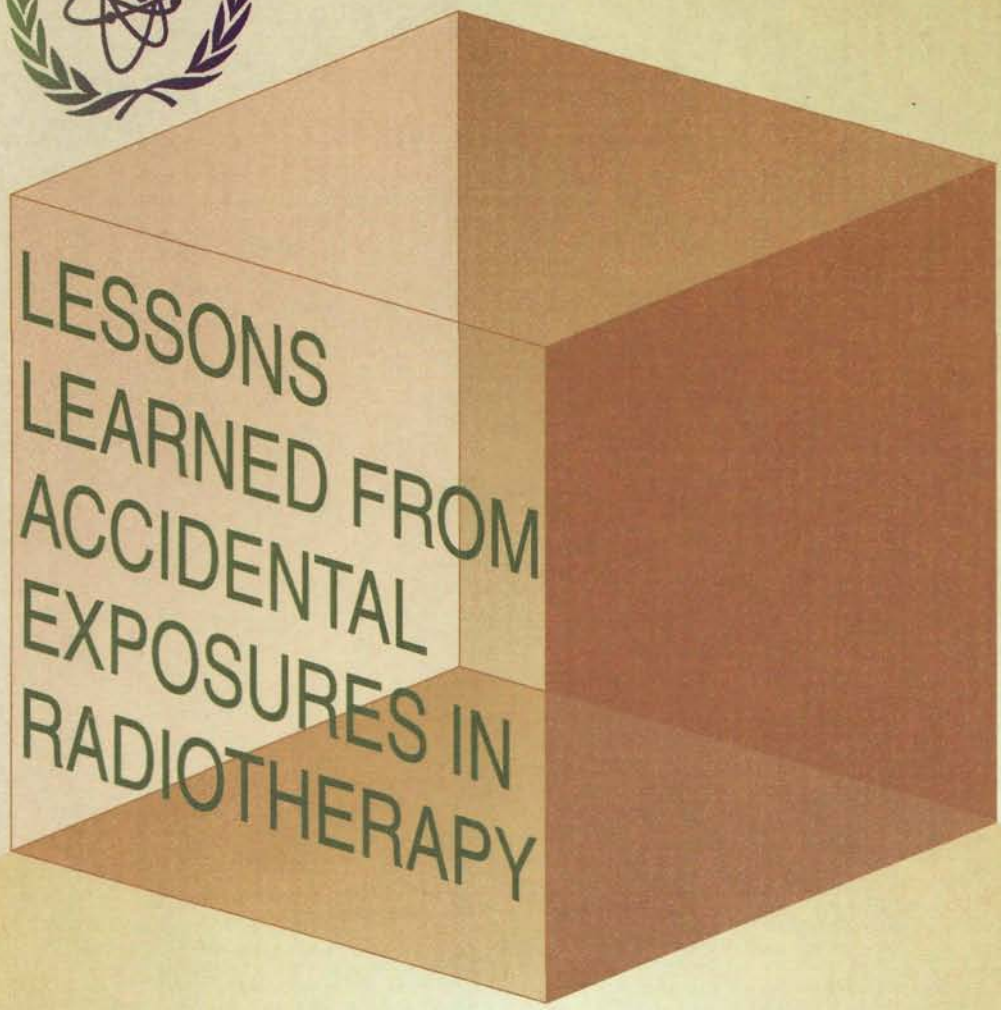
Safety Reports Series

No. 17



LESSONS LEARNED FROM ACCIDENTAL EXPOSURES IN RADIOTHERAPY

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Printed by the IAEA in Austria
February 2000
STI/PUB/1084

SAFETY REPORTS SERIES No. 17

LESSONS LEARNED FROM ACCIDENTAL EXPOSURES IN RADIOTHERAPY

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2000

VIC Library Cataloguing in Publication Data

Lessons learned from accidental exposures in radiotherapy — Vienna : International Atomic Energy Agency, 2000.
p , 24 cm — (Safety reports series, ISSN 1020–6450 ; no 17)
STI/PUB/1084
ISBN 92–0–100200–9
Includes bibliographical references.

1. Radiotherapy—Exposure 2. Radiotherapy—Safety measures. I. International Atomic Energy Agency II Series

VICL 00–00236

FOREWORD

The medical use of radiation is unique in that patients are intentionally exposed to radiation. The aim in radiation therapy is twofold: to deliver a dose and dose distribution that is adequate for tumour control, but which also minimizes complications in normal tissues. In therapeutic applications, the doses are high and a deviation from the prescribed dose may have severe or even fatal consequences. There is therefore a great need to ensure adequate radiation protection and safety in radiotherapy by verifying that all personnel involved are appropriately trained for their duties, that the equipment used meets relevant international specifications for radiation safety and that safety culture is embedded in routine activities in radiotherapy departments.

Many individuals must interact and work together on highly technical measurements and calculations, and therefore the potential for mistakes is great. A review of the mistakes shows that most are due to human error. The International Basic Safety Standards for Protection against Ionizing Radiation and the Safety of Radiation Sources (IAEA Safety Series No. 115) require that a prompt investigation be conducted whenever an accidental medical exposure of patients occurs. The report of the investigation is to be disseminated to the appropriate parties so that lessons can be learned to prevent similar accidents or mitigate their consequences in the future.

This Safety Report is a collection of a large number of events that may serve as a checklist against which to test the vulnerability of a facility to potential accidents, and to provide a basis for improving safety in the use of radiation in medical applications. A further purpose of this report is to encourage readers to develop a questioning and learning attitude, adopt measures for the prevention of accidents, and prepare for mitigation of the consequences of accidents if they occur.

The IAEA officer responsible for preparation of this report was M. Oresegun of the Division of Radiation and Waste Safety, Department of Nuclear Safety.

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1. INTRODUCTION

1.1. BACKGROUND

This Safety Report provides a review of events that constitute incidents or accidents related to the therapeutic use of ionizing radiation. The events concern external beam therapy, brachytherapy and nuclear medicine. Most of the cases involve patients, although some examples illustrate accidental exposure of medical personnel or the general public. Most events involve radiation exposure; however, a few examples are included that illustrate injuries resulting from mechanical or electrical failure of equipment.

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) state that the regulatory authority should require all parties to develop a safety culture that includes measures to encourage a questioning and learning attitude and discourage complacency with respect to safety [1]. Information on unusual events during operation of the facilities which led or might have led to accidents provides background material that can be used to prevent accidents when such information is disseminated to regulators, manufacturers, users and radiation safety specialists.

With regard to patients, the BSS require prompt investigation by licensees in the event of an accidental medical exposure, defined by the BSS (p. 55) as follows:

"(a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong radiopharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue secondary effects;

⋮

(c) any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from the one intended."

Following an investigation, the BSS requires the licensee to:

"(a) calculate or estimate the doses received and their distribution within the patient;
(b) indicate the corrective measures required to prevent recurrence of such an incident;

(c) implement all the corrective measures that are under [the local] responsibility;
(d) submit to the Regulatory Authority, as soon as possible after the investigation or as otherwise specified by the Regulatory Authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the Regulatory Authority; and
(e) inform the patient and his or her doctor about the incident."

1.2. OBJECTIVE

This Safety Report is a collection of a large number of events that may serve as a checklist to test the vulnerability of a facility to potential accidents and to provide a basis for improving safety in the use of radiation. The plain presentation of many facts may permit a reader to ask whether events that took place at other institutions might also occur at his/her own institution. A further purpose of this report is to encourage readers to develop a questioning and learning attitude, adopt measures for the prevention of accidents and prepare for mitigation of the consequences of accidents if they occur.

1.3. SCOPE

The events presented here have been reported to regulatory authorities and professional associations, published in scientific journals, or otherwise become known through publication. No individuals, institutions or countries are identified in this report. The rationale behind this anonymous method of presentation is to encourage individuals and institutes to report events of misadministration or accidents without the fear of being professionally prosecuted. This report is not intended to be an exhaustive analysis of individual accidents.

1.4. STRUCTURE

Section 2 contains descriptions of the events. Each description consists of a short account of what happened, followed by the *initiating event* and the relevant *contributing factors,* as well as the *remedial action* taken, if known.

Section 3 discusses lessons learned from the events, with references to specific events described in Section 2. Section 4 presents general principles for the prevention of misadministrations and accidents. Section 5 discusses recommendations for implementing safety at a radiotherapy facility.

2. REVIEW OF ACCIDENTS

2.1. DEFINITIONS

For the purposes of this report, the terms below are defined as follows, in line with the BSS:

— **Potential exposure** is exposure that may result from an accident due to an event or sequence of events of a probablistic nature; the probability, while not negligible, is significantly less than one.
— **Normal exposure** is exposure which is expected to be received under normal operating conditions, including minor mishaps or errors whose probability of occurring is not significantly less than one.

The preceding two definitions encompass the full range of exposures from a radiation source and apply to occupational, public and medical exposure.

— **Medical exposures** are exposures incurred by individuals in the course of diagnostic examinations or treatment and exposures (other than occupational) endured knowingly and willingly by individuals helping in the support and comfort of patients undergoing diagnosis and treatment. Medical exposure also includes exposures incurred by volunteers participating in programmes of biomedical research.
— **Accident** refers to any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

Potential exposure is concerned with the potential for accidents in radiotherapy or involving radiotherapy sources, the consequences of which are relevant to safety. However, when an accident actually occurs it is no longer potential. It is real.

There are aspects of potential exposure that are unique to the medical use of radiation sources since patients are intentionally exposed to direct radiation beams and radiation sources are incorporated in their body as part of the diagnosis and treatment. In therapeutic applications, the doses are extremely high, and a small departure from the prescribed dose may have severe or even fatal consequences. Potential exposure, in the context of the treatment of patients, concerns not only doses significantly above the intended dose but also doses significantly below the intended dose, since these too can have severe consequences.

The expression 'substantially differing from the prescription' deserves further consideration to establish a common understanding in this review of accidental

medical exposures. The ultimate goal of radiotherapy is to deliver a specified radiation dose to the prescribed target volume with the least dose to healthy tissues. The demands for precision and accuracy are high, because any deviation in the radiation dose will increase the probability of a detrimental effect to the patient [2], as explained in the following paragraph.

The dose and dose distribution within the patient are aimed at maximizing the local tumour control probability (TCP) while minimizing the normal tissue complications probability (NTCP). The margin for the overall error is very small (ideally below 5% overall deviation). A simplified example of this statement is illustrated in Fig. 1, where the TCP and NTCP curves are presented in relation to the dose to the planning target volume. The probability of local tumour control without complications has a maximum value, which provides the basis for the justification and optimization of the radiotherapy treatment (dose, dose fractionation and dose distribution).

It is worth taking a more detailed look at Fig. 1: the slope of the sigmoid curves is usually steep. In the simplified example, if the maximum is situated at a dose where the slopes of the sigmoids are near 2, a deviation of 15% means a decrease in TCP or an increase in NTCP of 30%, which may jeopardize the justification of the decision made. However, this is only one example and the slope of the curves varies depending

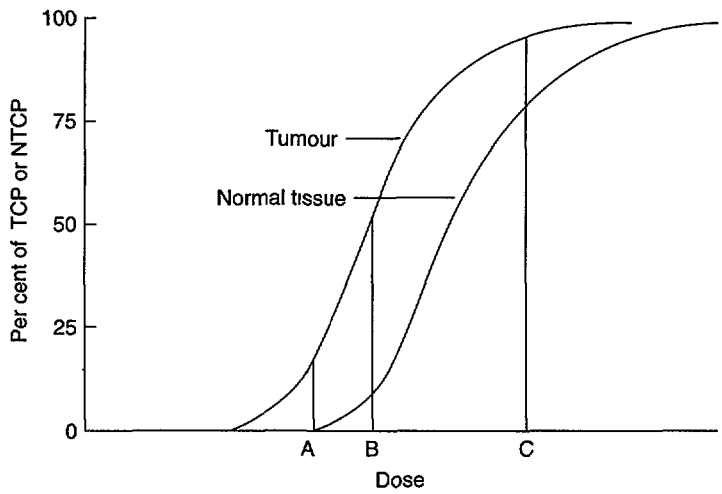

FIG. 1. Tumour control probability (TCP) and the probability of normal tissue injury as a function of radiation dose, in a hypothetical case. If normal tissue injury is to be avoided altogether, the radiation dose cannot exceed A; the TCP is low. By accepting a relatively small probability of normal tissue injury, the radiation dose can be increased to B, and the TCP is significantly improved. A further increase in the radiation dose above C results in an increased complication rate with very little improvement in TCP.

on the types of tumour and normal tissue as well as on the separation between the TCP and NTCP. Therefore, there is no single and sharp limit for the deviation on which the decision that a deviation is 'substantial' enough to constitute an accidental exposure from the point of view of the outcome can be based; nevertheless, for practical reasons, the generic level of 20% has been chosen by some national authorities to make an investigation mandatory (10% if the prescribed number of fractions is equal to or less than three).

On the basis of these considerations, it is understandable that mistakes and equipment faults have an immediate influence on the outcome of the treatment, and that most of the accidents in this report involve patients, in some cases with serious, even fatal, consequences.

In addition to concern for patients undergoing radiotherapy treatment, potential exposure from radiotherapy sources includes medical exposures to persons helping in the comfort of patients, occupational exposures to staff and exposures to members of the public.

Accidental exposures may occur to visitors helping in the support of brachytherapy patients if rules are misunderstood or violated or if a radiation source becomes accidentally exposed (i.e. accidentally falls out of the patient).

Potential exposures to staff may result from equipment failure such as a stuck source in a teletherapy machine or a remote control after-loading device, or when a brachytherapy source is accidentally removed from a patient. Accidents with severe consequences have also occurred during maintenance or source exchanges.

With regard to potential exposures to the public, the most important case of exposure is due to loss of control or abandonment of sources. Very serious consequences have also occurred with teletherapy units that are not well controlled or are improperly decommissioned. A patient discharged from the hospital with brachytherapy sources mistakenly left inside his or her body may not only risk death, but also expose members of the public. A particular problem is posed by old ^{226}Ra brachytherapy sources introduced in many countries several decades ago before any regulatory control existed. The owners may have died, and the sources may remain with members of the public who have no knowledge of the potential hazards they entail.

2.2. METHODOLOGY FOR THE REVIEW

The description of an accidental exposure consists of a short account of the accident itself, followed by the initiating events and the relevant contributing factors. Consistent with its objectives, the emphasis in this Safety Report is on the collection and collation of a large selection of events and contributing factors, rather than on an exhaustive analysis of individual accidents.

Care has been taken to avoid making judgements. Rather, the plain presentation of a collection of facts was considered to be more effective towards increasing awareness, contributing to a questioning and learning attitude and adopting measures for the prevention of accidents and mitigation of their consequences.

In some accident scenarios where the dosimetric units are relevant to the primary cause of the accident, SI units have not been used. Instead the old units such as millicurie (mCi) and milligram radium-equivalent (mg Ra-eq) were quoted as used.

An initiating event is the action which triggers the chain of events (or event sequence) which results in an accident. A contributing factor is any circumstance, condition, action or omission which plays a part in the precipitation of an accident.

Frequent contributors to accidents were: insufficient education in radiotherapy physics; a lack of a set of procedures and protocols integrated into a comprehensive quality assurance programme; and/or the lack of supervision over compliance with the programme. Another finding was that training generally addresses only normal situations and does not prepare radiotherapy staff for unusual situations, resulting in a lack of a 'safety culture'.

The review focuses on pure facts from which general lessons can be drawn and integrated into the oncology service as part of a system for safety and quality. Contributing factors have been indicated by a general statement (which is common to a number of accidents), followed by detailed information specific to that particular event. As an example, for Event No. 26, the general statement: "lack of or ineffective procedures, protocols and documentation" is followed by the more specific information: "incorrect tables were accepted for use".

However, overly general statements such as "lack of overall quality assurance" have been avoided, since they would apply to most of the accidents and would convey very little information. The reader will be able to conclude that quality assurance was lacking whenever procedures were not complied with (or did not exist at all), or whenever safety provisions to prevent accidents (such as independent checks for safety critical issues) were non-existent.

2.3. CLINICAL CONSIDERATIONS RELATED TO QUALITY ASSURANCE

In clinical institutions and hospitals where accuracy and precision are not maintained within a narrow range, there can be a tendency to avoid normal tissue complications by lowering the prescribed dose. The consequence is a drastic decrease in the probability of tumour control. The only acceptable solution is improvement of accuracy and precision so that the right doses can be prescribed. This practice of prescribing lower doses than desirable cannot be considered as a potential exposure

or accident since the problem is associated with the prescription itself. This is an issue of ethics and is therefore not included in the methodology dealing with potential exposures.

2.4. RADIATION MEASUREMENT SYSTEMS

The output of a therapy machine is measured by an ionization chamber and electrometer with a calibration by, or traceable to, an authorized standard dosimetry laboratory. Malfunction or improper use of this basic equipment can affect many patients. Consistency among different sets of equipment requires frequent inter-comparison. Constancy checks verify that equipment performs correctly over time.

Event No. 1: Dosimeter calibration report used incorrectly

The institution had its ionization chamber and electrometer calibrated for ^{60}Co at a standards dosimetry laboratory. The calibration certificate was in terms of dose to water, but was interpreted as specifying dose in air. The resulting error caused an overdose to patients of approximately 11% for at least one year.

Initiating event

— Calibration error: Incorrect use of a calibration certificate.

Contributing factors

— Insufficient education, training or expertise: The physicist did not seem to understand the calibration certificate.
— Insufficient safety provisions (defence in depth): There was no independent beam calibration by another physicist.

Event No. 2: Incorrect use of a plane parallel chamber

A new physicist at a hospital used a pancake chamber to calibrate several electron beams. A label on the chamber, placed by the previous physicist, indicated the side on which the beam should be incident. Although the previous physicist had used the chamber correctly, his labelling was incorrect and the new physicist used the chamber upside down in the beam, resulting in the following errors in dose delivery, with the electron beams having the indicated energies:

6 MeV: 20% overdose,
9 MeV: 10% overdose,
12 MeV: 8% overdose,

16 MeV: Correct dose,
20 MeV: 1% underdose.

Mailed thermoluminescence dosimeters (TLDs) from an independent laboratory were used routinely by the institution for quality assurance of radiation beam calibration. These dosimeters revealed the above discrepancies, which prompted the physicist to investigate the cause. By the time the error was corrected, the incorrect beam outputs had been used for part of the treatments of only a few patients.

Initiating event

— Incorrect calibration: Incorrect use of the plane parallel chamber to measure the output of the electron beams.

Contributing factors

— Insufficient education, training or expertise: The physicist used a chamber unfamiliar to him without verifying the proper technique.
— The previous physicist had labelled the chamber incorrectly.
— Deficient communication/transfer of essential information: Either there was miscommunication, or a faulty method was transferred from one physicist to another.

Remedial action

— The calibration measurements were repeated, with the chamber properly oriented in the beam. The label on the chamber was corrected.

