Prevention of high-dose-rate brachytherapy accidents

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Abstract—High-dose-rate (HDR) brachytherapy is a rapidly growing technique that has been replacing low-dose-rate (LDR) procedures over the last few years in both industrialised and developing countries. It is estimated that about 500,000 procedures (administrations of treatment) are performed by HDR units annually. LDR equipment has been discontinued by many manufacturers over the last few years, leaving HDR brachytherapy as the major alternative.

HDR brachytherapy techniques deliver a very high dose, of the order of 1.6–5.0 Gy/min, so mistakes can lead to under- or overdosage with the potential for clinical adverse effects. More than 500 HDR accidents (including one death) have been reported along the entire chain of procedures from source packing to delivery of dose. Human error has been the prime cause of radiation events. In the present report, the International Commission on Radiological Protection concludes that many accidents could have been prevented if staff had had functional monitoring equipment and paid attention to the results.

Since iridium has a relatively short half-life, the HDR sources need to be replaced approximately every 4 months. Over 10,000 HDR sources are transported annually, with the resultant potential for accidents; therefore, appropriate procedures and regulations must be observed.

A number of specific recommendations on procedures and equipment are given in this report. The need for an emergency plan and for practising emergency procedures is stressed. The possibility of loss or theft of sources must be kept in mind.

A collaborating team of specifically trained personnel following quality assurance (QA) procedures is necessary to prevent accidents. Maintenance is an indispensable component of QA; external audits of procedures re-inforce good and safe practice, and identify potential causes of accidents. QA should include peer review of cases. Accidents and incidents should be reported and the lessons learned should be shared with other users to prevent similar mistakes.

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Editorial

BETTER SAFE THAN SORRY

Back in 2001, Publication 86 (ICRP, 2002a) dealt with the prevention of accidental exposures of radiotherapy patients. In a sense, that report touched upon two important areas that were somewhat outside our ordinary turf, but definitely worth the attention. One of these areas concerns the nature and philosophy of regulating risks, and the other area concerns the responsibility for safety within a licensee organisation.

The Commission is an advisory body, not a regulatory organisation, so while many ICRP members are or have been regulators, the Commission is not primarily concerned with regulatory methodology. Nevertheless, the 1990 Recommendations in Publication 60 (ICRP, 1991) did include a chapter on national (regulatory) infrastructure. Publication 75 (ICRP, 1998a) on occupational exposures provided some more comments, Publication 86 (ICRP, 2002a) dwelled on the same concepts, and the present report also touches on this.

The main message in the present context of accident prevention is that successful regulation requires mutual trust between trustworthy and equal parties. In other words, prescriptive regulations can never work in the long run. The operator, not the regulator, must take the primary responsibility for safety, and the job of the regulator is to ensure that the operator is capable of taking that responsibility, not to handle the actual safety cases.

In Publication 86 (ICRP, 2002a) and in the present publication, the importance of incidence reporting is underscored. A successful programme of incidence reporting obviously requires that licensees are reasonably convinced that regulators will use such reports to improve safety, not to find culprits for punishment. Very few operators would be likely to display their shortcomings publicly if their candour were rewarded with punishments. Conversely, as amply shown in the aviation industry, real and significant safety improvements are achieved if people learn of problems encountered by their peers and how these problems can be tackled.

This is not to say that punishments are unnecessary. Regulators (and legislators) need to have a full complement of tools, including punishments when required but that tool should be reserved for those who try to hide problems, and not for those who turn to the regulator for help and advice in an honest effort to improve their ways.

So, who is responsible for safety in a licensee organisation? The first reply should, of course, be ‘everybody’. Safety culture is defined in the International Basic Safety Standards as ‘the assembly of characteristics and attitudes in organisations and individuals which establishes that, as an over-riding priority, protection and safety issues
receive the attention warranted by their significance. This requires that every employee feels that they have a personal share of responsibility. In Publication 55 (ICRP, 1989) on optimisation methods and later in Publication 81 (ICRP, 2000) on disposal of long-lived radioactive waste, this was described as ‘to engender a state of thinking in everyone . . . such that they are continually asking themselves the question: “Have I done all that I reasonably can to reduce these radiation doses?”’.

Another type of reply focuses on power, and specifically the power to change unsatisfactory conditions. We can all contribute to safety, but individual employees are not always able to take corrective action. Thus, while everybody has a responsibility, the management has a particular role.

