, they are attributed to simple professional errors. Noted that, with sufficient information, some of the events in this category might have been assigned other direct causes (implying preventability through practical corrective measures). These types of errors might be easily prevented by incorporating effective human factors design principles into the treatment system. It is not likely, however, that any practical means will ever be found to eliminate all such professional errors.

Communication problems. This direct cause represents the third most significant primary direct cause of single misadministrations in the data base. Communication problems include a lack of communication or the communication of incorrect information, either in written or vocal. The data base contains 24 single misadministrations (26%) primarily caused by communication problems. Of these, nine were caused by a lack of a written directive, 10 were caused by oral miscommunications, such as relying only on a verbal means of identifying a patient, and five were caused by written miscommunications such as errors in transcribing information. Communication problems appeared as either a primary or a secondary cause in (and thus are common to) 42% of the single misadministrations in the data base.

Other direct causes. As mentioned above, no other single primary direct cause accounted for more than 5% of the single events in the data base. Of the remaining primary direct causes, hardware failures accounted for 5%, inadequate training accounted for 4%, inadequate supervision

accounted for 2%, errors of interpretation accounted for 2%, and other direct causes or unknown causes accounted for 3%. Figure 5-2 shows the relative contributions of the direct causes as both primary and secondary causal factors.

5.3 Correlation's Between Direct Causes and Severities of Misadministrations

The first issue encountered during investigation of whether or not correlation's exist between direct causes and severities of misadministrations was how to go about defining severity. Several possible measures of severity were considered. Perhaps the best measure of severity is *reduced life expectancy resulting from the misadministration*. Of course, such a measure was not available for any of the events in the data base, would be fraught with uncertainty, and would be very difficult to determine. *Likelihood of developing cancers as a result of the misadministration* makes little sense in view of the fact that many of the patients involved were already being treated for cancer. *Percent overdose* measured relative to the intended dose was rejected because a number of misadministrations involved erroneous doses administered to tissue volumes not intended to be irradiated. In such cases, the intended dose to the effected tissue would be zero and the percent overdose measure would be meaningless. Finally, as a rough cut approximation, *delta dose* (actual dose minus intended dose) was chosen as a proxy for severity.

In searching for correlation's between direct causes and delta dose, two plots were developed. Figure 5-3 shows the relationships between primary direct causes and delta dose, and Figure 5-4 shows the relationships between both primary and secondary direct causes and delta dose. Both plots are area curves in which dose appears on the vertical axis and number of events appears on the horizontal axis. The tabular data that underlie the plots are included with each figure. Delta dose on both plots was filtered by direct cause and sorted in ascending order such that the area under each curve is directly proportional to increasing severity. The height of each curve is a function of delta dose, and the width of each curve is a function of