Event No. 3: Error in correction for atmospheric pressure

An institution did not own a barometer and the physicist relied on the local airport for measurement of atmospheric pressure. Pressure reported by the airport was corrected to sea level, but the physicist interpreted the pressure report as appropriate for the elevation of the site, about 1000 m. The use of the incorrect pressure resulted in errors in the measurement of machine outputs, which caused a 13% overdose to patients. The error affected the calibration of all machines at this institution.

Initiating event

— Calibration error: The use of incorrect pressure values to correct for atmospheric pressure resulted in an incorrect beam output.

Contributing factors

— Shortage of instruments: The institution did not have its own barometer.

— Insufficient awareness:
  - Physicists relied on pressure data from an airport without knowing that the data referred to sea level (requesting both station pressure and pressure corrected to sea level should eliminate ambiguity).
  - Physicists did not consider altitude as having a bearing on atmospheric pressure.

Remedial action
— The institution purchased its own barometer which measured local pressure.

Event No. 4: Error in correction for atmospheric pressure

Atmospheric pressure was determined using data from nearby weather stations. The physicists concerned did not realize that these data were actually corrected to sea level. This happened at four institutions, and six physicists were involved.

In at least two of the treatment centres the same incorrect pressure was obtained redundantly. At three of the centres the overdose was 13–14% and at one centre the overdose was 21%. Many patients were treated at each institute. The 21% overdose by a ^{60}Co unit continued for about ten months until a different physicist calibrated the machine and informed the radiation oncologist of the miscalibration. The radiation oncologist chose to continue with the older and incorrect calibration.

Initiating event
— Incorrect calibration: The use of incorrect pressure values to correct for atmospheric pressure resulted in an incorrect beam output.

Contributing factors
— Shortage of instruments: The institutions did not have their own barometers.
— Insufficient awareness:
  - Physicists relied on pressure data from an airport without knowing that the data referred to sea level (requesting both station pressure and pressure corrected to sea level should eliminate ambiguity).
  - Physicists did not consider altitude as having a bearing on atmospheric pressure.

Event No. 5: Lack of consistency between dosimetry at affiliated institutions

Three radiation oncologists and two physicists worked at three affiliated hospitals. Each person worked in at least two, sometimes three, of the hospitals. There were two sets of calibration equipment (ionization chambers and electrometers),

usually assigned to a particular hospital. The two sets of equipment were never intercompared although they were used by both physicists.

A review by an outside physicist showed a discrepancy of up to 15% between measurements made with the two sets of equipment. After discussion with the physicists and radiation oncologists, one physician stated that he had noticed a difference in clinical results at two hospitals and had allowed for the difference by prescribing 70 Gy to the prostate in one hospital and 60 Gy in the other hospital for an equivalent treatment.

Initiating event

— Incorrect calibration: An invalid calibration factor was used.

Contributing factors

— Lack of or ineffective procedures: Different sets of equipment, which differed in calibration, were used, without intercomparison, at two hospitals served by the same radiation oncologists and physicists.

— Ineffective communication or transfer of essential information: Physicians failed to inform physicists that apparently there were differences in clinical results at two hospitals presumed to be using the same dosimetry techniques. Rather than discuss the problem with the physicists, at least one clinician dealt with the discrepancy by using a 'clinical prescription correction factor'.

2.5. EXTERNAL BEAM THERAPY: MACHINE COMMISSIONING AND CALIBRATION

Event No. 6: Incorrect calibration procedures

A new physicist adopted the calibration procedures used by the previous physicist. The previous physicist had calibrated all beams for a linear accelerator using 200 monitor units, with the exception of one beam, which he calibrated at 300 monitor units. For the latter beam, he used a 'conversion factor' to convert from 300 to 200 monitor units. The new physicist calibrated all beams at 200 monitor units; however, he applied the previous physicist's conversion factor to one beam although it was now unnecessary. The miscalibration resulted in an overdose of 50% for patients treated with that beam.

Initiating event

— Incorrect calibration: Use of an inappropriate correction factor.

Contributing factors

— Lack of or ineffective procedures and protocols: A physicist used data and procedures established by a previous physicist without understanding them.
— Ineffective communication or transfer of essential information: Poor handing over of procedures from one physicist to another.
— Lack of safety provisions (defence in depth): There was no independent beam calibration by another physicist.

Event No. 7: Incorrect calibration of machine output

An institution had a new ^{60}Co teletherapy source installed. The installer left a certificate specifying the exposure in röntgen per minute (R/min) at 1 m for the largest field available. The institution used the installer's output, with corrections for inverse square and decay, as the output in centigray per minute for all field sizes. When field size dependence, backscatter, röntgen to centigray conversion, timer, etc., were considered, the correct calibration revealed that patients received doses that were approximately 15% too low; the magnitude of the error depended on the field size.

Initiating event

— Incorrect calibration of the beam: The machine 'calibration' was based on the manufacturer's certificate of source strength for conditions inappropriate for treatment.

Contributing factors

— Lack of education in radiotherapy physics: There was poor understanding of the factors needed to convert from the installer's statement of source strength to the data used clinically.
— Lack of procedures and protocols: The physicist did not measure the machine output.
— Lack of safety provisions (defence in depth): There was no independent beam calibration by another physicist.

Event No. 8: Calibration error after a source change in a ^{60}Co unit

After a source change in a ^{60}Co unit, the physicist incorrectly calibrated the output. An incorrect time of 30 s instead of 18 s (0.3 min) was used to calculate the absorbed dose. This resulted in a 166% overestimation of the exposure time. Over a period of about one month, 115 patients were treated and received overdosage, resulting in severe health effects including fatalities. Inconsistencies in the dosimetry were detected by the IAEA/WHO postal dose quality audit and by an external expert, but this did not trigger any significant improvements in the procedures.

Initiating event

— Incorrect calibration of the beam: The dose rate used clinically was incorrect because of a mistake in the exposure time during calibration.

Contributing factors

— Insufficient education on radiotherapy physics.

— Lack of procedures, protocols and documentation: The absence of documented procedures allowed the mistake to go unnoticed.

— Lack of safety provisions (defence in depth):

- There was no independent calibration by another physicist of a new beam (after a source change).
- There was no comparison of the calibration for compatibility with the source manufacturer's certificate of source strength or output.
- The treatment times were not reviewed for consistency with previous treatments.

— Lack of awareness of physicians and of the person in charge of the dosimetry: Inconsistencies previously detected and notified were not investigated.

Event No. 9: Incorrect calibration of machine output

Electron beams of 7 and 11 MeV were calibrated incorrectly, resulting in underdosage of 17–18%. On the same machine, a photon beam was calibrated incorrectly, resulting in overdosage of 5%. In addition, there was a drift in the beam output over time, up to 7%. Mailed TLDs indicated a potential problem, and a review by an independent, outside physicist revealed that the calibrations were incorrect. Apparently, the incorrect calibrations had been used clinically for at least 11 months. During that time, there was no record of quality control performed by the institution's physicist. The cause of the incorrect calibrations was unknown.

Initiating event

— Incorrect calibration of the beam: The cause was unknown.

Contributing factors

— Insufficient safety provisions (defence in depth): There was no independent beam calibration by another physicist.

— Lack of or insufficient quality control: Over an 11 month period no checks were carried out on the beams.

Remedial action

— Calibrations were corrected as a result of an external review by an independent physicist. At the time of this report, it is not known whether the deviation in beam output has been corrected.

Event No. 10: Calibration error after changing a ^{60}Co teletherapy source

Physics staff calibrated the output of a new source installed in a ^{60}Co unit. About three and a half months later, nursing staff began to notice that the skin reactions of some of the patients treated on the machine were not healing as rapidly as would be expected. These concerns were communicated to the physics staff, who reviewed the output tables in clinical use as well as the original calibration; they reported that the data were correct. There was no explanation for the slow healing of the patients, which continued to be observed.

An intercomparison exercise, organized by a national association of medical physics, led to the discovery of a miscalculation in the original calibration. Over the five month period, the 207 patients treated on the ^{60}Co machine had received a dose that was 25% higher than prescribed.

Initiating event

— Incorrect calibration of a beam (the specific reason for the miscalibration was not reported).

Contributing factors

— Lack of safety provisions (defence in depth):
  - There was no independent beam calibration by another physicist.
  - There was no comparison of the calibration for compatibility with the source manufacturer's certificate of source strength or output.

— Inefficient quality control:
  - A verification of the calculations did not reveal the error. It is possible that the time for a calibration measurement was recorded incorrectly.
  - Subsequent reviews of the calculations by the local staff were ineffective, despite indications of clinical problems.

— Insufficient investigation of unusual patient response: There was no persistent search for the causes of the slowly healing skin effects.

Event No. 11: Incorrect calibration of a machine with asymmetric jaws

A linear accelerator with asymmetric jaws was calibrated with the detector positioned in the penumbra region and did not represent the dose in the centre of the field. The result was that patients received an overdose of 27%.

Initiating event

— Incorrect calibration of the beam: The calibration was made in the penumbra.

Contributing factors

— Insufficient education and training in radiotherapy physics: There seemed to be a lack of understanding of the features of an asymmetric beam.
— Insufficient defence in depth: There was no independent beam calibration by another physicist.
— Lack of or inefficient procedures and protocols: Procedures for the commissioning of a new machine were not appropriate.
— Insufficient awareness and alertness.

Remedial action

— The machine was calibrated correctly and new data placed in clinical use.

Event No. 12: Incorrect decay of a ^{60}Co source and fabrication of records

A ^{60}Co unit was calibrated correctly initially, but subsequently corrected for decay in the wrong way and no re-measurement of the output was made. The overdose to patients increased progressively over a period of 22 months, reaching 10% in 5.5 months and as much as 50% in the subsequent 16.5 months. During the latter period, 426 patients were treated. Of the 183 patients who survived beyond one year, 34% had severe complications in various sites, including the brain, spinal cord, skin, oropharyngeal mucosa, colon and rectum, which led to the death of some patients.

Initially the incorrect machine output was attributed to a faulty measuring system. The physicist at the institution produced ten calibration documents, which turned out to be fabricated, that showed that the machine output used clinically was correct.

When some patients showed symptoms of overexposure, the hospital asked consultant physicists to investigate the dosimetry. Their findings were that:

(a) Both the ^{60}Co unit and the measuring system apparently had been functioning correctly during the 22 month period.
(b) The hospital physicist had fabricated all but one of the reports of measurement of machine output. The output used clinically had been calculated, without a check by measurement, and the calculation was incorrect.

Initiating event

— Incorrect calculation of output: The output was based on an incorrect decay of source output.

Contributing factors

— Apparently, insufficient staff resources were devoted to dosimetry and quality control: The beam output was not checked over a 22 month period, since the physicist was assigned to a new accelerator.

— Insufficient defence in depth: There was no independent check of decay curves.
— The physicist falsified records in an attempt to justify his calculations.

Remark
— The number of staff and training needs should be reviewed whenever the workload increases, a new machine is purchased or a new technology or treatment technique is introduced.

Event No. 13: Use of incorrect tables for decay of a ^{60}Co source

A physicist generated tables of decay factors to correct the output of a ^{60}Co irradiator. The tables were generated by a computer, with the year incorrectly entered as one year earlier. Consequently, for a three month period, patients received a dose approximately 12% less than that prescribed. The error was detected during a review of dosimetry by an outside physicist.

Initiating event
— Incorrect calculation of output (it was based on incorrect decay of source output).

Contributing factors
— Insufficient safety provisions (defence in depth):
- There was no independent check of decay curves.
- The treatment times were not reviewed for consistency with previous treatments.

Event No. 14: Lack of communication regarding units of output of a treatment machine

A physicist calibrated a ^{60}Co unit in terms of röntgen/minute at a 5 cm depth in a Masonite phantom. The radiation oncologist, who performed all treatment planning and dosimetry calculations, assumed that the output was in rad/minute to a miniphantom (muscle) at the depth of maximum dose (0.5 cm). The magnitude of the error, depending on the field size, can reach an overdose of 20–25%.

Initiating event
— Incorrect clinical use of a beam calibration.

Contributing factors
— Lack of or ambiguous assignment of responsibilities: The entire dosimetry system, from calibration of machine output to calculation of treatment time, was not the responsibility of one person (preferably the physicist).

— Ineffective communication/transfer of essential information: There was a lack of communication between the physicist who calibrated the machine and the physician who performed treatment planning.
— Lack of or inefficient procedures, protocols and documentation: The technique used by the physicist for calibrating the machine output, in terms of röntgen in a Masonite phantom, was unusual and does not follow accepted protocols.

Remedial action

— A review of dosimetry by an outside physicist revealed the misunderstanding concerning the machine outputs and corrections were made.

Event No. 15: Radiation leakage from the collimator of a linear accelerator

A patient who had been treated for prostatic cancer was seen a few days after he had finished his treatment course. The patient had developed a severe skin reaction on the ventral part of the right arm, the right part of the thorax and the right part of the head. In addition, he had lost some hair from his head. The skin reaction was investigated further, leading to the diagnosis of radiation dermatitis caused by an estimated dose of 10–20 Gy. The treatment had consisted of a course of 25 × 2 Gy with 25 MV photons, using a three beam technique (anterior plus lateral–oblique beams), produced by a 14 year old accelerator.

During the radiotherapy treatment period of this patient, the accelerator showed a slow start at 'radiation on' and radiation was sometimes delivered at a dose rate that was less stable than normal, especially at some gantry angles; sometimes the starting procedure failed completely. Qualified hospital and manufacturer's technicians made a thorough investigation of the origin of these problems, resulting in some additional maintenance and an increase in the frequency of quality control checks. The functioning of the accelerator was monitored almost daily. No deviations from the normal beam properties was observed. The interlock system had never been set off during patient treatment.

Detailed observations of the skin reaction of the patient revealed that a skin reaction was not seen behind the right ear and that the oral mucosa did not show any reaction. It was therefore concluded that the skin reaction could have been caused only by low energy radiation.

The most probable position and direction of the apparent source of radiation leakage was reconstructed from the region of the skin reactions in relation to the gantry and collimator position of the accelerator under the treatment setup. From this reconstruction it was concluded that the source of radiation leakage was located at the upper end of the beam guidance tube close to the last part of the bending system.

It was thereby demonstrated that, despite the relatively high degree of control and the presence of safety systems, this old accelerator could be prone to producing a large amount of radiation leakage which was harmful to patients.

Initiating event

— Unknown, but thought to be a misadjustment of an accelerator parameter which made the accelerator operate in a very unusual mode.

Contributing factor

— Possibly, advanced age of the installation. The only unusual symptom was beam instability. Operating procedures called for this to be investigated but did not recognize it as a reason to stop operation of the machine when the beam properties appeared normal.

Event No. 16: Treatment with an accelerator operated in the PHYSICAL mode

During clinical use of a linear accelerator, a problem arose with the selection of electron and X ray energies. A technician from the manufacturer reported that the problem was associated with a microswitch required to select the scattering foil for electron beams or the beam flattening cone for photon beams. About one month later, on two consecutive days, the same problem reappeared briefly. The machine was not repaired at this time. Four days later the problem returned permanently and the machine could be operated only at two X ray energies and one electron energy (10 MeV). Two weeks later, it was impossible to start the accelerator in the MEDICAL mode. The electronics engineer informed the chief radiation oncologist about the problem. The radiation oncologist asked the electronics engineer to alter the machine so that patients could be treated in the PHYSICAL mode.

The electronics engineer switched the linear accelerator to the PHYSICAL mode and made the following provisions for treatment:

(1) He covered the push buttons that are operative in the MEDICAL mode with paper;
(2) In co-operation with the technician, he measured the absorbed dose under standard conditions for all beams;
(3) He prepared a written report describing procedures for the treatment of patients under the PHYSICAL mode and fixed it to the console of the linear accelerator;
(4) He instructed two radiographers regarding operation of the linear accelerator for treatment in the PHYSICAL mode and observed the treatment of the first four patients.

Thirteen patients were treated with apparently no problems, the last patient being treated with a 10 MeV electron beam. Data for the next patient were set on the console for treatment with 20 MV X rays, dose rate 300 MU/min, without any problem. The treatment started but was terminated by a timer after 21 s; the timer was the third independent safety system designed to switch off the beam if two ionization chamber monitors failed. (According to the radiographer, the audible dose rate indicator beeped with a very low frequency.) When the treatment was terminated, only a few monitor units were displayed on both monitors; the radiographer therefore immediately called the electronics engineer to check the machine. When the patient was removed from the treatment room, the radiographer observed a skin reaction on the patient, which indicated a high degree of overexposure. Treatment was immediately suspended.

The electronics engineer used an ionization chamber to measure the accelerator output under the same operating conditions used for treatment. He found that there was an extremely high dose in the centre of the field, caused by a failure to deploy the X ray target, monitor chamber and beam flattening cone, leaving the 10 MeV electron scattering foil and (disconnected) electron monitor chamber in position. This malfunction was due to the failure of a power supply, which supplied the interlock systems, that should have been active in the non-clinical mode. Hence, no indication of the wrong positioning of the essential elements in the beam line appeared on the control panel. Operation in the PHYSICAL mode had disabled interlocks that could have detected this dangerous condition.

Initiating event

— Treatment in non-clinical, PHYSICAL mode (decision by the radiation oncologist after several failures with interruption of treatments).

Contributing factors

— Equipment failure: The accelerator failed to operate in the clinical (MEDICAL) mode.

— Maintenance problems: Intermittent, unresolved equipment failures, the cause of which was not identified.

Event No. 17: Mishandling of equipment failure

Staff operating a linear accelerator noted that the machine would not produce an electron beam. They reported the fault to a maintenance technician from the manufacturer, who was working on the ^{60}Co unit located in an adjacent room. The technician performed corrective maintenance but, after the repair, the analog display of electron energy permanently indicated 36 MeV regardless of the energy selected.

The energy selection keys correctly indicated the energy selected. The analog indication of the 36 MeV was interpreted as a faulty meter displaying only 36 MeV.

Patients were treated under the above conditions for ten days before the problem with the energy display was reported to the Department of Physics and Radiation Protection. Treatments were then terminated. Physicians began to correlate the poor tolerance and severe reactions observed in some patients with the malfunction of the machine.

A dosimetric check performed the next day showed that the energy of the electrons was 36 MeV, regardless of the energy (7, 10 or 13 MeV) selected on the console. The manufacturer was informed and sent technicians to repair the machine.

The failure to select the electron beam energy was due to a short circuit of the system that selects the trajectory of the electron beam. The path curvature is a function of both the electron energy and the intensity of the magnetic field generated by the coils. Instead of correcting the basic cause (the wrong coil current resulting from the short circuit), the energy of the electrons was manually adjusted to match the wrong current. The correct trajectory was obtained for the electron beam, but at the wrong energy (permanently 36 MeV). The analog indicator of the energy (which indicates the current of the bending coil and depends on the selected energy) was permanently indicating 36 MeV, even between treatments, owing to the short circuit in the control of this current.

When the maintenance technician had selected the manual mode of energy adjustment, he effectively put the machine into a non-clinical mode in which it would ignore the energy selected on the console. Therefore, the energy of the electrons was always 36 MeV, with the beam concentrated in the centre of the field. The result was treatment with electrons that delivered a dose several times higher and irradiated a volume deeper than prescribed. The malfunction affected 27 patients.