Publication 60 (ICRP, 1991) emphasises that ‘The primary responsibility for achieving and maintaining a satisfactory control of radiation exposures rests squarely on the management bodies of the institutions conducting the operations’. All too often, we read in the newspapers that a worker in some organisation caused an accident because of poor training, poor performance, or something suchlike. But was it really the individual worker’s fault? Should not the top management have ensured that there was a quality system in place such that all workers have the necessary training and are capable and willing to perform adequately? And if an error is committed in spite of this, should there not have been redundant mechanisms to ensure that a single failure would not lead to disaster? The very top management may not be involved in day-to-day operation, but they can never evade the over-riding responsibility for providing a system and an organisation that are inherently safe.

Finally, a third type of reply brings us back to the medical arena where we started: in such establishments, those who are employed specifically to handle radiological protection issues may also have a particular responsibility for safety.

At installations in the nuclear fuel cycle, there are usually ‘safety experts’ and even ‘safety departments’ where engineering and behavioural aspects of safety are combined in a fruitful manner. Other large industries often have similar resources at hand. Such ‘safety departments’ are usually responsible for safety in the sense that they advise the top management and help management at all levels with their expertise.

However, at many hospitals and universities, there is no specific department or person with this particular experience. Thus, it often falls on the radiological protection experts in the organisation to provide advice in the area of safety as well as radiological protection. Publication 64 (ICRP, 1993) on potential exposures and, in particular, Publication 76 (ICRP, 1998b) with applied examples from outside the nuclear fuel cycle emphasise the importance of safety issues and the possible safety responsibility of those otherwise concerned with radiological protection. The Commission hopes that the present report will contribute to their successful handling of the complicated safety issues in connection with high-dose-rate brachytherapy units.

Jack Valentin
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PREFACE

Over the years, the International Commission on Radiological Protection (ICRP), referred to below as ‘the Commission’, has issued many reports providing advice on radiological protection and safety in medicine. Its *Publication 73* (ICRP, 1997) is a general overview of the area. These reports summarise the general principles of radiological protection and provide advice on the application of those principles to the various uses of ionising radiation in medicine and biomedical research.

Most of the earlier reports are of a general nature. The Commission now wishes to address some more specific situations where difficulties have been observed. It is desirable that reports on such problem areas should be written in a style that is accessible to those who may be directly concerned in their daily work, and that every effort is taken to ensure wide circulation of such reports.

A series of such reports was initiated at the Commission’s meeting in Oxford, UK in September 1997. On the recommendation of Committee 3, the Commission has established a number of Task Groups to produce reports on topical issues in medical radiation protection.

Several such reports have already appeared in print as *Publications 84, 85, 86, 87, 93*, and *94* (ICRP, 2001a,b, 2002a,b, 2004a,b), and *Supporting Guidance 2* (ICRP, 2002c). The present report continues this series of concise and focused documents, and several further advisory reports are being prepared.

In 2001, Committee 3 formed a Working Party to study problems associated with the widespread introduction of high-dose-rate brachytherapy. The Working Party concluded that a full report addressing such problems was desirable, and the Task Group on Prevention of High-Dose-Rate Brachytherapy Accidents was launched at the Commission’s meeting in Albuquerque, NM, USA in October 2002. Its terms of reference were to identify reported accidents and incidents by category (transport, handling, procedures, dosimetry, indications, commissioning, decommissioning); to identify (unreported) potential events; and to analyse the geographic distribution of machines and trends. Furthermore, the Task Group was requested to provide recommendations as necessary concerning transport, handling, procedures, dosimetry, indications, and training.

The membership of the Task Group was as follows:

L. Pinillos Ashton (Chairman)  J.-M. Cosset  V. Levin
A. Martinez  S. Nag

The corresponding members were:

M. Hiraoka  P. Ortiz-Lopez  W. Yin

The membership of Committee 3 during the period of preparation of this report was:
This report aims to serve the purposes described above. In order to be as useful as possible for those purposes, its style differs in a few respects from the usual style of the Commission’s publications in the *Annals of the ICRP*.

The report was approved for publication by the Commission through a postal ballot in August 2004.
MAIN POINTS

• High-dose-rate (HDR) brachytherapy is a rapidly growing technique that has been replacing low-dose-rate (LDR) procedures over the last few years in both industrialised and developing countries. It is estimated that about 500,000 procedures (administrations of treatment) are performed by HDR units annually.
• LDR equipment has been discontinued by many manufacturers over the last few years, leaving HDR brachytherapy as the major alternative.
• HDR techniques deliver a very high dose, of the order of 1.6-5.0 Gy/min, so mistakes can lead to under- or overdosage with the potential for clinical adverse effects.
• More than 500 HDR accidents (including one death) have been reported along the entire chain of procedures from source packing to delivery of dose. Human error has been the prime cause of radiation events.
• Many accidents could have been prevented if staff had had functional monitoring equipment and paid attention to the results.
• Since iridium has a relatively short half-life, the HDR sources need to be replaced approximately every 4 months. Over 10,000 HDR sources are transported annually, with the resultant potential for accidents.
• A team of trained personnel following quality assurance (QA) procedures is necessary to prevent accidents. QA should include peer review of cases.
• Accidents and incidents should be reported and the lessons learned should be shared with other users to prevent similar mistakes.
1. INTRODUCTION