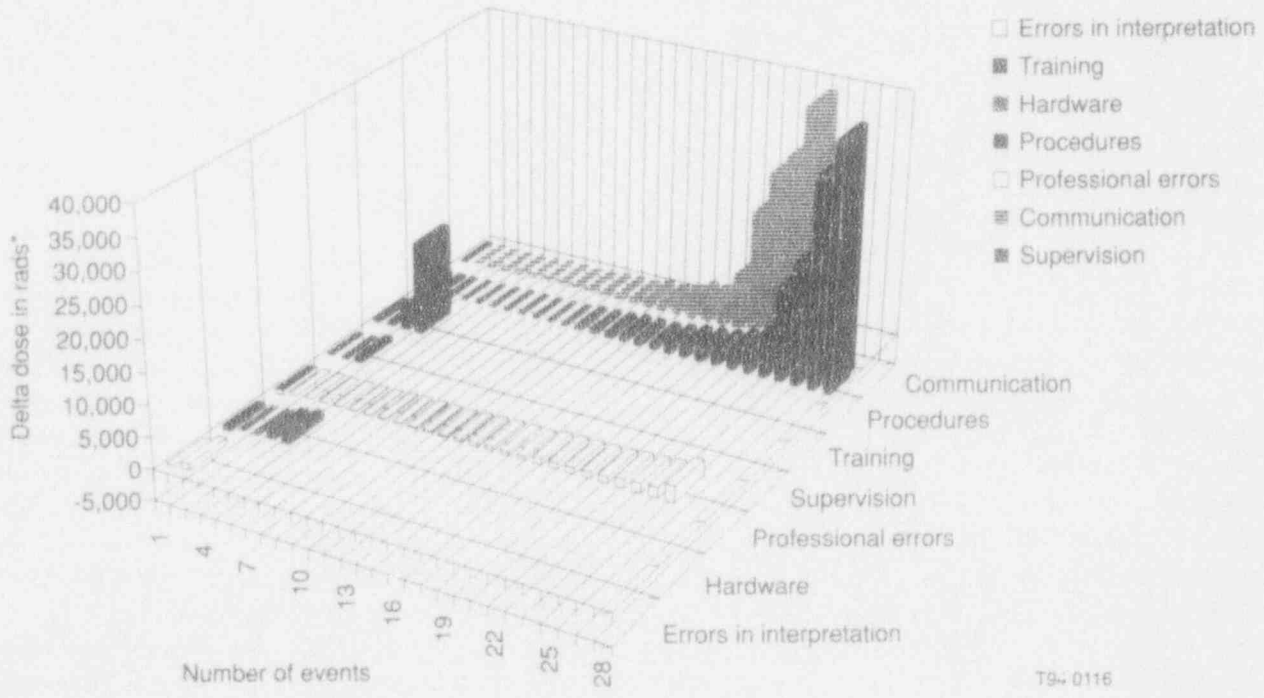

Figure 5-3. Relationships between primary direct causes and delta dose.

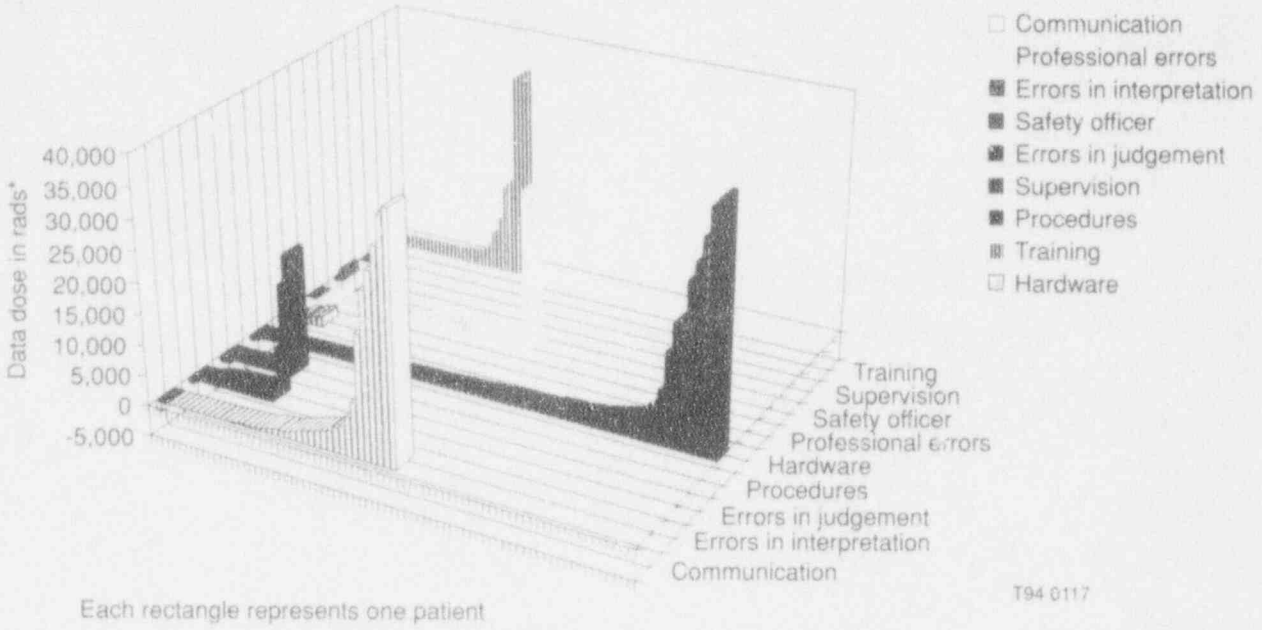

Figure 5-4. Relationships between all direct causes and delta dose.

the number of patients involved. Thus, tall, narrow rectangles represent a small number of patients being affected but very large overdoses for them.