Initiating event

— Incorrect maintenance: Misadjustment of the beam energy.

Contributing factors

— Ineffective communication/transfer of essential information and non-compliance with procedures: Physicists were not notified immediately about the malfunction of the machine (treatments were resumed without a check of the beam output). Thus procedures for transferring the machine to and from the maintenance technician were not followed.
— Incorrect interpretation of conflicting signals: The reading on the analog meter indicating the actual energy was ignored.
— It was possible to operate the accelerator with the energy selection disabled (equivalent to 'non-clinical mode').

— Shortage of instruments for quality control: Instruments for quick (daily) constancy checks of beam output and energy, compatible with patient workload, were not available.

Event No. 18: Dose on central axis incorrect because of a loose wedge mounting mechanism

Wedge factors were measured on a ^{60}Co unit with the beam in the vertical position. When the machine gantry was rotated 90° for treatments with a horizontal beam, a loose wedge mounting mechanism allowed wedge filters to shift so that the dose distribution and the central axis wedge factor were incorrect. The error was as large as 8%, with the dose to the patient too high across the beam for one horizontal machine position and too low for the other horizontal beam position.

Initiating event

— Deficiency in the design of accessories of the machine: Mechanical deficiency related to the wedge holder.

Contributing factor

— Lack of or ineffective procedures for commissioning: Wedge factors were not measured with a horizontal beam at the time of commissioning of the machine (the use of accepted protocols with documentation of the data would avoid omitting measurements).

Event No. 19: Holder for port film left in beam during treatment

A lucite plate 1.25 cm (0.5 in) thick used to hold port films was left in the beam during treatment with a linear accelerator. There was no interlock system to detect the presence of the plate. An independent check of beam output with TLDs indicated the following per cent relationship between the measured and expected output:

Radiation beams	Institution's expected dose/ dose measured by TLD (%)
Photons: 10 MV	90
Electrons: 6 MeV	10
9 MeV	26
12 MeV	30
16 MeV	46
20 MeV	57

Further investigation by the institution's physicist revealed that the output measured by the TLDs was correct when the plate was in the beam.

Initiating event

— Mistake in the treatment setup: A holder for portal films was left in the beam during treatment.

Contributing factor

— Equipment design deficiency: There was no interlock to detect the presence of the portal film holder.

Remedial action

— The linear accelerator was retrofitted with an interlock to detect the presence of the portal film holder.

Event No. 20: Design error in accelerator control software

A linear accelerator equipped with computer controlled electron and photon beams was in clinical operation. Several serious incidents led to the recognition of a problem whenever an initial instruction for 25 MV X rays was changed quickly to an electron beam instruction. The computer process for setting and verifying the machine parameters required about 20 s to complete after the X ray mode was selected. If an electron mode was selected before the computer process for X rays was completed, the monitor displayed electron mode but operated from hybrid instructions. The resulting beam consisted of 25 MeV electrons with high beam current appropriate for X rays but without beam scanning, with no X ray target and no X ray beam flattener in the beam. The resulting electron dose at the position of maximum dose was 160–180 Gy before the beam cut off automatically, in one second or less.

When the above sequence of events first occurred it was not recognized as a fault by the manufacturer of the accelerator. One month later the same sequence occurred at another hospital and was attributed to microswitch failure. Six months later a third hospital reported a similar experience with yet another patient. The manufacturer made some modifications in response to the assumed microswitch failure.

Three months later, following a fourth occurrence at another hospital, the possibility of a malfunction was rejected by the manufacturer. One month later a further accident in the same department led to an investigation by the hospital physicist. The fault was demonstrated and software errors were suggested as the cause. The physicist verified that other machines of the same type functioned in the same way. One additional accident occurred before all accelerators of that type were

withdrawn from clinical use. Of six patients treated during the machine malfunction, two died, apparently of overexposure.

Initiating event

— Equipment malfunction due to operation in extreme conditions (it operated on hybrid instructions after the operator changed too quickly from the X ray mode to electron mode).

Contributing factors

— Insufficient factory testing: Computer controlled radiation equipment was not factory tested for extreme or unusual operating conditions that could occur in practice.
— Staff operating the linear accelerator requested the electron mode before the computer had completed processing of the previously requested X ray mode.
— Insufficient follow-up by the manufacturer: The reported incidents were misinterpreted or dismissed by the manufacturer until, after similar incidents in six different hospitals, a hospital physicist identified and demonstrated the nature of the fault.

2.6. EXTERNAL BEAM THERAPY: TREATMENT PLANNING, PATIENT SETUP AND TREATMENT

Event No. 21: Inconsistent sets of basic machine data

For one machine, an institution had two sets of data for output factors, depth dose and other basic parameters. The two sets of data differed by 10%, with one set being correct. The data were used interchangeably for a period of time, with the result that some patients were underdosed by 10%.

Initiating event

— Incorrect data for patient dose calculations

Contributing factors

— Lack of or ineffective procedures, protocols and documentation: The institution had two sets of data that were inconsistent.
— Insufficient safety provisions (defence in depth): An incorrect table of values was used without verification.

Event No. 22: Incorrect data for tissue maximum ratios

Tables of tissue maximum ratios were generated for a 10 MV photon beam, based on the institution's measurements. Inspection of the tables during a review of dosimetry by an outside physicist after several months of use revealed an inconsistency in the trend of data with increasing depth and field size. Checks against the original measurements showed that at least 15 entries in the table were incorrect, some by as much as 13%.

Initiating event

— Incorrect data for patient dose calculations.

Contributing factors

— Insufficient safety provisions (defence in depth): Tables of measured tissue maximum ratios were not verified against published values before clinical use.

Remedial action

— The tables were corrected. Charts of patients affected by the incorrect data were reviewed and the calculations corrected.

Event No. 23: Insufficient understanding of the treatment planning system (TPS) algorithm

A treatment planning computer was used to calculate ^{60}Co treatment plans involving wedges. The technologist and dosimetrist were not sure whether the computer calculation included the wedge factor. They asked the consultant physicist and were told that the wedge factor was not included in the computer calculation and should be accounted for manually. Three patients were treated in this way. While preparing to treat an additional patient following the same treatment protocol, a hand calculation of the treatment time indicated a large discrepancy with the computer generated value. The computer already included the wedge factor, so that this factor had been applied twice. A review of cases revealed misadministration for three other patients, who received overexposures of close to 11, 12 and 14% for prescribed doses of 62, 65 and 50 Gy, respectively.

Initiating event

— Incorrect data for patient dose calculations (the wedge factor was applied twice, once by hand and once by the treatment planning computer).

Contributing factors

— Lack of or ineffective procedures, protocols and documentation: Commissioning with incomplete validation of the computer TPS.

— Insufficient safety provisions (defence in depth): There was no regular manual checking of computer calculations.

Event No. 24: Incorrect basic data in a TPS

Basic data used in a TPS differed from measured data for a particular linear accelerator; the inconsistency was not detected during commissioning of the planning system. The result was that patients received a 15% overdosage. The data had been entered into the computer by the hospital's previous physicist and the reason for the errors was unknown.

Initiating event

— Incorrect data for patient dose calculations (incorrect basic data used in a TPS).

Contributing factors

— Lack of or ineffective procedures, protocols and documentation:

- Inadequate commissioning (TPS).
- Inadequate transfer of responsibilities and/or taking over by newly appointed staff, in this case the physicist.

— Insufficient safety provisions (defence in depth): No manual checks of the treatment plans were made.

Remedial action

— The data in the TPS were corrected.

Event No. 25: Incorrect depth dose data

During installation of a linear accelerator, an institution contracted the services of the manufacturer to measure depth dose data. The institution's physicist later checked the data and found an 8% discrepancy between his measurements and those of the manufacturer for some field sizes and depths. He concluded that the manufacturer's data were correct and used them clinically. A review by an outside consultant physicist revealed that the physicist's measurements were correct. During a period of several months, some patients received doses that were 8% lower than prescribed.

Initiating event

— Incorrect data for patient dose calculations: The manufacturer provided basic data that were incorrect for some field sizes and depths.

Contributing factors

— Lack of or ineffective procedures, protocols and documentation: Incorrect commissioning (data generated by the manufacturer were accepted for treatments, although the institution's physicist found an 8% discrepancy when he compared these data with his measurements).
— Insufficient education, training or expertise: A known discrepancy was not resolved.
— Lack of or ineffective assignment of responsibilities: The physicist did not take responsibility for all aspects of dosimetry.

Event No. 26: Incorrect calculation of treatment times

Tables of treatment times used clinically were incorrect; the reason for the errors was unknown. Thirteen patients who were prescribed ^{60}Co teletherapy treatments received doses that were from 15 to 40% lower than the doses intended.

Initiating event

— Incorrect data for patient dose calculations: Basic data (tables of treatment times) were incorrect.

Contributing factors

— Lack of or ineffective procedures, protocols and documentation: Incorrect tables were accepted for use.
— Insufficient safety provisions (defence in depth):
  - There was no independent verification of basic data (time charts used to calculate treatment times).
  - There was no independent check of treatment times calculated for individual patients.

Remedial action

— A new departmental policy required a check by an independent person of daily treatment times for each patient. The check was performed on a weekly basis or whenever a treatment time was changed.

Event No. 27: Misapplication of distance correction

An institution treated most patients with a constant source–skin distance (SSD) technique, although some patients were treated with a constant source–axis distance (SAD) or isocentric technique. For an isocentric treatment plan, the dosimetrist assumed that it was necessary to use a correction factor to convert from SSD to SAD. The physicist checked the method. However, the computer program for isocentric

techniques had already allowed for this factor. This practice of manually correcting for isocentric treatments continued for nine years, until the systematic error was discovered.

Over the nine year period, all patients treated isocentrically received incorrect doses due to the double application of the inverse square correction. Although these patients were a small percentage of all patients, at least 1000 patients received doses less than prescribed. The magnitude of the error depended upon the depth of the isocentre, but for some patients the error may have been 30%.

Initiating event

— Incorrect patient dose calculations: The SSD was entered manually into a computer treatment planning program for isocentric techniques, although the program allowed for that already.

Contributing factors

— Insufficient education, training or expertise: The training should include the particular piece of equipment TPS.
— Lack of or ineffective procedures, protocols and documentation: Incorrect commissioning of the treatment planning computer, with poor understanding of the computer algorithm.
— Insufficient safety provisions (defence in depth): Lack of independent checking and verification procedures.

Event No. 28: Incorrect calculation using the inverse square law

A patient was prescribed a ^{60}Co teletherapy treatment of 20 fractions of 2 Gy each. The prescribed SSD was 70 cm; the SSD used for most patients was 80 cm. The physicist who calculated the dose used an incorrect inverse square correction factor that led to a given dose which was 70% too high. Consequently, the patient received 3.4 Gy per fraction instead of the intended 2 Gy for the first eight fractions. The calculations were not checked until after the eighth fraction, when a junior physicist discovered the mistake. The dose for the remaining fractions was reduced to compensate for the excess dose delivered during the earlier treatments.

Initiating event

— Incorrect data for patient dose calculations (an incorrect inverse square conversion factor was used).

Contributing factors

— Insufficient awareness: The treatment was unusual (the treating distance was unusual, 70 cm rather than 80 cm SSD), without there being sufficient awareness of the difference.

— Insufficient safety provisions (defence in depth): Lack of an independent check of the treatment plan.
— Lack of or ineffective procedures, protocols and documentation: Treatment times were not checked until the patient received eight fractions of his treatment.

Remedial action

— A procedure was introduced which required that calculations be checked before the third fraction of treatments consisting of more than three fractions. For treatments requiring three or fewer fractions, calculations were to be checked by the first fraction.

Event No. 29: Incorrect calculation of treatment times for open and wedged beams

One field was treated with a combination of open and wedged beams on a ^{60}Co unit. The treatment times were reversed when calculating the dose distribution for the total treatment, with the result that the patient received an overdose of 10%.

Initiating event

— Incorrect patient dose calculations (treatment times were reversed for open and wedged beams).

Contributing factor

— Insufficient safety provisions (defence in depth): Lack of an independent check of the treatment plan.

Event No. 30: Error in the wedge factor

During a review of past treatment data, 12 wrong treatments were discovered. Some patients were found to have received doses 10–18% *higher* and some 10–27% *lower* than the prescribed doses. The overdoses resulted from erroneous information in the treatment planning computer reference data. All these treatments, with one exception, involved the use of wedge filters.

The treatment discrepancies were first discovered when a therapy technologist examined the files of previously treated patients in order to practice hand calculated dosimetry for an upcoming board certification test. The radiation oncology staff then began recalculation of doses to all patients who had received wedge related treatments since the introduction of that type of treatment two years earlier. The staff also re-ran the original computer calculations, which showed that administered doses

had deviated significantly from prescribed doses. In 11 of 12 wrong treatments the planning staff failed to use a computer program 'wedge normalization factor' in making initial dose calculations. The use of this wedge normalization factor is described in the manufacturer's computer instruction manual. Instead of using this generated factor, the planning staff used different measured wedge factors.

Initiating event

— An incorrect procedure was used for computerized treatment planning involving wedges.

Contributing factors

— Lack of or ineffective procedures, accepted protocols and documentation.
— Insufficient safety provisions (defence in depth):
  - Lack of an independent check (of dosimetry involving the use of wedges).
  - Computer calculations were also not manually checked.

Event No. 31: Wedge factors used twice in the calculation of treatment times

A physicist began employment at a new institution, which had the same TPS he had used in his previous place of employment. At the new institution, the wedge factors were included in the computer calculations; at the previous institution, the wedge factors were applied manually for each patient. The physicist used, in error, the TPS in the same way as he had used it in his earlier position. In other words, he applied the wedge factor at the new institution manually for each patient, which meant that this factor was used twice for the calculation of treatment times. For one patient the result was a 53% overdose for a boost (wedged) field, resulting in a total dose that was 17% higher than prescribed.

Initiating event

— Incorrect patient dose calculations (a wedge factor was applied twice in the calculation of the treatment time).

Contributing events

— Insufficient education, training or expertise: Lack of understanding of the TPS operation.
— Insufficient safety provisions (defence in depth):
  - Application without verification of a calculation adapted from another hospital.
  - The computer calculations were not manually checked.

Event No. 32: Failure to include intended wedges in the treatment setup

A patient was prescribed a ^{60}Co teletherapy treatment of 16.6 Gy. The treatment required two fields using 30° wedges. The physicist failed to record the wedges in the setup portion of the patient's chart and the wedges were not used during treatment. When the error was detected, the patient had received a dose of 23.0 Gy to the reference point on the central axes instead of the prescribed 16.6 Gy, an overdose of almost 40%. In addition to the overdose at the reference point, the dose distribution was non-uniform, with the hottest region receiving a much larger overdose.

Initiating event

— Incorrect patient dose calculations: The physicist failed to specify wedges in the setup instructions.

Contributing factors

— Insufficient safety provisions (defence in depth):
  - There was no independent verification of the treatment parameters.
  - There was no inspection of the resulting isodose distribution.

Event No. 33: Misunderstanding of a complex treatment plan given verbally

A patient was prescribed a ^{60}Co teletherapy treatment to two different treatment sites. The two sites were to be treated daily, with the first site receiving 2.4 Gy each day for 20 days and the second site receiving 2.5 Gy each day for 10 days. The two technologists involved in this procedure misunderstood the physician's verbal instruction concerning the treatment plan and failed to recognize the different number of treatment fractions for the two sites. Therefore, the second site received an additional four days of treatment before the error was detected. The patient received 10 Gy more than was prescribed, an overdose of 40%.

Initiating event

— Incorrect treatment setup.

Contributing factors

— Lack of or ineffective procedures, protocols and documentation:
  - There were no written procedures for treatment prescription.
  - Unclear verbal prescription.
— Unusually complex treatment involving two sites that were to receive different doses in different fractions.

Remedial action

— A new protocol required that a 'stop' mark be placed in each patient's daily treatment log, indicating the projected final day of treatment for each site.

Event No. 34: Incorrect identification of patient

The radiation technologist called the patient's name but did not confirm his identity by looking at his photograph in the record. The radiation technologist had not seen the patient and, therefore, did not realize that another patient had responded. When he was being positioned for therapy, freckles on his back were mistaken for treatment positioning tattoos and were used for the setup. The radiation technologist did not recognize the absence of treatment tattoos in the patient's lumbar/sacral spine area despite a photograph. The patient indicated that his setup was not correct and the radiation technologist called the oncology physician to verify that the treatment was correct. The physician verified that the treatment was correct on the chart but did not speak to or examine the patient. The patient was then administered 2.5 Gy from a teletherapy unit to the lumbar/sacral spine, i.e. the wrong site.

Initiating event

— Incorrect treatment setup: A patient responded when another patient's name was called.

Contributing factors

— Non-compliance with procedures:
  - For patient identification: There was no check of the patient's photograph or identity bracelet, if there was one.
  - For site identification: There was no confirmation of anatomical marks for beam location.

— Lack of awareness: No one heeded the patient's warning and objection to being treated at the wrong site.

Event No. 35: Treatment setup based on another patient's chart

A patient was prescribed a ^{60}Co teletherapy dose to the brain but received an unintended dose of 0.45 Gy to the lung. For instructions regarding setup, the technologist picked up the chart of another patient, who was prescribed a lung treatment. The technologist positioned the patient without confirming his identity against the chart and proceeded with the lung treatment. During the treatment, a second technologist noted the discrepancy between the patient's name and the chart and terminated the treatment.

Initiating event

— Incorrect treatment setup: The technologist used another patient's chart to set up the treatment.

Contributing factors

— Inattention or lack of awareness.

— Non-compliance with procedures for patient identification.

Event No. 36: Calculation error after a change of treatment regimen

A ^{60}Co teletherapy treatment was prescribed to the larynx, a total of 76.8 Gy in 64 fractions of 1.2 Gy each, two fractions per day. After 18 treatments, the oncologist revised the treatment plan. He reduced the field size and moved the radiation field off the spinal cord. The technologist made a mistake in the calculation of the new treatment time and the patient received twice the prescribed dose for the next 22 fractions. Instead of the intended 26.4 Gy for the second part of the treatment, the patient received a dose of 52.8 Gy. The physicist reviewed the treatment plan and patient chart on a weekly basis, but failed to notice the mistake until the third review. The treatment was immediately suspended. By then, 40 fractions had been administered. It was estimated that the patient received a total dose of about 75 Gy in 40 fractions rather than the prescribed dose of 76.8 Gy in 64 fractions.

Initiating event

— Incorrect patient dose calculation: The technologist miscalculated the treatment time for the revised treatment plan.

Contributing factors

— Insufficient safety provisions (defence in depth): Lack of an independent check of the treatment plan (treatment times).

— Procedures followed mechanically without sufficient awareness: Ineffective weekly checking of the patient's chart.