(1) Surgery, chemotherapy, and radiation therapy or a combination thereof can be used to treat cancer. Radiation therapy may be delivered by teletherapy [external beam radiation therapy (EBRT)] or brachytherapy (sources inserted into or immediately adjacent to tumours). Teletherapy may be delivered with a conventional multifield technique or by varying degrees of conformality to target volumes. Brachytherapy includes low-dose-rate (LDR) manual afterloading, LDR remote afterloading, and medium-dose-rate (MDR), high-dose-rate (HDR), and pulsed-dose-rate (PDR) techniques.

(2) Brachytherapy came into use soon after the discovery of radium by Pierre and Marie Curie in 1898. Before the 1950s, the radioactive material was generally inserted directly into the tumour or cavity (‘hot loading’). Although brachytherapy was effective, its major disadvantage was exposure of medical caregivers to radiation. This and the advent of high-energy teletherapy for deep tumours led to a decline in the use of brachytherapy in the 1950s.

(3) To reduce the radiation exposure hazard, manual afterloading was introduced. First, hollow needles or tubes were inserted into the tumour or tumour region and then the radioactive material was loaded through the tubes, thus increasing the accuracy and reducing the radiation exposure of caregivers.

(4) Sievert first proposed the concept of remote manual afterloading in 1937 (Sievert, 1937). In this technique, hollow tubes are inserted into or close to the tumour and are connected to the radioactive material that is housed in a shielded container. By remote control, the radiation source is driven through the transfer cables into the tumour, thus eliminating radiation exposure to the personnel.

(5) Automated remote afterloading, whereby source entry and egress were automated, was developed in the 1980s. This was necessitated as:

- very high activity sources could not be safely handled manually;
- dwell times at predetermined positions were short and required accuracy of a fraction of a second; and
- single to few (< 10) fractions were required repetitively.
2. WHAT IS THE PURPOSE OF THIS REPORT?

(6) The expected audience of this report includes those radiation safety personnel, administrators, technicians, and radiation oncologists who have recently begun to engage in HDR brachytherapy or who are planning to introduce it in the near future. It is expected that the radiation oncology staff will already be proficient in other types of radiotherapy and radiation safety. This report may also be helpful to regulators who do not have specific regulations dealing with HDR brachytherapy.

(7) The report seeks to:

- review known accidents that have been reported and the lessons learned; and
- address measures to minimise the risk of untoward events.

(8) Over the last two decades, there has been a large increase in the use of automated remote HDR brachytherapy techniques, which involve a very high dose given over a short time period. Radiation risks cover the full chain of procedures, prior and up to the delivery of the therapeutic dose. Several hundreds of events have been reported of varying degrees of severity, and unfortunately there is a very large under reporting of accidents. The reported cases not only involve mistakes that have led to treatment of the wrong patient, unwanted under- or overdosage, or treatment of the wrong area, but also exposures to the public or people handling the sources. Utilisation of HDR brachytherapy involves transport of over 10,000 high activity sources/year to over 1500 machines located in more than 1000 centres all over the world. These centres differ in the level of staff training and different clinical utilisation.

(9) The scope of this document does not include intravascular brachytherapy. It is recognised that some facilities are using high activity HDR$^{60}$Co sources in an effort to save money and to reduce the required number of source changes, but as iridium is by far the most common source material, it will be the main radionuclide considered in this report. General guidelines for HDR brachytherapy installations can also be found elsewhere (IAEA, 1998, 2001; Nag et al., 2000).

2.1. What is remote HDR brachytherapy?

(10) LDR, MDR, or HDR techniques can be used to perform remote-controlled brachytherapy. ICRU Report 38 (ICRU, 1985) categorised the dose rate, which is rather arbitrary, as follows:

LDR: \[ 0.4 \text{ Gy/h} \]

MDR: \[ 2.0 \text{ Gy/h} \]

HDR: \[ > 12.0 \text{ Gy/h} \]