Figure 5-3 and its associated tabular data show that a lack of procedure, or failure to follow procedures and communication problems appear to be associated with the highest severities. Inadequate training and professional errors are also noteworthy and have approximately the same areas under their two curves. Note, however, that inadequate training has a rather tall, narrow curve, while professional errors has a rather wide, short curve. Unfortunately, the implications of this are not clear. For reasons that are familiar (the question of linear versus threshold health effects models), it is not clear whether it is more severe for 100 people to be overdosed by 10 rads or for 10 people to be overdosed by 100 rads. Such is the issue faced in trying to distinguish between training and professional errors as primary direct causes in terms of severity. Prudent interpretations of Figure 5-3 indicate that communication problems and a lack of procedures, or failure to follow procedures, appear to be associated with the greatest severity. Inadequate training and professional errors also appear to directly cause more severe misadministrations.

Figure 5-4 presents information regarding both primary and secondary direct causes with respect to severity. In terms of both primary and direct causes, inadequate procedures or a failure to follow procedures appears to be most associated with misadministrations of greater severity. Communication problems, inadequate training, professional errors, and errors in judgment are also significant.

When interpretating the information in Figures 5-3 and 5-4. Several factors should be kept in mind. First, correlation does not imply causality. That is, there may be no inherent characteristic of any of the direct causes that physically leads to greater or lesser severity of misadministrations. Consequently, conclusions regarding whether or not one cause might be generally worse than another in terms of severity must be stated as hypotheses, not facts. Secondly, because of the subjective nature of assigning direct causes to events, fine distinctions regarding correlation's between causes and severity probably cannot be legitimately made. The only prudent conclusion to reach regarding the data presented in these two

figures is that, based on information in the data base, communication difficulties and inadequate procedures, or a failure to follow procedures, tentatively appear to be positively correlated with misadministration severity. Training, professional errors, and errors in judgment also tentatively appear to be correlated with severity, but likely only as secondary causes. Secondary causes are defined as direct causes that also resulted in the misadministration but were of lesser importance than the primary direct cause. Accordingly, a misadministration can have only one primary direct cause but may have several secondary direct causes. The physical bases (causes) of these correlations, if any, have not been investigated, and no such hypotheses have been formulated.

5.4 Preventability of Past Misadministrations through Proper Implementation of Licensee Quality Management Plans

The Quality Management Rule (10 CFR 35.32) generally requires that every licensee develop a QMP that will provide a high degree of assurance that byproduct material and radiation will be administered as directed by authorized users. A summary of the provisions of the QM rule indicates that 10 CFR 35.32 basically requires

1. Preparing a written directive for most types of procedures regulated by the QM rule
2. Verifying the patient's identity by at least two independent means prior to the administration
3. Performing the final treatment planning and related calculations for brachytherapy, teletherapy, and gamma stereotactic surgery in accordance with the written directive
4. Performing the treatment in accordance with the written directive
5. Identifying unintended deviations from the written directive and taking appropriate action.

Although 10 CFR 35.32 did not go into effect until January 27, 1992, all misadministrations in the INEL data base were analyzed to assess the likelihood that the event would have been prevented if the licensee had a properly implemented QM plan in place prior to the time of the event.

A rigid interpretation of the requirements of the QM rule would lead one to the conclusion that a properly implemented QM plan (one that meets the intent of 10 CFR 35.32 and related sections, and is always adhered to by all licensee staff) would prevent all misadministrations from occurring. This is because the QM rule, in effect, says "prepare a written directive and administer the treatment according to the written directive." Any unintended deviation from the written directive, then, must represent, by definition, a deficiency in the implementation of the QM plan. By such reasoning, virtually all of the misadministrations in the data base that were used for this task would have been prevented by proper implementation of the QM plan. Looking at the issue of preventability from what is perhaps a more realistic perspective, however, requires looking at QM plans and their implementation in a less rigid way.

For the purposes of this task, each event in the data base was assigned to one of three categories based on an assessment of the relative preventability of the event through effective implementation of the QM plan. Events that occurred primarily from a lack of a written directive or a failure to properly identify the patient were termed *very likely* to be preventable through proper implementation of the QM plan. The basis for this categorization is the belief that any properly implemented QM plan should, at an absolute minimum, ensure that these two requirements are met in every case. Events for which a written directive had been prepared and the proper patient was identified, but that occurred from an error in treatment planning or administration, were most often determined to be *somewhat likely* to be preventable. Inadequate training, a lack of rigorous procedures, inadequate supervision, judgment

and interpretation errors, and communication problems should all be addressed by a well-implemented QM plan and, hence, most events that have these direct causes should be preventable. Misadministrations that occurred from what can best be characterized as *slips* or *lapses* were often placed in the *unlikely* preventability category. These events are ones that, in our judgment and based upon available data, would probably have occurred with or without a properly implemented QM plan. This categorization is based on the belief that even when very rigorous procedures, training, and supervision are in place, certain types of human errors cannot realistically be eliminated. It may not be practical, for example, to have triply redundant checking of arithmetic calculations or to have two dosimetrists independently assay sources and transcribe data prior to administration. Without going to such extremes, some types of human errors will continue to occur with even the best implementation of the QM plan.