Event No. 37: Confusion of fractional dose and total dose

A child was prescribed ^{60}Co teletherapy treatment to the brain. The total prescribed dose was 3 Gy, to be delivered in two fractions of 1.5 Gy each. The dosimetrist calculated the dose for 3 Gy per treatment. Three other individuals reviewed the calculations before the treatment started and failed to notice the error. As a result, the patient received a total dose of 6 Gy. The error was discovered by a student therapy technologist who reviewed the treatment plan.

Initiating event

— Incorrect patient dose calculation: The dosimetrist misunderstood the total dose for the fractional dose in a two fraction treatment.

Contributing factors

— Ineffective communication/transfer of essential information.
— Procedures followed mechanically without sufficient awareness: Three persons failed to detect the error.
— The nature of the treatment combined with insufficient awareness favoured the mistake.
  - The treatment was unusual (fractionation).
  - The treatment was very short (two sessions), which increased the risk of not detecting the error before treatment was completed.

Event No. 38: Incorrect positioning of treatment beams

A patient was prescribed ^{60}Co teletherapy to both the right hip and the thoracolumbar spine, to be completed on different days. After the patient completed the thoracolumbar spine treatment, the technologist mistakenly continued treatment to the same region for a total of 12 Gy. The staff technologist involved in this treatment failed to notice the statement in the patient's chart that the treatment to the spinal area had been completed. Six more treatments were given. The mistake was not detected during the routine chart review by a physicist.

Initiating event

— Incorrect treatment setup: The technologist did not check the patient's chart carefully before setting up a field and administering radiation.

Contributing factor

— Inattention or insufficient awareness.
— Insufficient safety provisions (defence in depth): The patient setup was not checked by another person (the technologist worked alone).

Event No. 39: Wrong tattoo used in treatment setup

A patient was prescribed a ^{60}Co teletherapy treatment to the lumbar spine but received an unintended dose of 2.5 Gy to the thoracic spine. The patient had previously received teletherapy treatments over the thoracic spine, and the tattoo (anatomical marker) was still visible. The technologist setting up the treatment failed to review the patient's chart, which indicated the proper treatment, and used the tattoo from the previous treatment.

Initiating event

— Incorrect treatment setup: The technologist used a tattoo from a previous treatment to set up a new series of treatments.

Contributing factors

— Ineffective procedures: The patient had two tattoos, one of which was from a previous treatment that was near the site of the tattoo for the current treatment

— Inattention or insufficient awareness: The technologist did not carefully review the patient's chart for the location of the treatment site.

Remedial action

— After this incident, technologists were instructed to have a physician or dosimetrist present during patient setup.

Event No. 40: Treatment of the wrong patient and lack of communication because of language problems

A patient was scheduled to receive treatment to the head and neck area using a linear accelerator. The patient spoke little English and the oncologist did not speak the patient's language. The oncologist asked the patient which area of the body was being treated and the patient pointed to his head. Without reviewing the patient's chart, the physician assumed that he was scheduled for treatment with a ^{90}Sr plaque and administered a dose of 10 Gy to the surface of the right eye.

Initiating event

— Incorrect treatment setup: Incorrect patient identification.

Contributing factors

— Non-compliance with procedures for patient identification: The oncologist did not check the patient's chart.

— Inattention or insufficient awareness: The radiation oncologist relied on the patient to locate the treatment site.

— Ineffective communication/transfer of essential information: The patient and the oncologist did not speak the same language.

Event No. 41: Incorrect labelling of a simulator film

A patient was to receive a ^{60}Co treatment of 2.16 Gy to the left posterior neck. However, the treatment was delivered to the right posterior neck. Because the treatment simulation was performed in the prone position rather than in the routine supine position, the right side of the simulator film was marked as the left and the

patient was set up incorrectly. In reviewing the simulator film, the oncologist failed to notice that the treatment simulation was to the wrong side of the patient's neck.

Initiating event

— Incorrect simulation/localization: Incorrect labelling of the localization film.

Contributing factors

— The treatment was simulated in an unusual position.

— Insufficient safety provisions (defence in depth): There was no check of the orientation of the anatomical site relative to the film.

Event No. 42: Field improperly located on patient

A patient was prescribed a treatment of 3 Gy to the cervical spine. The technologist looked at the patient's chart but still mistakenly set up the treatment field on the thoracic spine. The patient received 2.87 Gy to the thoracic spine instead of the prescribed 3 Gy to the cervical spine The patient had previously received treatment to the thoracic spine, leading the technologist to assume that the thoracic treatment was continuing.

Initiating event

— Incorrect treatment setup: Failure to adequately examine the patient's chart before administering treatment.

Contributing factor

— Insufficient safety provisions (defence in depth): There was no independent check of the chart and the setup.

Event No. 43: Field improperly located on patient

A patient was prescribed ^{60}Co teletherapy of 2 Gy per fraction to the mediastinum. The technologist marked the beam setup incorrectly as a brain treatment and the patient received ten fractions to the brain before the error was detected, even though the technologist was to have been supervised by qualified staff members.

Initiating event

— A technologist set up a new patient and marked the wrong beam position.

Contributing factors

— Ineffective communication/transfer of essential information: The prescription of the oncologist was misread, by the technologist, ten different times.

— Inattention or insufficient awareness: Checks by three staff members failed to detect the setup mistake.

Event No. 44: Incorrect positioning of patient

A patient was to receive ^{60}Co treatments of 10 fractions, 3 Gy each, to the right scapula. After the second fraction, the oncologist reviewed the port film and noticed that 80% of the intended target area had been missed. A chart review indicated that during simulation of the treatment, the oncologist had placed a mark on the patient's chest as indicated by the ceiling laser. However, for treatment the back pointer on the teletherapy unit was used to position the beam. Since the back pointer and ceiling laser locate the radiation beam at different angles, the tissue volume treated was medial to the intended site.

Initiating event

— Incorrect treatment setup.

Contributing factor

— Ineffective communication/transfer of essential information:

- Poor communication between the radiation oncologist and radiation technologist during simulation.
- Procedures were misunderstood: Procedures for simulation were unsuccessful in ensuring that the technologist understood the treatment plan of the oncologist.

Remedial action

— The oncologist changed the original prescription to include two additional treatment fractions in order to bring the total treatment dose to 30 Gy.

Event No. 45: Improper positioning of the patient for treatment

A patient with metastatic lung disease received a bone scan in the prone position (face down). A metastatic lesion was found in the left hip, for which the patient was to receive 27 Gy. For radiation therapy, the patient was positioned in the supine position (face up). The orientation of the bone scan was misinterpreted and the patient was treated on the right hip rather than the left hip. The treatment continued for two weeks, until a resident oncologist discovered the error while reviewing the patient's chart.

Initiating event

— A nuclear medicine bone scan was misinterpreted with regard to laterality of a hip lesion.

Contributing factors

— Ineffective procedures, protocols and documentation:
  - Different imaging conventions (for X ray and nuclear medicine images).
  - The radiotherapy staff was not familiar with imaging conventions in the nuclear medicine department and did not review the report of the bone scan.
  - The prescription for radiotherapy did not indicate clearly which hip was to be treated.

Event No. 46: Machine incorrectly set for rotation rather than for a stationary field

A patient was prescribed a stationary field treatment of 40 Gy to the pelvis, in 20 fractions of 2 Gy each For the 14th fraction, the technologist, who was working alone, performed the setup but did not notice that the machine was still set for the rotational technique used for the previous patient. She also failed to visually check the operation of the machine after the beam-on switch was activated. Therefore, the patient received 0 8 to 1.0 Gy and 0.6 to 0.7 Gy to the left and right sides of the pelvis, respectively, both of which were outside the region of the intended treatment.

Initiating event

— Incorrect treatment setup (machine settings).

Contributing factors

— Design deficiency. The machine design allowed the use of parameters from the previous treatment.
— Insufficient safety provisions (defence in depth): There was no independent check of the machine settings.
— Ineffective procedures or non-compliance with procedures: The technologist did not observe the patient during irradiation.

2.7. DECOMMISSIONING OF TELETHERAPY EQUIPMENT

Event No. 47: Abandonment of a ^{137}Cs machine

A private radiotherapy institute moved to new premises, leaving behind a ^{137}Cs teletherapy unit without notifying the licensing authority. Because of partial demolition of the building, the teletherapy unit became totally unsecured. Two people entered the building and removed the source assembly from the radiation head. They tried to dismantle the source assembly at home and in the attempt the source capsule was ruptured. Because the radioactive source was in the form of caesium chloride,

which is highly soluble and easily dispensed, there was considerable contamination of the environment, resulting in external irradiation and internal contamination of several persons.

After the source capsule was ruptured, remnants of the source assembly were sold for scrap to a junkyard owner. He noticed that the source material glowed blue in the dark. Several persons were fascinated by this and over a period of days friends and relatives came to witness the phenomenon. Fragments of the source the size of rice grains were distributed to several families. Five days later, a number of persons showed gastrointestinal symptoms that were not recognized initially as being due to exposure to radiation. However, one of the persons irradiated connected the illnesses with the source capsule and took the remnants to the public health department. This action started a chain of events that led to investigation of the accident.

Many individuals received external and internal radiation exposure exceeding acceptable limits. In total, some 112 000 persons were monitored; 249 persons were contaminated either internally or externally. Some suffered very high internal and external contamination owing to the way they had handled the caesium chloride powder, such as daubing their skin, eating with contaminated hands, and handling various objects. Four persons died within four weeks of admission to hospital, having received total body doses of at least 5 Gy.

Initial radiation surveys were conducted on foot over the contaminated areas. Seven main sites of contamination were identified, including the junkyards concerned, some of them with dose rates of up to 2 $Sv \cdot h^{-1}$(~200 R/h) at 1 m. Aerial surveys were conducted over 67 km^2. Of 159 houses monitored, 42 required decontamination. The final volume of waste stored was 3500 m^3 or 275 lorry loads. The radioactivity accounted for in the decontamination was estimated at 44.4 TBq, compared with the known activity of the source before the accident of 50.9 TBq.

Initiating event

— The abandoned machine was stolen and dismantled; the source capsule was broken.

Contributing factors

— Lack of compliance with regulations:
  - There was no safe, formal and complete decommissioning of the facility.
  - The ^{137}Cs teletherapy unit, no longer in use, was abandoned and unsecured.
— The source was not recognized by the general public as being dangerous.
— The chemical form of the source facilitated the spread of radioactive contamination.

Event No. 48: Illegal import, storage and disposal of a teletherapy unit

A teletherapy unit with a 37 TBq ^{60}Co source was purchased and imported without complying with all the existing import requirements. It was stored in a warehouse for six years, when its scrap value attracted the attention of a maintenance technician, who dismantled the head of the unit and removed the cylinder containing the ^{60}Co.

The technician removed the cylinder and other metal parts from the unit, loaded them into a pickup truck, drove to a junkyard and sold the parts as scrap. Before arriving at the junkyard, he deliberately ruptured the cylinder containing the source. The pickup truck thus contained a large quantity of radioactive material from the source.

The source consisted of about 6000 tiny pellets (1 mm × 1 mm in diameter) of ^{60}Co, a metal with magnetic properties and low mechanical resistance. When the cylinder ruptured, several pellets were dispersed and remained in the truck when the heavy parts were unloaded at the junkyard.

When the ruptured cylinder was moved by cranes, together with the other metal pieces, the ^{60}Co pellets were spread over the junkyard, attracted by the crane's magnetic field, and mixed with the other metal materials. Consequently, pellets and pellet fragments were also transferred to the vehicles used for transporting scrap to various foundries. The main purchaser of the scrap was a firm that manufactured construction reinforcing rods and connecting rods for motor vehicles. Owing to mechanical defects, the truck that was contaminated with ^{60}Co pellets remained parked on the street for 40 days. The truck was then moved to another street where it stood for a further ten days.

It was later found that scrap contaminated with ^{60}Co had been used by steel production plants to manufacture reinforcing rods and metal table bases. A lorry transporting contaminated rods passed near a nuclear laboratory where radiation detectors were used to monitor removal of radioactive material. The detectors not only indicated the presence of radioactivity, but also activated a camera that photographed the contaminated vehicle. Two days later the authorities ascertained the origin of the contaminated rods.

An extensive investigation showed that 30 000 table bases and 6600 t of reinforcing rods had been made from the contaminated material. Aerial surveys of an area of 470 km^2 were conducted, resulting in the recovery of 27 cobalt pellets. Visits were made to 17 636 buildings to determine whether contaminated material was used in their construction Acceptable radiation levels had been exceeded in 814 buildings, that were then partly or completely demolished.

The accident exposed approximately 4000 people to radiation, about 80 of whom received doses greater than 250 mSv. Apparently, five people received doses of 3–7 Sv over a two month period.

Initiating event

— A person dismantled an insecurely stored head of a ^{60}Co teletherapy unit and broke the source capsule.

Contributing factors

— Non-compliance with regulations:
  - A radiotherapy unit was illegally imported and transported.
  - The unit remained in storage for six years under unsafe and unsecured conditions.
— A technician did not recognize the potentially dangerous situation.
— Radioactive parts of the unit were sold as scrap for industrial processing.

2.8. MECHANICAL AND ELECTRICAL MALFUNCTIONS

Event No. 49: Mechanical failure of a ^{60}Co unit

A spider gear in the drive unit of a vertically mounted ^{60}Co unit was not fully engaged. As a result, the head of the unit fell on the patient, causing a fatal injury.

Initiating event

— Failure of equipment (fault in spider gear in the drive unit).

Event No. 50: Accidental fall of lead blocks

During treatment with a linear accelerator, a lead block weighing 1.4 kg fell from a height of 0.5 m, striking the patient, after the therapist accidentally knocked it off the accessory mount.

Initiating event

— Inadequate setup of accessories (lead block accidentally knocked off the mount).

Contributing factors

— Inadequate securing of block.
— Positioning of lead block, which had the potential of falling and hitting patients if it fell.

Event No. 51: Electrical failure of a simulator

Failure of a diode on the limit switch allowed the image intensifier on a simulator to over-travel. The power cables to the intensifier were subsequently pinched by the unit covers, causing an electrical shock to the patient.

Initiating event

— Equipment failure.

Contributing factor

— Radiotherapy machines involve other risks (electrical, mechanical, chemical) to patients and staff in addition to those arising from radiation. These should always be recognized and appropriate inspection should be ensured.

Event No. 52: Mechanical failure of cassette holder assembly

When the gantry on a simulator was being rotated, the cassette holder assembly, weighing approximately 9 kg, detached and fell to the floor, glancing off the head of the patient. The accident was caused by two sheared cassette holder screws which were to have been replaced by the manufacturer.

Initiating event:

— Inadequate setup of accessories.

Contributing factor

— Delayed maintenance of the sheared cassette holder screws.

2.9. BRACHYTHERAPY: LOW DOSE RATE SOURCES AND APPLICATORS

Event No. 53: Incorrect dose calculations due to the use of incorrect source strength units

To calculate brachytherapy dose distributions, a physicist used a treatment planning computer that required input of the source strengths in terms of exposure rate at a distance in special units of $R \cdot cm^{-2} \cdot h^{-1}$ He specified the source strength in SI units, reference air kerma rate in $\mu Gy \cdot m^{-2} \cdot h^{-1}$. Therefore, five patients received doses 14% higher than prescribed.

Initiating event

— Incorrect patient dose calculations: The physicist specified the source activities in units which were inconsistent with the manufacturer's calibration.

Contributing factors

— Lack of harmonization of source strength units: Different units were used by the manufacturer of the TPS and by the physicist.
— Insufficient training/understanding of TPS software.
— Insufficient safety provisions (defence in depth): There was no independent check of the computer calculations either by another person or by the use of a manual method.

Event No. 54: Inconsistent units of source activity

A patient received a brachytherapy implant of the prostate gland using ^{192}Ir seeds encased in nylon ribbon. The prescribed dose to the prostate was 32.6 Gy. Two months later, while reviewing the shipping documents associated with the implant, the dosimetrist noted a discrepancy in the units of activity between what she had ordered and what she had received. The hospital had ordered ribbons containing 0.79 mCi per seed. This is equivalent to 29 MBq. However, the vendor had delivered brachytherapy ribbons containing 0.79 milligram radium-equivalent (mg Ra-eq)[1] per ribbon. This is equivalent to 60 MBq. When the shipment was received, the dosimetrist had checked the prescription order against the activity received and noted that the numbers (0.79) matched; she failed to notice that the units differed. Therefore, the dose to the prostate was 56.7 Gy rather than the prescribed 32.6 Gy, an overdose of 74%.

Initiating event

— Incorrect data provided by the vendor for dose calculation.

Contributing factors

— Lack of harmonization of source strength units: Different units were used by the manufacturer of the sources and by the physicist.
— Insufficient safety provisions (defence in depth):
  - The dosimetrist did not verify consistency between the activity of the sources ordered and those received.
  - The strength of the source was not measured at the hospital.

[1] 1 mg Ra-eq = 2.06 mCi.

Event No. 55: Sources of incorrect activity

A patient was prescribed a brachytherapy dose of 28.8 Gy to the prostate, using a transperineal interstitial implant containing 70 ^{192}Ir seeds encased in ten nylon ribbons. The hospital ordered ^{192}Ir brachytherapy ribbons containing seven seeds per ribbon with an activity of 0.79 mCi (29 MBq) per seed. However, the vendor delivered ribbons containing seven seeds each but with an activity of 0.79 mg Ra-eq (50 MBq) per seed. Ten catheters containing the sources were implanted in the desired treatment site.

During the course of the treatment two catheters became displaced and were removed by the physician. As the treatment progressed the patient became confused and removed four additional catheters, which were recovered by an attending nurse. The treatment was discontinued prior to the planned time of removal. The error in the strength of the sources was discovered during a recalculation procedure after removal of the catheters. Because of the higher strength of the sources and the early removal of the catheters, the administered dose was estimated to be 35.2 Gy rather than 28 8 Gy, an overdose of 22%. The overdose was enhanced by the fact that the radiation was delivered in a time shorter than that prescribed. In addition, removal of sources at different times altered the dose distribution.

Initiating event

— Incorrect data provided by the vendor for dose calculation.

Contributing factors

— Lack of harmonization of source strength units: Different units were used by the manufacturer of the sources and by the hospital.
— Insufficient safety provisions (defence in depth):
  - The dosimetrist did not verify the consistency between the activity of the sources ordered and those received (the number 0.79 was checked but not the unit of activity).
  - The strength of the source was not measured at the hospital.

Event No. 56: Implant of the wrong ^{137}Cs source

A patient was prescribed brachytherapy of the cervix, using two ^{137}Cs sources. The prescription required source strengths of 20 and 25 mg Ra-eq for 26 h. After the treatment was completed and the sources had been returned to the storage facility, it was discovered that a 5 mg Ra-eq source had been used instead of the prescribed 25 mg Ra-eq source. Therefore, the patient received about 56% of the intended dose.

It was reported that the ^{137}Cs sources were appropriately colour coded and that the storage drawers in the safe were clearly labelled with the strength as well as the colour code of the sources. Nevertheless, one drawer contained sources of two different strengths. It was concluded that the mix-up was due to human error, leading to the selection of a source of the wrong strength.

Initiating event

— Use of the wrong source.

Contributing factors

— Lack of or ineffective procedures, protocols and documentation:
- The labelling of the sources was ineffective.
- A storage drawer contained sources of different activities.
- There was no verification of source activity prior to treatment.

Event No. 57: Use of the wrong ^{137}Cs sources

A patient was prescribed a gynaecological brachytherapy treatment of 27 Gy using five ^{137}Cs sources with a total activity of 4322 MBq. The individual loading the applicators selected two sources with incorrect activity owing to faded colour coding on the sources. The total activity used was 5937 MBq. Consequently, the patient received an overdose. The error in the selection of sources was not detected by the individual responsible for performing an independent verification of source activity.

Initiating event

— Use of the wrong source.

Contributing factors

— Lack of or ineffective procedures, protocols and documentation: The colour coding for source identification was faded.

— Insufficient awareness: The sources were verified prior to the implant, but the error was not detected.

Event No. 58: Treatment time based on the wrong isotope

A patient was prescribed a brachytherapy treatment of 32.5 Gy using a ^{137}Cs low dose rate afterloading unit. The physicist calculated the treatment time using the characteristics of ^{192}Ir rather than data for ^{137}Cs. The patient received a dose of 22 Gy, an underdose of about 30%. The error resulted because the console button which activated calculation of the treatment plan was selected by mistake.

Initiating event

— Incorrect patient dose calculation (calculation of the treatment time was based on ^{192}Ir rather than ^{137}Cs).

Contributing factor

— Insufficient safety provisions (defence in depth): There were no independent checks of the treatment plan and calculation of treatment time.

Remedial action

— The hospital modified the isotope selection system to require more than one step when selecting an isotope and instituted independent verification of all treatment plans and calculations.

Event No. 59: Treatment planning based on the wrong isotope

A patient was treated with combined interstitial brachytherapy and hyperthermia. Both ^{125}I and ^{192}Ir seeds were discussed as potential brachytherapy sources with respect to cost and availability. The decision was taken to use ^{125}I. However, for the final dose calculations, the dosimetrist used ^{192}Ir instead of ^{125}I. Therefore, the patient received 5 Gy instead of the prescribed 25 Gy, or 20% of the intended dose. The error was discovered during a review of the patient's record at a routine brachytherapy conference.

Initiating event

— Incorrect patient dose calculation: The dosimetrist based the treatment plan on the wrong radionuclide.

Contributing factors

— Ineffective communication/transfer of essential information: There was a misunderstanding between the radiation oncologist and the dosimetrist.

— Insufficient safety provisions (defence in depth): There was no effective independent check of the treatment plan.

Event No. 60: Error in the calculation of dose from an eye plaque

A patient was prescribed brachytherapy for ocular melanoma by means of a custom made eye plaque containing ^{125}I seeds. The prescription was for 300 Gy to be administered to the base and 143 Gy to the apex of the tumour.

The physicist designed the eye plaque and calculated the dose to the prescribed points. However, before implantation he modified the plaque to have a different radius of curvature. He changed the co-ordinates for placement of the ^{125}I seeds in the

plaque but failed to change the associated points for calculation of the dose to the points of interest.

Four days after application of the eye plaque, while he was planning the treatment of another patient, the physicist suspected that he had made a mistake in the earlier case. He retrieved the relevant data from the computer, reviewed the calculations, and confirmed that an error had been made. The patient's eye plaque was then removed. As a result, the patient received a dose of about 590 Gy (an overdose of 97%) to the base of the tumour and 195 Gy (an overdose of 36%) to the apex of the tumour.

Initiating event

— Incorrect patient dose calculation: The physicist altered the eye plaque without changing the dose calculations.

Contributing factors

— Insufficient safety provisions (defence in depth): The dose calculation was not verified by a second person.

— Lack of or ineffective procedures, protocols and documentation: The procedure for the calculation was not well defined.

Event No. 61: Incorrect source strength

Intracavitary radium tubes that were 35 years old, were stored in the nuclear medicine hot laboratory. No certificates of activity were available. The sources were put back into clinical use, despite the fact that a note attached to the door of the safe stated that they were not to be used for therapy. The sources were identified incorrectly, with activities interchanged, so that the 10 mg source was assumed to be 15 mg and the 15 mg source was used as 10 mg. In addition, the filter was assumed to be 0.5 mm Pt when it was actually 1 mm Pt. The interchange of sources could result in either over- or under-dosage for an individual patient, as well as in an incorrect dose distribution. The error in regard to filter thickness resulted in a dose to the patient that was approximately 7% lower than prescribed.

Initiating event

— Incorrect source identification: The sources had been labelled with incorrect activities.

Contributing factors

— Non-compliance with procedures:

- Sources removed from use were used clinically, contrary to instructions.
- Sources were used for which there were no manufacturer's certificates of activity.

— Insufficient safety provisions (defence in depth): Source activities were not verified by a measurement.

Event No. 62: Error in calculating the time of removal

A patient was prescribed a brachytherapy dose of 40 Gy, using a ^{137}Cs implant for a period of 50 h. However, an error was made in calculating the time of removal and the sources were left for an additional 22 h. The resulting overdose was approximately 44%.

Initiating event

— Incorrect patient dose calculation. There was a miscalculation of the time for the removal of the implant.

Contributing factor

— Insufficient safety provisions (defence in depth): There was no independent check of the time of removal.

Event No. 63: Wrong treatment distance in dose calculation

A patient was prescribed endobronchial brachytherapy treatment using ^{192}Ir seeds to a dose of 30 Gy to the treatment area. The physicist performed calculations for a treating distance of 1 cm instead of the prescribed distance of 1.5 cm. The brachytherapy calculation was based on an old calculation form with an algorithm that was incorrect for this procedure. There was only a manual calculation of dose to one point, without a full isodose distribution. The patient thus received a dose of 20.5 Gy at 1.5 cm, approximately 32% less than the prescribed dose.

Initiating event

— Incorrect patient dose calculation: The physicist used a form and a calculation method that were obsolete.

Contributing factors

— Lack of or ineffective procedures, protocols and documentation:
  - Copies of the obsolete form had not been withdrawn and were still available for clinical use
  - The documentation of the dosimetry calculations did not include the treating distance.

— Insufficient safety provisions (defence in depth): There was no independent check of the calculations.

Event No. 64: Treatment based on an obsolete treatment plan

The radiation oncologist prescribed a dose of 30 Gy from ^{137}Cs sources by means of a brachytherapy afterloading device. Before initiating treatment, the dosimetrist revised the original treatment plan and the oncologist approved the revision. The physicist who loaded the ^{137}Cs sources into the applicator used the original instead of the revised treatment plan. As a result, the patient received 14.6 Gy rather than 30 Gy, or 49% of the prescribed dose.

Initiating event

— Incorrect patient dose calculation: The patient's treatment was based on a plan that was later revised.

Contributing factor

— Insufficient safety provisions (defence in depth): There was poor communication between the oncologist, dosimetrist and physicist.

Event No. 65: Failure to implant all sources as planned

A patient was prescribed a brachytherapy treatment of 24 Gy using an implant that combined ^{192}Ir and ^{137}Cs sources. The licensed radiation oncologist was not present during insertion of the sources. The oncology resident who performed the implant inserted only the ^{192}Ir sources and left the ^{137}Cs sources in the transport container. Therefore, the patient received a dose to the treated area of 10 Gy instead of 24 Gy, or 42% of the prescribed dose.

Initiating event

— Incomplete source setup: The oncology resident failed to carry out the treatment as prescribed.

Contributing factors

— Insufficient education, training or expertise: The oncology resident performing the procedure was inadequately trained and was not given proper supervision.
— Lack of or ineffective procedures, protocols and documentation: There were no procedures to account for the total activity in the implant or the activity remaining in the carrier.
— Ineffective communication/transfer of essential information: The oncologist did not ensure that the prescription was clearly understood.
— The implant was unusual in that it combined two different isotopes.

Event No. 66: Sources with incorrect activity

A review of source activity by an independent consulting physicist showed that some ^{137}Cs sources which had been in clinical use for several years had a lower measured strength than the stated strength used to calculate treatment times. The nominal, stated and measured source strengths were as follows:

	Source strength (mg Ra-eq)[a]		
Nominal activity (mg Ra-eq)	Stated activity (mg Ra-eq)	Measured activity (mg Ra-eq)	Measured/stated (mg Ra-eq) (%)
5	4.8	3.4	71
10	9.1	8.4	92
10	9.1	8.6	95
10	9.5	9.4	99
20	17 6	16 4	93
25	22.7	21.1	93

[a] 1 mg Ra-eq = 76 MBq

Upon investigation, the hospital's physicist found that when the institution switched from radium to ^{137}Cs, a conversion factor was derived for use with a source calibrator that was based on an incorrect assumption regarding the filtration of the radium sources. As a result of this and possibly other errors, sources were used that had a measured activity lower than the stated activity, many by more than 5% and some by as much as 29%. Furthermore, the activity of the nominal 10 mg sources differed among themselves to such an extent that they should not have been used interchangeably.

Initiating event

— Incorrect supplier data for patient dose calculations.

Contributing factors

— Incorrect calibration: An incorrect factor was used in checking the source strength in a calibrator.

— Insufficient safety provisions (defence in depth):

- Sources grouped in a batch of the same nominal strength (10 mg) were not checked for consistency.
- Sources were used clinically without correct assessment of their strengths.

Remedial action

— The stated strengths of sources used clinically were corrected. Sources of the same nominal strength were batched and those that deviated more than 2% from the average were withdrawn from clinical use.

Event No. 67: Treatment based on incorrect source activity

Three new ^{137}Cs sources were ordered, to contain a nominal strength of 20 mg Ra-eq each. When they were received, the manufacturer's certificates stated that the strength of each was 17.5 mg Ra-eq. After a period of clinical use, measurement of the source activities showed that two sources contained 15.7 and 20.7 mg Ra-eq, respectively. The sources had been used interchangeably, with treatment times based on a nominal activity of 20 mg Ra-eq each. Therefore, one source resulted in an overdose of 4% and the other caused an underdose of 22%.

Initiating event

— Incorrect supplier data for patient dose calculations: Sources used clinically had large and variable differences between nominal and measured activities.

Contributing factors

— Lack of or ineffective procedures, protocols and documentation:

- Sources were accepted from the manufacturer although their stated strengths were 12.5% lower than the strength ordered.
- Sources were accepted from the manufacturer although their activities did not meet the criterion for interchangeable use.
- Sources with a wide range of activities were not individually identified and labelled.
- Source strengths used clinically were as ordered and not as stated on the manufacturer's certificates.

Event No. 68: Clinical use of a source with essentially no activity

An external review of a large inventory of ^{137}Cs sources showed agreement within 1% between the measured and stated strengths, with the exception of one source. A source with a stated strength of 20.8 mg Ra-eq was found to have a strength of only 0.20 mg Ra-eq. The source strengths had not been checked upon receipt, although the sources had been used clinically for three months. It was not possible to determine for which patients the low strength source had been used. However, depending upon the total activity and geometry of an implant, this source would cause a lower dose than prescribed and a distorted dose distribution.

Initiating event

— Incorrect supplier data for patient dose calculations: One ^{137}Cs source of essentially no activity was used clinically.

Contributing factor

— Lack of or ineffective procedures, protocols and documentation: There was no verification of source activity prior to accepting the source from the manufacturer.

Remedial action

— The defective source was returned to the manufacturer.

Event No. 69: Loss of a ^{137}Cs brachytherapy source

When preparing for a brachytherapy procedure, the medical physicist noted that there were only two ^{137}Cs sources in the source storage drawer instead of the expected three. The activity of the missing source was 1960 MBq. The radiation safety officer and the physicist made a physical search and radiation survey with a Geiger–Müller counter and a scintillation detector but did not locate the source. A review of the brachytherapy source inventory records revealed that the source had not been returned to the storage safe after completion of a brachytherapy procedure two months earlier.

At this facility, all sealed sources are colour coded according to their nominal activity; the 20 mg Ra-eq sources are colour coded in white. The licensee speculated that the 20 mg source may have been mistaken for a cut piece of white nylon spacer and, therefore, inadvertently placed in the trash can. Personnel monitoring devices had not indicated unusual levels of radiation exposure, although one technologist who had been involved in the earlier procedure did not wear a ring badge. It was not possible to determine whether there was unusually high exposure to personnel. It was concluded that the source probably had been disposed of in a local landfill and was buried at a depth of approximately 8–13 m below the surface, and that no radiation survey of the patient had been conducted following removal of the sources; the possibility that a lost source remained in the patient could not be eliminated.

Initiating event

— The staff did not return all brachytherapy sources to the source storage area promptly after removal from the patient.

Contributing factors

— Lack of or ineffective procedures, protocols and documentation: The procedures to account for the return of sources to the safe were inadequate.

— Insufficient safety provisions (defence in depth):
  - Monitoring of the patient and the treatment area after removal of the applicator was not performed or was ineffective.
  - No radiation survey of disposable waste material was performed after sources were removed from a patient.

Event No. 70: Inaccurate implantation and loss of sources

A patient received a permanent implant of ^{125}I seeds to the prostate. The physician localized the sources by means of a transrectal ultrasound guided probe. The prescribed dose was 120 Gy from 58 seeds, each with a nominal activity of 11 MBq.

Shortly after the implant, radiographs and computerized axial tomography scans revealed that two of the seeds had been excreted in the urine. In addition, 21 of the 56 remaining seeds were located in tissue surrounding the prostate rather than the prostate gland. Calculations showed that the tumour received a dose of 50 Gy instead of 120 Gy, 42% of the intended dose.

Initiating event

— Incorrectly performed medical implant.

Contributing factors

— Either the equipment used to implant the seeds did not work properly or the operator was not sufficiently trained in its use.
— Insufficient safety provisions (defence in depth): Precautions for the recovery of lost sources were insufficient.

Event No. 71: Loss of ^{192}Ir sources

Seven ^{192}Ir seeds, each of a strength of 266 MBq, were obtained for the treatment of a patient with lung cancer. It was decided that only five of the seven seeds would be needed to deliver the prescribed dose. Therefore, the nylon ribbon containing the seven seeds was cut into two pieces. The two ribbons, one containing two seeds and the other containing five seeds, were placed in a transport container and taken to the patient's room. The five seed ribbon was implanted into the patient and removed 10 h later. The two seed ribbon was left in the storage container in the patient's room during the 10 h treatment period. At the time of source removal, the radiation oncologist counted the seeds removed from the patient and verified that they matched the number of seeds implanted. After removal, a radiation survey of the patient and the patient's room was conducted and showed no detectable radiation above background.

Three weeks later, an inventory of seeds, carried out in preparation for their return to the supplier, revealed that the ribbon containing the two seeds was missing. A search revealed two seeds in a crack between the carpet and the wall in the patient's room where the brachytherapy procedure had taken place. It is assumed that the seeds were pushed into the crack when the room was vacuumed after the patient was released. If so, the seeds remained in the room for 22 d before being recovered. The room had remained empty for three weeks, after which time another patient was admitted to the room; this patient and his wife stayed in the room for the next 15 h, at which time the sources were found and removed

Initiating event

— Source not returned to the safe: two ^{192}Ir seeds were left unsecured and were subsequently lost.

Contributing factors

— More sources were sent to the patient's room than were required for the implant.
— An implant was performed in a patient's room rather than in an operating suite or treatment room.
— Insufficient safety provisions (defence in depth):
  - Sources removed from the patient were accounted for, but not the total number of sources sent to the room.
  - There was no monitoring of the room after the patient completed treatment and left the area.

Event No. 72: Use of a leaking ^{125}I source

A 333 MBq source of ^{125}I was used in an implant to the brain. After the implant, it was discovered that the source was leaking and a review of records indicated that it was one of 36 seeds that had been used in previous treatments. It was possible that the source had been ruptured during removal from an earlier implant, although the manufacturer had specified that the seeds could be reused after temporary implants. The accident was discovered because personnel had become aware of the potential for such an event through a notice describing a similar event in another hospital.

Initiating event

— A leaking ^{125}I source was re-used for therapy.

Contributing factors

— Insufficient safety provisions (defence in depth):

- The leakage of the source was not detected before implantation.
- Available information on a similar incident that had occurred elsewhere had not triggered a checking procedure, although personnel were alert to the possibility after the implant.

Event No. 73: Physical sizes of sources and applicators incompatible

A patient was prescribed a treatment with ^{137}Cs tubes. The technologist mistakenly used sources that were physically too small to fit the applicator. In fact, because of their size, the sources had been withdrawn from clinical use. As a result, the sources slipped out of the applicator and irradiated normal tissue. The error was discovered at the midpoint of the treatment, at which time the incorrect sources were replaced by proper sources and the treatment continued. The dose to normal tissue was estimated at 4–5 Gy.

Investigation showed that the technologist who loaded the applicator had never performed the procedure before and the supervising technologist had not loaded an applicator for eight years.

Initiating event

— Incorrect treatment setup: Sources were used that were not suitable for the applicator and, therefore, could not be properly secured.

Contributing factors

— Insufficient education, training or expertise: The personnel handling sources and applicators lacked proper training.

— Lack of or ineffective procedures, protocols and documentation: Sources withdrawn from clinical use were not sent elsewhere for disposal nor properly labelled and stored.

Remedial action

— The hospital arranged for safe, remote storage of sources no longer in use, posted a map of the source storage vault indicating the type of source at each location and enhanced source accountability practices.

Event No. 74: Sources became dislodged before the calculated time of removal

A patient received an endobronchial implant with ^{192}Ir seeds. During the night, a ribbon containing 25 seeds became dislodged, although the endotracheal catheter remained in place. At about midnight, a nurse noticed the dislodged ribbon but took no action. At about 02:00 on the same night, the same nurse returned and taped the

ribbon to the side of the patient's face. At approximately 04:15, another nurse called the radiation safety officer, who removed the ribbon using a remote handling tool.

Dose estimates showed that the side of the patient's face received approximately 10 Gy, with 2.8 Gy to the eyes. The scalp received 3.5 Gy, since the patient at one point folded the ribbon into her hair The nurse who handled the ribbon received an estimated 0.2 Gy to her fingers. The tumour received a much lower dose than prescribed, although no quantitative estimate was possible.

A few days later the patient was readmitted to the hospital complaining of burning eyes and visual sensitivity to light. An ophthalmologist diagnosed her condition as keratoconjunctivitis, probably radiation induced.

Initiating event

— Sources dislodged from the catheter in the patient.

Contributing factors

— Insufficient education, training or expertise: Owing to the lack of training for nurses caring for brachytherapy patients, a nurse taped the sources to the patient's face.
— Ineffective communication/transfer of essential information: Neither the patient nor the nurse understood the nature of the treatment; they did not recognize that the seeds were radioactive.
— The event occurred at night, when there was less bedside nursing care; the ribbon taped to the face might otherwise have been noticed earlier.

Event No. 75: Improper handling of dislodged sources

A patient was implanted with a total of 1776 MBq of ^{192}Ir in two nylon ribbons. The ribbons were inserted into two catheters that extended from the patient's abdomen into the common bile duct. The procedure was scheduled to last 20–23 h and deliver 15–20 Gy to a colon tumour obstructing the common bile duct.