Using the rationale outlined above, it was determined that 36% of the misadministrations involving only a single patient would be *very likely* to have been prevented by proper implementation of the QMP, 42% would be *somewhat likely* to have been prevented, and that 21% probably would not have been prevented. For the multiple misadministrations, it is believed that all 11 of the events (involving 128 patients) would be *somewhat likely* to have been prevented by proper implementation of the QMP. Thus, misadministrations to 203 of the 216 patients included in the data base (94%) would be at least *somewhat likely* to have been prevented by the proper implementation of a QMP that meets the intent of 10 CFR 35.32.

5.5 Multiple Misadministrations and Effectiveness of Corrective Actions

The final issue examined by analyzing the data base was the effectiveness of corrective actions. Specifically, the data base was analyzed to determine the number of licensees who had experienced multiple misadministrations and why corrective actions, if implemented in response to a misadministration event, did not effectively prevent later misadministrations resulting from the same cause.

As stated in the discussion of common causes above, multiple misadministrations can be defined as misadministrations affecting more than one patient resulting from the same underlying cause. As discussed above, the NUREG-0090 reports for the time period under consideration had previously identified eight multiple misadministrations that involved 121 patients. In each of these multiple misadministrations, the fact that misadministrations had occurred was not discovered, and thus corrective actions were not taken, until all of the affected patients had been misadministered. Because no further misadministrations occurred at these facilities following implementation of corrective actions, it appears that the corrective actions were adequate.

Three additional licensees in the data base also had multiple misadministrations. For the purposes of this report, these three licensees will be referred to as Licensee X, Licensee Y, and Licensee Z. For each of these three licensees, the determination that they had experienced multiple misadministrations is based on multiple occurrences of misadministrations involving the same treatment modality and the same direct causes.

In the case of Licensee X, both misadministrations occurred so closely together in time (within two days) that no corrective actions had likely been implemented between the two events.

Licensee Y had three misadministrations during the period covered by the data base. Little information is available regarding corrective actions implemented between the first and second misadministrations. The improved procedures and training implemented after the second event, however, appear to have been inadequate, based on available information, to prevent the third event, which occurred approximately 20 months later. Additional training and improved procedures were implemented following the third event. Following these added corrective actions, no additional misadministrations occurred

through the end of the period covered by the data base.

Past misadministration findings are shown in Figure 5-5.

Finally, in the case of Licensee Z, it appears from the available information that the corrective actions taken following the first event were inadequate to prevent another event approximately one year later, even though the causes and characteristics of the second event appear to be very similar to the first.

Based on the above discussion of multiple misadministrations and corrective actions, it can be concluded that relatively few licensees have experienced more than one misadministration and that with few exceptions, corrective actions implemented following a misadministration appear to be generally adequate for prevention of similar events.

5.6 Summary and Conclusions

Development and analysis of the INEL misadministration events data base led to a number of conclusions regarding common causes, severities, and preventability of misadministrations. These conclusions are summarized below. All conclusions are based solely on observations regarding the data base compiled for the period of 1987 through 1992.

1. A relatively small number of licensees (11) have experienced multiple misadministrations caused by common causes. These 11 multiple misadministrations, however, involved 60% of the patients included in the data base. Common causes apparently have the potential to result in large numbers of patient misadministrations.

2. Errors in computer programs or in entering data into computers were overwhelmingly the dominant causes of multiple misadministrations caused by common causes. Independent checking of data and programs, or increased attention to the human-computer system interface, may have prevented many of these multiple misadministrations.