After the ^{192}Ir ribbons were inserted into the catheters, the implant site was dressed and the nursing personnel were instructed not to change the dressing. Nursing staff on the next shift were not aware of these instructions since they were not written on the patient's chart. Therefore, owing to excessive drainage of bile at the implant site, the dressing was changed and reinforced with additional absorbent several times during the evening and early the next morning.

At about 04:00, the nurse on duty noted that the dressing was completely displaced and replaced the dressing. The nurse noticed the two ribbons of iridium seeds but, not knowing what they were, coiled the ribbons in her hand and taped them to the patient's abdomen. A routine radiograph of the patient late next morning showed that the seeds were no longer in the catheters. The ribbons were removed

from the surface of the patient's abdomen by a physician at approximately noon on the same day.

It was estimated that the patient received approximately 11.5 Gy to the target tumour site, between 1.7 and 10 Gy to the skin of the abdomen, 20 Gy to the liver and small bowel, 0.1 Gy to the kidney, 0.5 Gy to the colon and 0.03 Gy to the testes. The nurse who coiled the ribbons and taped them to the patient's abdomen received approximately 0.08 Gy to her hands.

Initiating event

— Inadequate instructions to brachytherapy nurses: Sources were displaced by the nurses from their implanted position.

Contributing factors

— Lack of formal training in radiation safety for workers in the nursing unit.
— Ineffective communication/transfer of essential information:
  - Instructions to nursing staff were not in writing.
  - Oral instructions to nurses on duty were not transmitted to the next shift.
  - A suitable nurses' manual for implants was lacking.
  - Neither the patient nor the nurse understood the nature of the treatment; they did not recognize that the seeds were radioactive.

Event No. 76: Source dislodged before implant was terminated

For treatment of the uterine cervix, a patient was to receive a 42 h insertion of applicators loaded with ^{137}Cs sources. The tandem applicator contained three sources (15, 10 and 10 mg Ra-eq) and the two ovoids each contained a 15 mg Ra-eq source. After the sources were inserted, the attending nurse discovered a 15 mg Ra-eq source in the patient's bed. The patient later developed an ulceration beneath her right thigh. Investigation showed that the source had apparently fallen out of the applicator as it was inserted; the reason was not known. The patient became uncooperative and refused further treatment.

Initiating event

— Inadequate source application: A ^{137}Cs source fell out of an applicator during treatment.

Contributing factors

— The sources were not well packed and secured in the patient during insertion of the applicators.
— Training of nurses in charge of brachytherapy patients was deficient.
— Ineffective procedures.

— Routine nursing care of the patient failed to detect a loose source in her bed.

Remedial action

— Members of the nursing staff were given refresher training in radiation safety. Procedures were changed to require the presence of two individuals during the insertion of brachytherapy sources. In addition, all tandem and ovoid applicators were to be taped securely with tamper resistant tape.

Event No. 77: Source removed prematurely by patient

For cancer of the uterine cervix, a patient was treated with applicators containing radium sources, which were to remain in place for a total of three days. The radiation oncologist and physicist came to the ward to remove the applicators and found them hanging on an intravenous stand next to the patient's bed. The patient reported that she had removed them sometime during the previous day because they were uncomfortable. The nursing staff had not noticed that the applicators had been removed. It was not possible to accurately estimate the underdosage, but the patient probably received a dose close to 30% lower than prescribed.

Initiating event

— The patient removed the applicators containing the radioactive sources.

Contributing factors

— Inadequate training of nursing staff.
— Failure to communicate the nature of the treatment to the patient.
— Failure of nursing staff to notice that the applicators had been removed by the patient.

Remedial action

— Nursing staff received written instructions concerning their responsibility to check that applicators are in place in a patient.

Event No. 78: Misadministration due to patient interference

A patient with cancer of the uterine cervix was treated with an applicator containing ^{137}Cs sources. During a routine check, the nursing staff found that the patient had removed the applicator, causing unintended exposure of her legs. The licensee estimated that the treatment area received 17% less than the prescribed dose and the patient's legs received some 6 Gy.

Initiating event

— The patient removed the applicators containing the radioactive sources.

Contributing factors

— The patient's removal of the applicators was not anticipated by the nursing staff.
— Ineffective communication: Failure to communicate the nature of the treatment to the patient.

Event No. 79: Brachytherapy equipment failure

A patient was prescribed ^{137}Cs brachytherapy treatment for uterine cancer, and a remote afterloading device was used for this purpose. During the procedure, a malfunction of the device disconnected the tube used to transfer the source from the shielded storage unit to the patient. The disconnection resulted in a ^{137}Cs source being located near the upper part of the patient's leg, rather than properly inserted into the patient. Estimates of the dose to the leg were highly uncertain, ranging from 0.23 to 237 Gy, as the length of time of the exposure was unknown. Later examinations of the patient revealed no physical signs of radiation damage, indicating that the exposure was at the lower end of the range.

Initiating event

— Equipment failure (disconnecting the source from the drive mechanism).

Contributing factors

— Possibly poor design and construction.
— Inefficient procedures: Staff failed to check key parts, such as the tube connector, prior to treatment.

Event No. 80: Mishandling of source ribbons

A patient was scheduled to have an endobronchial implant of two ribbons containing 35 ^{192}Ir seeds with a total of 2516 MBq. One ribbon contained 20 seeds and the other 15. During the insertion the physicist mistakenly gave the attending physician the inactive end of the 15 seed ribbon (the portion that did not include radioactive sources) and the physician inserted the inactive end into the patient. The other ribbon, containing 20 seeds, was inserted correctly. The physician cut off the remaining lengths of the ribbons and gave them to the physicist. The physicist, assuming that these pieces of ribbon contained no radioactive material, coiled them and held them in her hands. One of these pieces contained 15 seeds. After completion

of the procedure, the physicist discarded the unused pieces of ribbon in a wastebasket located in a waiting room across from the patient's room The dose rate in the waiting room was approximately 0.63 mSv per hour, a radiation level well above the regulatory limit of 0.02 mSv in any one hour in unrestricted areas.

The implant was performed at 14:30 and the patient was scheduled to have a tumour dose of 15 Gy. The physician decided to remove the ribbons from the patient earlier than planned because the dose rate was higher than he normally administered. The ribbons were removed at 20.30. Neither the physicist nor the hospital's radiation protection officer was present during the removal procedure.

The following morning at approximately 08:30, the medical physicist inventoried the sources removed from the patient and found that one of the ribbons contained no seeds. She immediately informed the radiation protection officer, who conducted a search for the missing radioactive material At approximately 11·00 in the morning two pieces of ribbon were found in the wastebasket. It was determined that the dose to the medical physicist's hands was approximately 2.7 Gy, assuming that she held the ribbon for about 5 min. The physician stated that the patient received approximately half the prescribed dose

Initiating event

— Incorrect treatment setup (the physicist failed to correctly identify the active end of one ribbon).

Contributing factors

— Lack of or ineffective procedures, protocols and documentation.
  - There was no survey of all radioactive sources before implanting them into the patient.
  - There was no radiograph of the implant after insertion of the ribbons.

— Insufficient safety provisions (defence in depth):
  - Unused parts of ribbons or other material potentially containing radioactive sources were not checked for radioactivity before being discarded as waste.
  - Neither a radiation protection officer nor a physicist was present during the removal of the sources from the patient.
  - Accounting for radioactive materials was delayed until it was of little value.

Event No. 81: Mechanical failure of brachytherapy equipment

Upon removal of an intracavitary applicator from a patient, it was noted that the weld of a pivot point had broken. This left a sharp, semicircular piece of stainless steel in the patient, which had to be removed surgically

Initiating event

— Equipment failure: An applicator broke owing to mechanical failure of a pivot point.

Contributing factor

— Lack of or ineffective procedures, protocols and documentation: The applicator was not properly inspected during cleaning and sterilization.

2.10. BRACHYTHERAPY (HIGH DOSE RATE)

Event No. 82: Delivery of tumour dose to the wrong site because of a defective catheter

A patient was prescribed a brachytherapy dose of 35 Gy to one lung using ^{192}Ir seeds. A kink in the catheter used to insert the seeds caused the seeds to be positioned 26 cm from the target site. The error was not discovered until the end of the treatment time. Because of the error, the hypopharynx received 35 Gy and the prescribed target site received only 0.1 Gy.

Initiating event

— Inadequate treatment setup: A kink in the catheter prevented sources from moving to the prescribed treatment site.

Contributing factor

— Lack of or ineffective procedures, protocols and documentation:

- There was no quality control of the catheter, such as physical inspection, before its use.
- There was no radiographic verification of the location of the source, which could have detected the error at the beginning of treatment.

Remedial action

— For future implants, dummy seeds were used to test the proper movement of sources through the catheter and radiographs were taken to ensure the correct location of the active sources after insertion.

Event No. 83: Using a high dose rate prescription for the wrong patient

A patient was undergoing a series of five treatments for cancer of the nasal septum, using a high dose rate ^{192}Ir afterloading unit. The first four treatments were completed without incident. However, prior to the fifth treatment the operating

physicist picked up a patient's chart located next to the control panel without realizing that it was the chart for another patient. As a result, he entered programme information for the wrong patient. While the treatment was under way, a student technologist inquired about the length of time to complete the treatment. The prescribing physician and the operating physicist responded with different times. The physician, realizing there was an error, terminated the treatment immediately. The erroneous information had led to the ^{192}Ir source being positioned so that the patient's lips were exposed for about 1 min, for a dose of approximately 0.75 Gy. The planned treatment would have delivered 0.25 Gy to the lips. (In this case, the overexposure of normal tissue was not serious, however, this type of error has the potential for harm to the patient.)

Initiating event

— Deficient patient identification: The physicist entered treatment information for the wrong patient.

Contributing factors

— Poor housekeeping: The treatment chart for the wrong patient was placed next to the machine console.
— Insufficient safety provisions (defence in depth): There was no independent check of the information used for the treatment.

Event No. 84: Malfunction of high dose rate equipment

A patient was to be treated with a high dose rate unit containing 159 GBq of ^{192}Ir The prescribed dose was 18 Gy in three treatments. Five catheters were placed in the tumour and the source was stepped through the preprogrammed positions in each catheter. During the first treatment, the physician experienced difficulty placing the source wire into the fifth catheter. Personnel disregarded the alarm from an area radiation monitor because the unit console indicated 'safe'. The staff assumed that the area radiation monitor was malfunctioning. In fact, the source wire had been broken and the source had remained in the patient.

The patient, with the source still in the catheter, was transported back to the nursing home. The source remained in the patient for almost four days, at which time the catheter containing the source fell out. Because of this misadministration, the patient received 16 000 Gy at 1 cm from the source instead of the prescribed 18 Gy. The nursing home staff placed the catheter in an area used to store non-radioactive medical waste. The waste was removed later by an incinerator company. The source was discovered when it tripped a radiation monitor located at the incinerator.

The patient died shortly after removal of the source; it was clear that radiation exposure had been a major contributing cause of death. The loss of the source resulted

in radiation exposure to 94 individuals, including persons at the cancer clinic and the nursing home, ambulance staff, and workers at the waste disposal company.

Initiating event

— Equipment failure: While it was inside a catheter in the patient, the source broke free from the source wire.

Contributing factors

— Staff ignored a monitor alarm and assumed that a 'safe' indication on the console was correct (previous false alarms of the external monitor contributed to this assumption).

— Insufficient safety provisions (defence in depth):

- There was no spare or backup portable monitoring equipment to verify the alarm.
- The patient and work area were not monitored before and after treatment.

2.11. UNSEALED SOURCES

Event No. 85: Treatment of the wrong patient because two patients had the same name

A therapeutic dose of 370 MBq of ^{131}I was prescribed to a patient for treatment of hyperthyroidism. The physician who was familiar with the patient was not available and asked another physician to administer the isotope. In arranging for transportation, a porter noted that the patient was listed as being assigned to a bed that she believed was occupied by another patient. The porter asked the nuclear medicine secretary to check the discrepancy. The secretary referred to a list for the patient's name, obtained the bed assignment area from a computer file and changed the request form. The secretary did not know that there were two patients in the hospital with the same first and last names, one for iodine administration and the other for treatment of a lung disease. In addition, the secretary did not know that the computer program that generated the patient list did not print (and in fact deleted) duplicate entries: the name of the patient who was to undergo treatment for hyperthyroidism was thus not printed on the list. The physician who administered the dose picked up the request form and the ^{131}I dosage and went to the nursing station on the floor of the patient with the lung problem. The physician did not inform the nursing staff that he was about to administer a therapeutic dose to one of their patients and went to the patient's room. There, he asked the patient's name and verified the name on the wristband, but did not cross-check the patient's identification number on the wristband with the number

on the request form. The physician completed the request form and returned the patient's folder to the nurse's station.

Within five minutes of the administration of ^{131}I, the nurses discovered the error and informed the physician and the radiation protection officer. As a remedy, a dose of 1000 mg of potassium iodide was administered immediately, followed by three subsequent doses of 1000 mg each at four hour intervals. The estimated radiation dose to the patient's thyroid was between 1 2 and 1 4 Gy.

Initiating events

— Incorrect patient identification.

Contributing factors

— Two patients in the hospital had the same first and last names.
— Computer software, designed to avoid duplicate entries, deleted the name of one patient
— Administration of ^{131}I treatments was not restricted to designated rooms or wards where the nursing staff had specialized training.
— Deficient procedures or non-compliance with procedures:
  - The physician did not communicate with the nursing staff at the ward, but went directly to the patient's room to administer the iodine.
  - Hospital protocol for the identification of patients was not followed with regard to verifying the patient's hospital number.

Event No. 86: ^{131}I treatment of the wrong patient

A therapy dose of 333 MBq of ^{131}I was given inadvertently to the wrong patient (patient A instead of patient B). Patient A was to receive 740 MBq of $^{99}Tc^{m}$ for a diagnostic bone scan; the $^{99}Tc^{m}$ was administered and the patient was seated in the waiting room Patient B, who was scheduled to receive a ^{131}I hyperthyroidism treatment, arrived, completed an interview, signed a consent form and sat in the waiting room pending the iodine treatment. The technologist prepared a dose of 333 MBq of ^{131}I and called patient B; however, patient A responded. The technologist explained the ^{131}I treatment, scheduled a follow-up appointment, and administered the dose to patient A. The patient then questioned the technologist, and it became evident that the wrong patient had been treated. Patient A was immediately informed of the error and his stomach was pumped, retrieving 118 MBq of the material. The patient was given potassium perchlorate and Lugol's solution to release ^{131}I trapped in the thyroid and to block further uptake. Patient A's dose to the thyroid was estimated at 8.2 Gy.

Initiating event

— Incorrect patient identification.

Contributing factors

— Ineffective communication: One patient responded to another patient' name.

— Non-compliance with procedures: Patient identification procedures were not followed.

Event No. 87: Wrong dose of ^{131}I

A 60 year old woman was referred to the nuclear medicine department for thyroid ablation following a thyroidectomy for cancer. The physician prescribed 6475 MBq of ^{131}I to be administered orally.

The hospital received from the distributor the patient's prescribed amount of ^{131}I in one vial, together with a second vial containing 5180 MBq of ^{131}I. A technologist assayed both vials and placed them together in a fume hood located in the nuclear pharmacy. Both vials were in their original lead shields with the contents correctly labelled.

When the physician was ready to administer the ^{131}I, the technologist who had assayed the vials was not available and another technologist went to the pharmacy to obtain the radiopharmaceutical. The administering technologist picked up both vials and, without reviewing the labels, assumed that both vials were required for the proper dose. The technologist did not consider the use of two vials for one administration to be unusual since this was a common occurrence at this facility. After reviewing the dosage record, the physician instructed the technologist to administer the ^{131}I. Without reviewing the labels on the containers, the physician assumed that the use of two vials was correct.

The mistake was discovered the next day when the nuclear pharmacist received a request for 925 MBq of ^{131}I and could not find the second vial. The resulting investigation determined that the vial had been used the previous day.

Initiating event

— Two unsealed sources were administered in place of one.

Contributing factors

— Ineffective communication: Improper identification of radionuclides, starting with receipt of the material, through the preparation of doses, to administration.

— Insufficient safety provisions (defence in depth): There was no independent check of the material to be administered.

Event No. 88: Radiopharmacy error

A patient was referred for treatment of Graves' disease with 555 MBq of ^{131}I. The radiopharmacist assumed that the dosage to be delivered was 1073 MBq rather than 555 MBq, since a 1073 MBq dose was routinely used for Graves' disease in that hospital. Therefore, he requested a 1073 MBq dose from a commercial radiopharmacy. The dose received was 1058 MBq, labelled as such. When the radiopharmacist logged the dosage into the computer after it had been measured by a dose calibrator, he failed to take note of the dose of 550 MBq in the referring physician's prescription. In addition, the physician who administered the isotope did not check the prescription. As a result, the patient's thyroid received about 319 Gy instead of the intended 167 Gy, an overdose of 91%.

Initiating event

— The wrong source was administered: Incorrect activity of ^{131}I.

Contributing factors

— Insufficient awareness/alertness: The radiopharmacist assumed that the prescribed dose was the usual dose, without verification.

— Lack of or ineffective procedures, protocols and documentation:

- The radiopharmacist failed to verify the dose received against that prescribed.
- The nuclear medicine physician failed to verify the activity before he administered the isotope.

Event No. 89: Confusion regarding the activity of ^{131}I

A patient was prescribed 370 MBq of ^{131}I for a thyroid treatment. A capsule containing 370 MBq was ordered, but the distributor shipped a capsule containing 444 MBq. Personnel receiving the capsule did not note the discrepancy. Prior to administration, the capsule was assayed in a dose calibrator. However, because the technician was expecting a reading of 370 MBq, he misread 444 MBq as 370 MBq. The administration of 444 MBq resulted in an overdosage of 20%.

Initiating event

— Incorrect source for patient treatment: The supplier shipped a capsule with an activity higher than had been ordered.

Contributing factors

— Lack of or ineffective procedures, protocols and documentation:

- Hospital staff did not check the activity stated by the supplier against the activity ordered.
- The calibrator scale was misread.

— Insufficient safety provisions (defence in depth): Lack of independent verification of the ^{131}I dose against the prescription.

Event No. 90: Dose to an ineligible patient

A patient was administered 180 MBq of ^{131}I for a whole body scan. The scan indicated an unusually high breast uptake of ^{131}I and it was discovered that the patient was a nursing mother. Before administering the dose, both the physician and nuclear medicine technologist failed to confirm that the patient was not breastfeeding. Consequently, the infant received an estimated 300 Gy to the thyroid and 0.17 Gy to the whole body and will require thyroid hormone medication for life to ensure normal growth and development.

Initiating event

— A therapy dose of ^{131}I was given to a nursing mother.

Contributing factors

— Insufficient awareness: The technologist was distracted and forgot to ask the patient a standard list of questions.

— There was a staff shortage on the day of administration.

Event No. 91: Radioactive spills from a patient during resuscitation efforts

A therapy dose of 7400 MBq of ^{131}I was administered to an 87 year old patient in an effort to relieve oesophageal compression caused by metastatic thyroid carcinoma. The patient had a gastrostomy tube and a Foley catheter in place. Approximately 34 h after receiving the dose, the patient had a cardiopulmonary arrest. Sixteen staff members attempted to resuscitate the patient; their efforts included insertion of a pacemaker. Blood and urine contaminated with radioactivity were spilled but the clothing of those present was not checked for activity. Although contamination was extensive, subsequent thyroid bioassays showed no uptakes by the involved staff. Monitoring of personnel showed that the highest reading was 0.3 mGy for one of the nurses.

Initiating event

— The patient experienced cardiac failure shortly after thyroid ablation therapy.

Contributing factors

— There were no contingency procedures in place for emergency situations involving patients with radioactivity.
— There had been no training exercises simulating emergencies.
— Shortage of instruments: Radiation monitoring instruments and decontamination utensils were not available.

Event No. 92: Administration of a wrong dose of ^{131}I

A patient was to be administered 259 MBq of ^{131}I The isotope was in the form of two capsules, 130 MBq each, which were labelled correctly. Previous doses of this level had been administered in the form of one capsule. When the vial was inverted by the technologist, only one of the two capsules fell out and she assumed that this was the entire dose. Later, when disposing of the vial shield, the technologist discovered the other capsule. As a result, the patient received only 50% of the prescribed dose.

Initiating event

— One of two ^{131}I capsules remained stuck in the vial.

Contributing factors

— Deficiencies in procedures, or procedures were not followed
  - Staff failed to check the vial label to ascertain the number of vials and the prescribed dose.
  - There was no measurement of the vials before and after administering the dose.

3. CLASSIFICATION OF ACCIDENTS

3.1 CLASSIFICATION OF CAUSES BASED ON RADIOTHERAPY TECHNIQUES

In order to gain an overview of the initiating events and contributing factors of the cases reviewed in this Safety Report, and to facilitate the practical application of the lessons to be learned, it is illustrative to identify the accidents following the chronological order of the treatment process. The following subsections attempt to do this. The numbers given in parentheses after some of the steps refer to the events described in Section 2.

3.2. EXTERNAL BEAM THERAPY

3.2.1. Events related to equipment, thus affecting many patients

Accidents related to problems with equipment, such as calibration of the beam output, involve all patients treated with the beam until the problem is discovered. The most important events were those resulting in an error in the determination of dose rate, and therefore wrong irradiation times for patients treated under these conditions. In the three worst cases, 115, 207 and 426 patients were involved, with dose deviations of up to 60% and many deaths. In addition, there were two major accidents related to maintenance of accelerators, one of them involving 27 patients (several of whom died as a direct result of radiation exposure).

Radiation measurement system: These include ionization chambers and electrometers.

Step at which the event occurred (chronological order)	Event Nos (see Sec 2)
Calibration of reference system	1
Intercomparison with secondary system	5
Routine use	2, 3, 4

Treatment machine

Step at which the event occurred (chronological order)	Event Nos (see Sec. 2)
Commissioning (acceptance)	7, 8, 10, 11, 14, 25
Calibration (annual)	6, 9, 12
Constancy check (daily, weekly)	13
Malfunction of machine	15, 16, 17, 18, 20, 49, 51
Incorrect use	19, 20, 23, 24, 48, 50

Simulator

Step at which the event occurred (chronological order)	Event Nos (see Sec. 2)
Malfunction	52, 53, 54 (malfunction)

Treatment planning system

Step at which the event occurred (chronological order)	Event Nos (see Sec 2)
Commissioning and input of basic data	21, 22, 24, 25, 30
Routine use	23, 26, 27, 28, 29, 31

3.2.2. Events involving individual patients

Some of the accidents reviewed occurred due to different conventions for the incorporation of different diagnostic imaging modalities that are used in treatment planning, including those from simulators, computer tomography scanners, nuclear medicine, ultrasound, etc. Also, accidents were caused by incomplete or inaccurate documentation of patient charts for all aspects of treatment planning, including isodose curves, use of wedges, special blocking and placement and orientation of beams, since these factors are used to calculate beam-on times for all fields.

There were cases of treatments to the wrong person or the wrong anatomical site, and of incorrect tumour dose and overdose to normal tissues because of ineffective institutional protocol for patient identification, such as a photograph of the patient, unique patient hospital number, ID bracelet and verbal confirmation of patient identification.

Prescription

Step at which the event occurred (chronological order)	Event Nos (see Sec 2)
Miscommunication of prescription	2, 3, 4, 33, 37, 45
Error in use of images	41, 44, 45

Treatment planning

Step at which the event occurred (chronological order)	Event Nos (see Sec 2)
Documentation	32
Calculation of treatment time or monitor units	28, 29, 36
Incorrect use of treatment planning system	27, 31, 36, 37

Execution of treatment

Step at which the event occurred (chronological order)	Event Nos (see Sec 2)
Patient identification	34, 35
Documentation of patient setup	32, 33, 38, 39, 40, 42, 43, 45, 47
Incorrect operation of treatment machine	19, 46
Final review at completion of treatment	47

3.3. LOW DOSE RATE BRACHYTHERAPY

3.3.1. Events related to equipment, thus affecting many patients

Cited in this review are accidents which occurred when source characteristics, such as source strength, isotope and filter thickness, are not verified by measurement upon receipt from a supplier and each time they are used, by identification of source marking. Mistakes arose when strengths of sources were quoted in two non-equivalent units, e.g. mg Ra-eq or mCi, and these were used erroneously or interchangeably, when users did not properly distinguish between nominal and measured source strength, and when suppliers provided source activities different from those ordered. Other causes of accidental exposures were when sources withdrawn from clinical use were not clearly labelled as such and taken out of circulation, as well as the improper use of leaky sources.

Step at which the event occurred (chronological order)	Event Nos (see Sec. 2)
Verification of activity	55, 56, 57, 58, 69, 70
Verification of batch uniformity	68, 69, 70
Verification of identification markers	58, 59
Storage and inventory	58, 71, 73
Performance of leakage test	74
Applicators: commissioning and maintenance	75, 83

3.3.2. Events involving individual patients

Brachytherapy requires an individual treatment plan based on the geometry of the target site and prescribed dose with the treatment time based on the geometry of the implanted or inserted sources. Serious misadministrations occurred when the source geometry or activities were not correct or the correct placement of sources was not maintained throughout the treatment time. Severe under-irradiation of the tumour and over-irradiation of normal tissues were also reported when sources were dislodged during treatment. In a few reported cases of accidents, nursing staff lacked the required special training in radiation safety needed to perform nursing care with minimal exposure to staff and visitors and to deal with emergencies. Patients were not informed that sources were radioactive and should not be removed or tampered with during treatment.

Step at which the event occurred (chronological order)	Event Nos (see Sec 2)
Prescription documentation and communication	67
Planning of application including activity, geometry, anatomical site, estimation of dose rate and treatment time	55, 56, 60, 61, 62, 65, 66
Identification of patient	85
Informing the patient	74, 79, 80
Documentation	62, 65, 67
Radiographic localization of sources	72, 82
Sources correctly in place for duration	57, 72, 76, 77, 79, 80, 81, 83
Source identification	58, 59, 63, 67
Final calculation of dose and treatment time	64
Correct delivery of prescription	78, 81, 82
Correct treatment time	82
Monitoring of patient after removal of sources	82

3.4. HIGH DOSE RATE BRACHYTHERAPY

3.4.1. Events related to equipment, thereby affecting many patients

High dose rate units, because they involve very high activity sources, have a potential for damage to patients as a result of misadministration Cited in this report are cases of misadministration owing to malfunctioning equipment, such as catheters that do not allow full movement of sources Also cited are cases of inadequately trained personnel operating equipment, resulting in misadministration of treatment Because high dose rate brachytherapy is relatively new compared with low dose rate brachytherapy, the total number of high dose rate events is lower.

Step at which the event occurred (chronological order)	Event Nos (see Sec 2)
Training of personnel	77, 78
Malfunction of equipment	81, 84, 86

3.5. USE OF UNSEALED SOURCES

Step at which the event occurred (chronological order)	Event Nos (see Sec 2)
Planning and dispensing	89, 90, 91
Administration	87, 88, 89, 92
Safety and contamination	92

4. LESSONS LEARNED AND MEASURES FOR THE PREVENTION OF ACCIDENTS

The purpose of radiotherapy is to achieve maximum control of the tumour with minimum complications to normal tissue. This objective sets very high requirements on systematic accuracy and precision in relation to the total dose, dose distribution and dose fractionation. In order to satisfy these requirements, both systematic and random errors must be kept within a few percentage points during the entire process, from the time of prescription to the completion of the radiation treatment, a chain of events that involves a number of persons.

A review of the initiating events and contributing factors described in Section 2 confirms that most of the accidents could have been prevented by consistent application of the requirements cited in Appendix II (medical exposures) and Appendix IV (potential exposures) of the BSS. The lessons learned from the accidents are discussed below.

4.1 RESOURCES: PERSONNEL AND EQUIPMENT

A radiotherapy department needs to have sufficient staff in relation to the number of patients and types of treatment modalities; guidelines have been recommended by national and international organizations. A shortage of staff usually leads to an increase in errors. In addition, a reassessment of staff and training has to be undertaken when the workload increases (more patients) or new equipment is purchased, or when a new technology or treatment modality is introduced. The failure to reassess staff workload led to a large scale accident in which a ^{60}Co beam was used for a period of 22 months without quality control checks because the only medical physicist available was assigned to a new accelerator.

4.2. HUMAN FACTORS

Radiotherapy is very much dependent on human performance. A large number of steps, tasks and subtasks have to be performed many times every day and differ only slightly from one patient to the next. Rarely are all steps in radiotherapy performed by a single individual; many people work together, each contributing a small part of the entire process. Many workers in several disciplines must interact in highly technical measurements and calculations, and the potential for mistakes is large if care is not taken. Even well trained and well qualified personnel make errors, owing to inattention to details, lack of alertness, or lack of awareness, especially if

they have to work in less than ideal conditions. In some of the accidents, even the review of charts and calculations failed to detect a mistake.

4.2.1. Identification of safety critical steps and activities

A list of safety critical activities and steps in the radiotherapy process is given below. The list is not intended to be exhaustive and is derived from the examples discussed in this report:

(a) Commissioning of radiotherapy machines and validation of treatment planning systems,
(b) Periodic calibration and constancy checks of beams and sources,
(c) Decommissioning of radiation sources and devices containing sources,
(d) Identification of the patient,
(e) Identification of the treatment target site ('localization'),
(f) Preparation of the treatment plan,
(g) Formal prescription of the treatment plan,
(h) Simulation of the treatment and placement of body marks (tattoos),
(i) First treatment session,
(j) Daily patient positioning and selection of parameters and treatment accessories,
(k) Accumulation of doses in the patient's chart,
(l) Modifications during the course of treatment,
(m) Radiopharmaceutical administration,
(n) Maintenance of radiotherapy equipment and devices,
(o) Removing sources from the patient after a brachytherapy treatment and returning them to storage,
(p) Identification of long lived brachytherapy sources kept in storage,
(q) Measurement of activity (dose rate) of short lived brachytherapy sources obtained for single treatments.

The assignment of functions and lines of authority and responsibility should ensure that there are no gaps or ambiguities which leave safety critical tasks insufficiently covered. At this stage, the necessary degree of human redundancy is established.

4.2.1 1. Measures for the prevention and mitigation of consequences

Measures in this group are:

(a) Clear and concise written instructions to prepare staff for unusual situations, in general as well as on a case by case basis. Clear job descriptions, assignment of responsibilities and lines of authority.

(b) Anticipation of unusual, unplanned situations following a review of all procedures. A drill or rehearsal of measures to be taken may be appropriate for some types of accident. A review of all procedures to identify those which could lead to an accident in an unusual or unplanned situation.

Special care needs to be taken when there are complex or unusual treatment plans or when there is a change in procedures, such as:

(1) A change of supplier of radioactive material;
(2) A non-typical dose, an unusual target area or a treatment with the patient in an unusual position;
(3) A complex treatment, for example, treatment of more than one anatomical site on the same day.

4.3. TRAINING

Oncologists, physicists and other paramedical staff necessarily require formal training to effectively carry out their duties. In addition, opportunity for continuing their education by attending professional meetings and refresher courses is necessary in a field as dynamic as radiotherapy. Acquisition of new equipment often requires attendance at training sessions provided by manufacturers. Membership in professional organizations provides a valuable mechanism for communication with colleagues through meetings, journals and other publications. These contacts promote further informal interaction, which is particularly important for a physicist working alone.

Nurses and ancillary personnel who interact with patients have to be trained in radiation safety. They need to be cognizant of techniques for reducing exposure to themselves, other workers and visitors. They have to be able to recognize emergencies, such as unintended removal of radioactive sources, and know which procedures are appropriate in such an event.

Training has to cover not only normal situations, but also the identification of abnormal situations (case histories) and unusual events, as well as measures for accident prevention.

4.3.1. Training for special or unusual situations

Experience has shown that in an unusual situation, for example after an equipment failure or when conflicting signals appear, the behaviour of staff is often unsafe. Wrong assumptions are made, leading to accidental exposures. This may be because the staff member makes the interpretation that matches his or her experience,

expectation or convenience. Expectations are usually based on experience gained during normal operation of equipment or routine procedures. Additional specific training is needed to cover special or unusual situations, for example how to deal with conflicting signals on a console, a change of supplier, or complex types of treatment. The inclusion of unusual situations, the discussion of case histories and contingency plans, and exercises in training coupled with periodic refresher training will help staff recognize potential problems.

4.4 COMMUNICATION

Communication between staff members is essential for all aspects of treatment, since many persons with various responsibilities must interact. Mistakes may be made owing to lack of adequate communication, incorrect information, or poor understanding of correct information.

The review of events reveals the following sources of error:

(a) Failure to transmit information.
(b) Transmitting incorrect communication.
(c) Communication to the wrong person.
(d) Correction of a problem by an unqualified person without help or review.
(e) Oral communication, either in person or by telephone, without written confirmation, resulting in misunderstanding.
(f) Mistakes in reading or transferring information.
(g) Unreadable or confusing handwritten communication, informal expressions or use of jargon that is not understood by everyone in the same way.
(h) Misunderstanding of communication in a foreign language: This may include manufacturers' instructions for the use of equipment, as well as communication between staff and between staff and patients
(i) Incomplete or poorly written instruction manuals for complex equipment such as treatment machines and treatment planning computers Of particular concern are instructions that do not cover unusual or special applications.

Not explicitly cited in this review of accidents, but often playing a role, are the following circumstances:

(1) Interpersonal problems among staff;
(2) Noisy working conditions, leading to distraction and loss of concentration;
(3) Insufficient access to, or non-availability of, personnel in essential positions at critical times

4.4.1. Measures for the prevention and mitigation of consequences

In any institution, one person, usually a medical physicist, should have overall responsibility for all aspects of the dosimetry system. It is his or her responsibility to see that the lines of communication concerning dosimetry of patients are working properly. Other measures are:

(a) Identification and posting of all rules for communication critical to safety.
(b) Clear assignment of responsibilities of the staff, including written job descriptions
(c) An organizational structure that clearly identifies the 'chain of command', i.e., each worker's supervisor and the persons he/she supervises
(d) Checklists that describe all steps of routine procedures as well as actions to be taken when accidents occur.
(e) Clear and concise written procedures for safety critical communications.
(f) Signatures on documents critical to safety. For example, prescriptions are to be written and signed by the physician. Basic data, treatment plans, daily logs of patient therapy, etc., are to be signed or initialled by the person performing or checking that step in the process.

Some examples of critical communications relevant to safety are given in Table I.

Once the safety critical communications have been identified, responsibilities for these communications are assigned. Formal procedures are established for safety critical communications, design of forms and checklists. Rules for clear, concise and complete communication and for developing protocols, drawings, charts, language and clearances with signatures are drawn up.

4.5. EQUIPMENT

Equipment failure accounts for only a moderate percentage of all accidents cited in Section 2. However, the consequences can be severe and many patients may be affected when equipment does malfunction. Contributing factors are:

(a) Insufficient redundancy in the design of equipment (single fault criterion, interlock failure);
(b) Software problems;
(c) Hardware incompatibilities in equipment and accessories (wedge or shielding block incompatible with coding system, or ionization chamber that does not fit an electrometer);
(d) Possibility of operating the equipment in a 'non-clinical mode' with the key in the usual 'beam-on' position.

TABLE I. EXAMPLES OF COMMUNICATIONS CRITICAL TO SAFETY[a]

Content of communique or memorandum	From	To
Prescription for treatment	Radiation oncologist, nuclear medicine physician	All staff involved in planning or delivering treatment
Input data for preparation of treatment plan	Simulation radiographer	Planning radiographer, dosimetrist
Proposed treatment plan and calculation, prescribed dose	Radiotherapy or nuclear medicine technologist	Medical physicist
Proposed treatment plan and confirmed calculation	Medical physicist	Radiation oncologist
Patient immobilization or shielding aids	Radiation oncologist	Mould room technician
Confirmed plan	Radiation oncologist	Medical physicist or radiation technologist
Equipment fault report	Radiotheraphy technologist	Medical physicist
Request for maintenance	Medical physicist	Maintenance organization
Instruction to discontinue treatment	Medical physicist	Radiation oncologist, radiotherapy technologist
Maintenance complete	Maintenance organization	Medical physicist
Check equipment and verify that it is ready for use	Medical physicist	Technologist

[a] In many organizations, a person may perform more than one function

4.5.1. Measures for the prevention and mitigation of consequences

In Appendix II of the BSS, which deals with medical exposures, the requirements in paragraph II.11 for the design of equipment used in medical exposure are in pertinent part as follows:

"(a) failure of a single component of the system [must] be promptly detectable so that any unintended medical exposure of patients is minimized; and

(b) the incidence of human error in the delivery of unintended medical exposure be minimized."

Methods for good engineering are well developed. One basic element is the single fault criterion, which leads to redundancy. In other words, failure of one component should not cause an accident; an accident should be possible only if two or more systems or components fail simultaneously. A faulty component should be repaired immediately in order to maintain redundancy and prevent accidents [3, 4]:

(1) Analysis of common failures is used to ensure that one common failure would not nullify the redundancy. For this purpose, redundancy is complemented by independence.
(2) Components and systems have to be designed to be fail-safe, so that a failure does not lead to an unsafe situation. For example, the source driver of a gamma teletherapy unit is designed so that the radioactive source returns to the shielded position if there is a cut-off of electrical power (see the BSS, Appendix II, paragraphs II.11–13 and 15).
(3) Prototype tests need to include special or extreme conditions of equipment operation. Tests need to involve clinical personnel and others who use equipment routinely and not be limited to engineers and personnel who design and install equipment.
(4) Equipment is to be designed so that when it is in 'non-clinical mode' (reduction of interlocks), it is impossible to enter a 'beam-on' command from the regular key in the control console.
(5) Validation of the equipment and its operation, under clinical conditions, has to be made before initiating treatment of patients. Detailed documentation describes the tests performed and the personnel responsible. Commissioning of equipment for clinical use is the responsibility of the institution's medical physicist.
(6) There is a need for manufacturers of radiation therapy equipment to promptly and thoroughly investigate any reported incident or unusual event and notify authorities and other users of their findings and appropriate preventive measures. A formal system of reporting and disseminating information from manufacturers to users is essential.
(7) Machine malfunctions are not to be corrected until the full dosimetric consequences to patients who were treated during the period of the malfunction are known. Measurements while the machine is malfunctioning may be necessary in order to estimate an incorrect dose delivered to a patient.