3. The major primary direct causes of single misadministrations were in descending

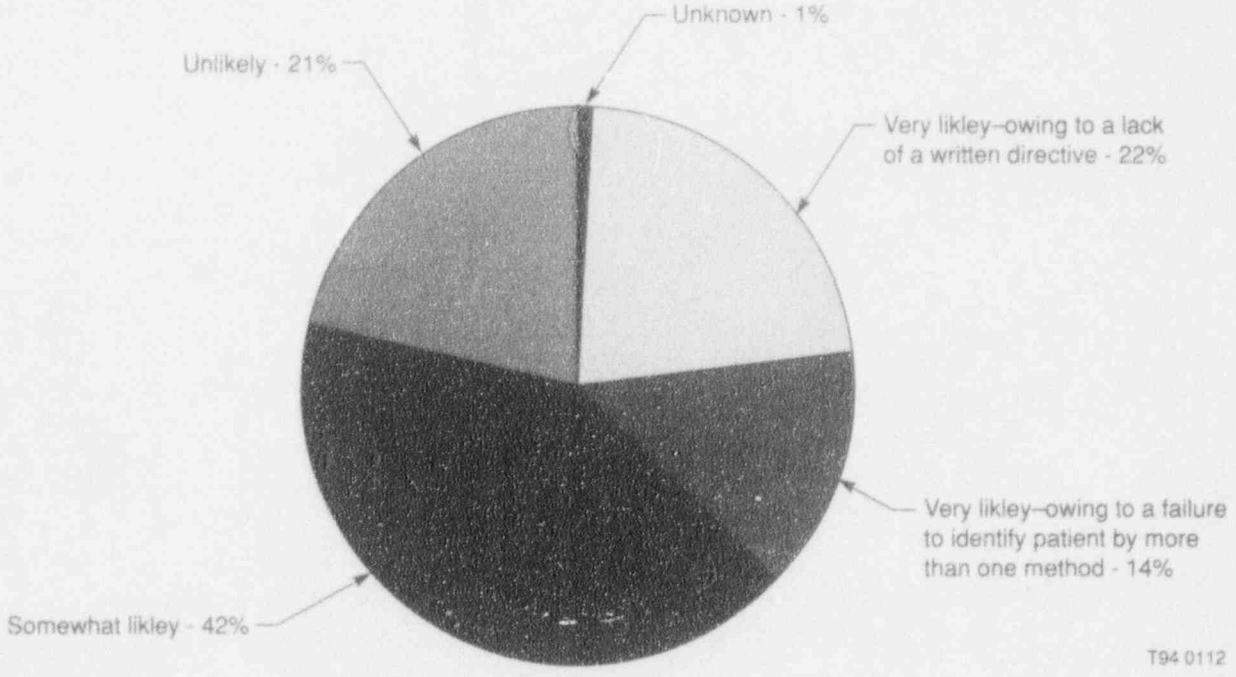

Figure 5-5. Preventability of past misadministrations through proper implementation of QM Plan.

order, a lack of procedures or a failure to follow procedures (30%), professional errors (28%), and communication problems (26%).

4. To the extent that it was possible to identify correlations, it appears that communication problems and inadequate procedures, or failure to follow procedures, were most highly positively correlated with severity of misadministrations.

5. Development and proper implementation of Quality Management plans that meet the intent of 10 CFR 35.32 has the potential to prevent a majority of the misadministrations that have occurred in the past. By even a rather liberal interpretation of what *proper implementation* means, 94% of the patient misadministrations in the data base were at least somewhat likely to have been prevented by proper implementation of the QM plan.

6. With few exceptions, the corrective actions implemented following a misadministration have been adequate to prevent the occurrence of similar events.

The subjective nature of the event analysis and data base development activities present a relatively large uncertainty in the percentage values presented in this report. We believe, however, that the findings of this analysis provide very valid indicators regarding the issues addressed. Most notable is the finding that a majority of the patient misadministrations in the data base would have been preventable through proper implementation of a QMP that meets the intent of 10 CFR 35.32.

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7. GLOSSARY

Afterloading Applicator	A treatment device in that the applicator or hardware that holds the radioactive sources is first inserted in the patient, and then the radioactive sources are loaded into the device, which remains in the patient for the duration of the treatment.
AP-PA	anterior posterior—posterior anterior
Brachytherapy	A radiation therapy procedure in which the radioactive sources are placed adjacent to or in the tissue being irradiated.
Caudal	Near the rear, tail, or inferior portion of the body or tail.
Cervical Os	Orifice of the cervix.
Co-60	Cobalt-60
Collimate	To adjust the radiation field by the use of a parallel device used to focus on the area of interest.
cGy	Centigray. This is a measure of absorbed radiation dose. One gray = 100 rads.
Cs-137	Cesium-137
Desquamation	The shedding or peeling of the superficial layer of the skin.
Epithelial Tissue	The nonvascular cellular layer that covers the internal and external surfaces of the body.
Henschke Applicator	A device for retaining radioactive sources in the vaginal area.
I-131	Iodine-131
Intrauterine Tandem	The part of a brachytherapy afterloading applicator that helps deliver a dose to the tumor volume. Figure 7-1 shows the positioning of the tandem in relation to the ovoids, cervix, and uterus.

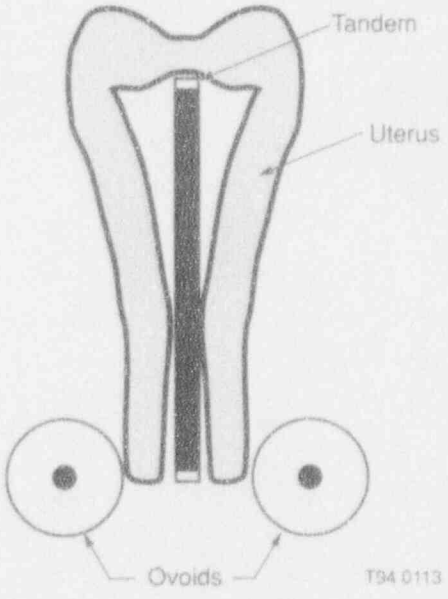

Figure 7-1. Positions of ovoids and tandem in relation to uterus.

Introitus	Entrance into a cavity or hollow organ.
Ir-192	Iridium-192
Ischial	Relating to the ischium.
Ischium	The lowest of three bones comprising each half of the hipbone. The ischium is the bone the body rests on when sitting.
Labial	Relating to the lip-like structure that surrounds the vulva.
Ovoids	The ovoids on a brachytherapy afterloading applicator help deliver a dose to the tumor volume. Figure 7-1 shows the positioning of the ovoids in relation to the tandem, cervix, and uterus
MIRD	Medical Internal Radiation Dose
Point A:	Point A is actually two reference points, one each on the left and right, and defined as being two-cm superior to the cervical Os and two-cm lateral on each side.
Squamous Cell Carcinoma	A malignant epithelial tissue tumor.
Tenesmus	Pain or cramping.
Thyroid Scan	Images are obtained of the thyroid, following administration of the radiotracer, which can be used for evaluation of thyroid size and thyroid nodules. Isotopes 99m Technetium, 123 Iodine or 131 Iodine, can be used for thyroid imaging, 99m Technetium being the most common.
Thyroid 131 Iodine Uptake	A probe counter measures the thyroid's ability to take up and retain iodine following 131 Iodine oral administration. This test is used in the evaluation of suspected hyperthyroidism, thyroiditis, goiters, and in calculating the therapeutic doses of 131 Iodine for treatment of hyperthyroidism.
Thyroid Whole Body Scan	The patient is administered an oral dose of 1-10 mCi of 131 Iodine and returns at 72 hours for whole body scanning. This study is done for patients who have previously undergone a partial or total thyroidectomy for thyroid carcinoma. The images are used to evaluate residual thyroid tissue, residual thyroid carcinoma and metastatic thyroid carcinoma.
Tuberosity	A rounded protuberance from the surface of a bone or cartilage.
Vulva	The external female genitalia.

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10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

Investigation teams composed of representatives of the Idaho National Engineering Laboratory (INEL), the U.S. Nuclear Regulatory Commission (NRC), and subcontractors investigated and analyzed seven misadministration events selected by the NRC concerning medical radioisotopes. Each team was led by an INEL member and, depending on the nature of the event, included three or more team members with appropriate expertise in of radiation oncology, medical physics, nuclear medicine technology, risk analysis, and human factors. The investigations focused on causes of the event, consequences, mitigating actions, and corrective actions. The investigation produced seven major findings:

1. Many misadministrations occurred primarily because procedures did not exist or because existing procedures that were not sufficiently detailed, comprehensive, specific, or clearly written.
2. Although the NRC's quality management (QM) rule can prevent many misadministrations, most licensees in this study had not effectively implemented their QM programs.
3. The lack of substantial, direct involvement by radiation safety officers and authorized users was often a direct cause of misadministration.
4. A change in routine or the advent of a unique condition often predisposed misadministration.
5. Hardware failures, though rare, had severe consequences, particularly when operating procedures, staff training, or other factors were not well implemented.
6. Licensees' corrective actions were often narrow in focus.
7. The licensees lacked systematic methods for detecting and mitigating a misadministration once an error occurred.

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