4.6 HUMAN–MACHINE PROBLEMS

4.6.1. Problems of human–machine interface

Personnel need to understand the functioning of equipment, including the significance of alarms, signals, and displays that indicate a malfunction.

4 6.1 1. Measures for the prevention and mitigation of consequences

(a) Inconsistent signals are investigated and the one indicating the more serious consequence is assumed to be correct until proven otherwise. For example, if a radiation monitor gives off an alarm indicating that a beam is on, but the console display shows that the beam is off, it is more prudent to assume that the beam is on, not that the alarm is malfunctioning.
(b) The human–machine interface in the clinical environment is considered in the design and testing of equipment.
(c) Specific training to recognize and respond to abnormal signals and display interlocks, as well as contradictory signals.

4.6.2. Bypassing of interlocks and operation in a 'non-clinical mode'

Operation in a 'non-clinical mode' sometimes is the response to frequent or unresolved maintenance problems. However, circumventing interlocks and other safety devices in order to continue with patient treatments increases the possibility of accidents, which can lead to serious or even fatal consequences.

4 6.2 1. Measures for the prevention and mitigation of consequences

(a) Plan and implement an efficient maintenance programme and avoid improvisation as far as practicable.
(b) Never treat patients with equipment operating in the 'non-clinical mode'.
(c) Never try for a 'quick-fix' or 'patch-job' in order to continue treatment of patients.
(d) Withdraw from clinical use equipment that is malfunctioning until formal repair is complete and its operation is checked in a thorough and deliberate way.
(e) Design equipment so that it is possible to turn 'beam on' in the 'non-clinical mode' only by using special tools or computer codes. It is only possible to operate the machine in the non-clinical mode for maintenance or other non-clinical work (BSS, Appendix II, paragraphs II.15 (c) and (d)).

4.6.3. Maintenance problems

Mistakes made in maintenance can and have affected many patients and have led to severe, even fatal, consequences.

4.6.3.1. Measures for the prevention and mitigation of consequences

(a) Maintenance personnel have to be cognizant of the potential consequences of any manipulation, alteration or adjustment of components of a machine for the safety of patients and personnel who use the machine clinically.
(b) Before a machine is released for clinical use following maintenance or repair, a check of the output, as well as any other operating parameters that could have been affected, has to be made. Formal procedures for handing over the machine after such maintenance or repair to the physicist must be in place for necessary checks before clinical use.
(c) Instructions for the use of a machine that has been altered must be clearly and unambiguously documented in writing. Machine functions are only to be altered by or with the authorization of the manufacturer. Unauthorized modifications may compromise safety and may also nullify a manufacturer's warranty obligations and product liability.

4.7. IMPROPER DECOMMISSIONING OF EQUIPMENT AND UNSAFE STORAGE OF RADIOACTIVE SOURCES

Unauthorized handling, dismantling or abandonment of teletherapy isotope units has led to large scale serious consequences, including fatalities and widespread environmental contamination [5].

4.7.1. Measures for the prevention and mitigation of consequences

(a) Governmental licensing needs to regulate the importation, storage, commissioning, operation, temporary suspension, decommissioning and disposal of radiation sources.
(b) There have to be clear, unambiguous and authorized procedures for the temporary or indefinite secure storage of radioactive sources until safe disposal. Formal control has to be in place during this period of time.
(c) Equipment no longer in use has to be disabled in a way that prevents connection to an electrical power supply.
(d) Sealed sources found to be damaged or leaking are to be stored in a way that prevents their clinical use and contamination of the environment.

(e) Obsolete brachytherapy sources have to be disposed of safely, in accordance with governmental regulations.
(f) Radioactive sources used in nuclear medicine are to be disposed of safely, in accordance with governmental regulations.
(g) Empty source containers have to be clearly labelled and stored in a location separate from containers with sources.

4 8. DOCUMENTATION

Documentation is essential for high quality and safe radiotherapy and to foster communication among staff and continuity of practice over time [6, 7].

Some of the accidents reviewed have a strong component of misinterpretation of instructions, displays and interlocks as well as signals relating to unusual events. Many maintenance mistakes are related to a lack of comprehensive training and continuing education, especially in dealing with unusual situations.

4.8.1. Measures for the prevention and mitigation of consequences

A log book is needed for each major item of equipment, such as ^{60}Co units, linear accelerators, TPSs, ionization chambers and electrometers, in which information concerning calibration, repairs, maintenance and checks of performance are routinely recorded Each entry has to be dated and signed by the responsible person.

For individual patients, all aspects of treatment have to be documented as a permanent part of each patient's chart and retained for at least as long as specified by local laws and regulations. The prescription has to be written by a physician. Treatment plans, generated by manual or computer methods, need to include isodose distributions, with placement of beams, any wedge filters or beam blocks. The basic data and TPS used to generate the plan, including data such as depth dose, tissue–air ratios, wedge factors, etc., have to be clearly written down. All details required for the setup of the patient and machine time or monitor units for each field are to be clearly shown. A diagram of the patient with location of the beams is essential, and a photograph of the patient in the treatment position is useful for more complex treatments, particularly those involving blocked or irregular fields. Each patient's treatment is to be detailed in a daily log, with beam times or monitor units listed.

Original documentation concerning equipment or a patient's treatment is never to be altered If errors are detected that require correction later, comments may be added to the record but the original documentation is not to be changed. Addenda to documentation must include the signature or initials of the person responsible.

Comprehensive training is complemented by familiarization with the manufacturer's documents. In this respect, as indicated, the BSS recommends that performance specifications and operating and maintenance instructions be provided in a major world language understandable to the users, in compliance with the relevant International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO) standards, and that this information be translated into local languages whenever appropriate. In addition, the operating terminology (or its abbreviations) and operating values must be displayed on operating consoles in a major world language acceptable to the user. The requirements imply that instructions be understandable, without ambiguity, to users of all categories, such as radiation oncologists, technologists, medical physicists and maintenance engineers.

It is emphasized that accompanying documents, according to the IEC definition, should be a part of the equipment (see IEC-601-1, subclause 6.8 [3]) and that equipment is incomplete if the accompanying documents are not delivered. According to IEC-601-1, the accompanying documents include at least:

(a) Instructions for use, including accessories, interlocks and displays, as well as any maintenance to be performed by the user;
(b) Technical descriptions, including, among other information, a statement that the supplier will make available on request circuit diagrams, component part lists, calibration instructions or other information that will assist appropriately qualified user personnel to repair those parts of equipment designated by the manufacturer as reparable;

In addition, it is strongly recommended that the user maintain:

(1) Records of repairs, revisions of the equipment and faults and lessons learned;
(2) Manufacturer's newsletters;
(3) Manufacturer's notes on investigations of malfunctions of the equipment, accumulated experience, preventive recommendations and, most importantly, warning notes on incidents with similar machines in other facilities.

4.9. INTEGRATION OF SAFETY AND QUALITY ASSURANCE

Technical and managerial principles need to be applied to prevent unintentional exposures and to mitigate the consequences, should they occur. These principles start with a systematic assessment of both equipment and treatment procedures, followed by the application of 'defence in depth' measures and the integration of prescription and delivery of treatment in an overall approach. This approach involves the attitudes

of all the persons involved in radiation therapy — physicians, physicists, technologists, nurses, equipment maintenance engineers and clerical staff. All need to demonstrate a 'culture of safety'.

Independent checks, internal and external, are an important means of avoiding errors or detecting them before they cause injury to patients.

External independent checks may be formal, such as those performed by an outside physicist from an authorized reviewing organization, as required by clinical trials. External reviews also may be informal, where colleagues intercompare ionization chambers and other measuring systems. In addition, mailed dosimeters from reviewing organizations provide an inexpensive means of checking machine output and other basic machine parameters.

Within an institution, having a second person check data and repeat calculations or measurements is an important way of finding mistakes before they result in incorrect doses to patients. Internal independent checks need to be part of the routine flow of work in a dosimetry system. Independent verification procedures can be effective only if physicists and other staff work together as colleagues, in a spirit of goodwill and co-operation. Staff at all levels need to feel free to challenge the work of any other person if they feel that an error has been made that would cause detriment to a patient.

Independent checks are successful only if each person involved is free to point out errors and discuss problems as well as accept correction of his or her own errors. It is crucial that interaction be conducted in a professional manner, bearing in mind the best interests of the patient. A professional attitude has to be maintained by all categories of radiotherapy staff, independent of their vantage point in the review process

4.10. SAFETY ASSESSMENT

The main requirements for a safety assessment — out in the BSS in Appendix IV, 'Potential Exposure: Safety of Sources' [1] — are also applicable to radiotherapy sources and installations.

A safety assessment requires a systematic approach to identify events that can lead to potential exposures and to estimate the probability and magnitude of such exposures There are two approaches to the safety assessment: deterministic and probabilistic methods.

The deterministic method is often used first to provide safety, with appropriate safety margins, in systems where accident scenarios can be identified. Appropriate measures may include changes in equipment design or operating procedures, with relevant training of personnel and formulation of contingency plans.

The probabilistic method is used to identify weaknesses in safety measures that may be overlooked by the deterministic approach, because they may not yet have

resulted in an actual accident. The method identifies and calculates the expected frequency of initiating events that may lead to potential exposure and calculates the expected detriment due to initiating events for comparison with acceptance criteria. The method also establishes the relative importance of individual events and quantifies the probability of their leading to the detrimental effect.

Probabilistic and deterministic methods should not be viewed as being mutually exclusive, but rather as complementary techniques.

4.10.1. System for quality management

Integrated therapy systems involve both quality and safety. In fact, most of the measures to monitor quality serve equally to detect any deviation concerning safety since the parameters to be controlled are often the same. The quality control programme can be designed to combine both quality and safety. For example, test tools that perform constancy checks serve to monitor quality and safety at the same time.

To meet the requirements of radiotherapy, many centres are implementing techniques used in other disciplines where the prevention of errors is an everyday issue. While the differences between industry and medicine should be allowed for, appropriate elements of these techniques known as the 'Quality Management System' and defined by ISO Standard 9000 can be incorporated into the planning and management of radiotherapy services. The system includes the calibration of sources, clinical dosimetry, quality assurance of medical exposures and records, as well as regular and independent quality audits, as listed in Appendix II of the BSS. A detailed description of quality assurance programmes and quality control tests has been set out in many recent publications [8–13].

4.10.2. Monitoring effectiveness

The vulnerability of a facility to accidental or erroneous exposures needs to

4.10.2. Monitoring effectiveness

(d) Testing the facility for vulnerability against initiating events and contributing factors emerging from item (c);
(e) Internal and external audits and intercomparisons to detect weaknesses and indicate corrective measures;
(f) Evaluation of mistakes made, with a review of steps for mitigation of their effects and future avoidance;
(g) Evaluation of protocols for patient follow-up after therapy to detect abnormal radiation reactions that may suggest errors in exposure.

4.10.3. Defence in depth

The term defence in depth is defined in the BSS as "the application of more

4.10.3. Defence in depth

The term defence in depth is defined in the BSS as "the application of more than one single protective measure for a given safety objective such that the objective is achieved even if one of the protective measures fails". There are layers of overlapping safety provisions, such as physical components, procedures and combinations of both. A low overall probability of failure can be more readily achieved by a combination of independent protective layers such that the probabilities are multiplicative.

Examples of defence in depth are:

(1) A treatment plan that is produced by a technologist, checked by the medical physicist and rechecked by in vivo dosimetry, and
(2) The output of a linear accelerator that is controlled by an ionization chamber, checked by a second ionization chamber preset to 7–10% higher dose, and a backup timer set to the prescribed time +15%.

4.10.4. Safety culture

An essential managerial principle for all individuals and organizations is to establish a 'safety culture' encompassing both personal attitudes and habits of thought as well as organizational policies and priorities.

Good practices are essential but not sufficient. There is a need to go beyond the implementation of a good practice, so that both personal attitudes and organizational policies are oriented towards the same goal: that all duties be carried out correctly, with alertness, full knowledge, sound judgment and a proper sense of accountability. Even some of the provisions for defence in depth, such as redundant reviews and checks, may fail to detect a problem. The basic principles of safety culture are that: "all duties important to safety should be carried out correctly, with due thought and full knowledge, sound judgment and a proper sense of accountability" [14].

Each person responsible for any aspect of patient treatment needs to have a critical view of his or her own and other people's work. Freedom to challenge the work of others in a spirit of goodwill points up potential accidents before they happen. It also discourages complacency amongst staff.

Furthermore, it implies a learning attitude by all concerned, whereby both operating experience and the results of new research are used to reassess and improve safety.

4.10.5. Emergency preparedness plans

Despite preventive measures, accidents or unusual events may occur. The safety assessment will identify possible accident scenarios and situations, and countermeasures for mitigation are designed. Some of the actions in the emergency response plan need to be taken immediately, without hesitation or mistakes. To achieve this, personnel need to be trained and simulation drills carried out. A clear and concise list of actions and responsible officers is posted in relevant places. There is written documentation of rules for action and training, including simulating exercises, for the emergency response plan. The development and periodic review of the plan is part of the system of protection for radiotherapy.

4.10.6. Investigation of accidental medical exposures and dissemination of information on accidents and unusual events

In a facility where an accident occurs, corrective measures can be applied only if a prompt investigation is made. With regard to accidental medical exposure, the BSS promulgates specific investigative action, calculation of dose and corrective measures, as well as the requirement to report the incident to the Regulatory Authority and to inform the patient (BSS, Appendix II, paragraphs 29, 30).

In addition to the investigation of accidents, which leads to corrective and preventive measures, the dissemination of operational experience can avoid accidents elsewhere. The number of reported events in a single country is usually insufficient to provide a significant number of lessons in a reasonable time. However, a compilation of accidents at the international level would allow all countries to benefit from the lessons from each of them. Moreover, the experience gained from unusual events that did not culminate in accidents can contribute to the knowledge needed to avoid accidents. The dissemination of this information can be used to test the vulnerability of many facilities worldwide and improve preventive measures without waiting until an accident occurs.

Therefore, a reporting system which allows for anonymous reports of cases that are otherwise not published is necessary for such reports to reach a wider community. An international reporting system of unusual events and operational experience is in

place in other fields, such as nuclear power, and a similar approach can equally serve to prevent accidents in radiotherapy.

4.11. REGULATORY CONTROL

The assessment of safety, together with measures to reduce the likelihood of unwarranted or unjustified radiation exposure, requires the incorporation of safety into the management system and the development of a safety culture as defined in Section 4.10.4. Furthermore, these measures need to be ensured by means of appropriate regulatory control. This implies a regulatory framework involving authorization, inspection and enforcement. Radiotherapy is a practice that is subject to licensing. Licensing requirements include mandatory safety assessment of all aspects of the acquisition, use and disposal of radiation sources, including construction, importation, storage, commissioning and decommissioning, whether temporary or permanent. In addition, plans for the prevention of mistakes and for emergency preparedness are to be assessed before licences are issued. In this regard, an IAEA technical document [15] gives detailed guidance on safety assessment requirements for the authorization and inspection of radiotherapy facilities.

Appendix

APPENDIX II OF THE BSS — MEDICAL EXPOSURE: OPTIMIZATION OF PROTECTION FOR MEDICAL EXPOSURES

DESIGN CONSIDERATIONS

General

"II.11. The requirements for the safety of sources specified in other parts of the Standards shall also apply to sources used in medical exposure, where relevant, and, in particular, equipment used in medical exposure shall be so designed that:

(a) failure of a single component of the system be promptly detectable so that any unplanned medical exposure of patients is minimized; and
(b) the incidence of human error in the delivery of unplanned medical exposure be minimized.

II.12. Registrants and licensees shall:

(a) taking into account information provided by suppliers, identify possible equipment failures and human errors that could result in unplanned medical exposures;
(b) take all reasonable measures to prevent failures and errors, including the selection of suitably qualified personnel, the establishment of adequate procedures for the calibration, quality assurance and operation of diagnostic and therapeutic equipment, and the provision to personnel of appropriate training and periodic retraining in the procedures, including protection and safety aspects;
(c) take all reasonable measures to minimize the consequences of failures and errors that may occur; and
(d) develop appropriate contingency plans for responding to events that may occur, display plans prominently, and periodically conduct practice drills.

II.13. Registrants and licensees, in specific co-operation with suppliers, shall ensure that, with regard to equipment consisting of radiation generators and that containing sealed sources used for medical exposures:

(a) whether imported into or manufactured in the country where it is used, the equipment conform to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards;

(b) performance specifications and operating and maintenance instructions, including protection and safety instructions, be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to 'accompanying documents', and that this information be translated into local languages when appropriate;

(c) where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user;

(d) radiation beam control mechanisms be provided, including devices that indicate clearly and in a fail-safe manner whether the beam is 'on' or 'off';

(e) as nearly as practicable, the exposure be limited to the area being examined or treated by using collimating devices aligned with the radiation beam;

(f) the radiation field within the examination or treatment area without any radiation beam modifiers (such as wedges) be as uniform as practicable and the non-uniformity be stated by the supplier; and

(g) exposure rates outside the examination or treatment area due to radiation leakage or scattering be kept as low as reasonably achievable."

"Requirements for radiation generators and irradiation installations for radiotherapy

II.15. Registrants and licensees, in specific co-operation with suppliers, shall ensure that:

(a) radiation generators and irradiation installations include provisions for selection, reliable indication and confirmation (when appropriate and to the extent feasible) of operational parameters such as type of radiation, indication of energy, beam modifiers (such as filters), treatment distance, field size, beam orientation and either treatment time or present dose;

(b) irradiation installations using radioactive sources be fail-safe in the sense that the source will be automatically shielded in the event of an interruption of power and will remain shielded until the beam control mechanism is reactivated from the control panel;

(c) high energy radiotherapy equipment:

  (i) have at least two independent 'fail to safety' systems for terminating the irradiation; and

(ii) be provided with safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel;

(d) the design of safety interlocks be such that operation of the installation during maintenance procedures, if interlocks are bypassed, could be performed only under direct control of the maintenance personnel using appropriate devices, codes or keys;

(e) radioactive sources for either teletherapy or brachytherapy be so constructed that they conform to the definition of a sealed source; and

(f) when appropriate, monitoring equipment be installed or be available to give warning of an unusual situation in the use of radiation generators and radionuclide therapy equipment."

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Technical Committee Meeting

Vienna, Austria: 17–21 March 1992

Consultants Meetings

Vienna, Austria 16–20 October 1993, 26 November–7 December 1995,
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ISSN 1020–6450