(11) By the ICRU definition, HDR is \( > 12 \text{ Gy/h} \), although the usual dose rate employed in HDR brachytherapy units is currently about 100-300 Gy/h (Arai et al., 1992; Nag et al., 1999a; Wakabayashi et al., 1971) or 1.6–5.0 Gy/min. One can see that minor errors in the time the source is at a given position can significantly and adversely affect the patient.
Remote-controlled afterloading eliminates the hazards of radiation exposure, allowing complete radiation protection for all hospital staff, regardless of whether LDR, MDR, or HDR brachytherapy is used. However, the use of HDR brachytherapy has the added advantage that the treatments can be performed in just a few minutes. Treatment time typically ranges from 1 to 12 min. This, together with fine applicators, allows the treatments to be given on an outpatient basis (no hospital beds are used), usually without the need for anaesthesia, with minimal risk of applicator movement and very little organ motion allowing precise determination of dose to the tumour and the adjacent normal tissues, and minimal patient discomfort. Another significant advantage if a stepping source is used in HDR brachytherapy is that variation of the dwell times at each dwell position of the stepping HDR source allows optimisation of the planned dose distribution to match the target volume more closely (Flores et al., 1994; Gaspar et al., 1997). This allows the delivery of intensity-modulated brachytherapy, i.e. the delivery of different doses to different areas of a determined tumour as needed.

Although sources of different sizes and activity can be used, microsource HDR using 192Ir sources of high specific activity are most commonly employed. These allow the use of a smaller source (about 1-mm diameter, 3.5-mm length), delivery of a high dose to the tumour, and short treatment times. The small diameter allows the source to be easily inserted through a thin delivery tube for interstitial, intracavitary, or endoluminal treatment. From the standpoint of radioactive waste management, 192Ir sources also have an advantage due to their short half-life of about 74 days. This is less than that for other radioisotopes used for brachytherapy, such as 137Cs (half-life of 30 years) or 60Co (half-life of 5.3 years). This, however, involves an ongoing hazard and cost penalty related to source replacement every 3-4 months.

Due to its numerous advantages, the use of HDR, particularly microsource HDR, brachytherapy has spread around the world. Currently, more than 1500 units exist in the world, including over 400 in developing countries. The figure on the flyleaf shows an example of this type of equipment. However, the proper training and knowledge for the safe and effective use of HDR brachytherapy is still lacking in many developing countries (Nag et al., 2002).

PDR brachytherapy has been developed most recently. As for HDR brachytherapy, it uses a single miniaturised source that moves step by step through fine implanted afterloading devices, and also has the possibility of variation in the dwell times so as to optimise dose distribution. In PDR brachytherapy, such a sequence of steps, also called a ‘pulse’, is repeated a number of times to obtain the prescribed total dose. By choosing an appropriate number of pulses, one can simulate, from a radiobiological viewpoint, a continuous LDR treatment for which the biological effects are well known. The disadvantage is the utilisation of special hospital rooms and the need for available personnel 24 h/day.

Inventory control and risk of the loss of individual sources is lower with remote afterloading brachytherapy units. The risk of source loss is extremely small in HDR or PDR brachytherapy as there is only one source, it is housed inside the afterloader, and that is kept in a locked and controlled area.
3. CURRENT CLINICAL USE OF HDR BRACHYTHERAPY

(17) The selection of an HDR brachytherapy modality depends on how common a particular cancer is in the country in question, and whether that site is amenable to effective HDR brachytherapy treatment. This is a dynamic field, with HDR brachytherapy being used increasingly as a sole modality for radiation treatment of early-stage localised tumours. Currently, it is most often used in conjunction with teletherapy.

(18) The most common indications for HDR brachytherapy are treatment of cervical, endometrial, oesophageal, breast, prostate, and lung cancers, and soft tissue sarcomas in adults and children. An area of development is intra-operative HDR brachytherapy.

(19) The summary of the common clinical indications of HDR brachytherapy provided here is necessarily brief and can be seen as an appendix at the end of the document. Treatment protocols are outside the scope of this document, and the reader is directed to standard textbooks or reviews for further details (Abitbol et al., 1998; Gerbaulet et al., 2002; Joslin et al., 2001; Nag, 1994, 1997).
4. INFRASTRUCTURE AND COMPONENTS OF THE REMOTE AFTERLOADING HDR SUITE

(20) In order to understand the nature of adverse events related to HDR brachytherapy, it is helpful to have a basic knowledge of the infrastructure and components of the remote afterloading HDR suite (Fig. 4.1) because such events (due to equipment-related problems, human error, or a combination of both) can occur at many points in the remote afterloading systems. A synopsis of the types of adverse events is presented in Section 8, and a fuller description of reported events is presented in Section 9. The roles of personnel training and quality assurance (QA) in contributing to the avoidance of such adverse events are noted in Sections 5 and 6, respectively.

(21) A remote afterloading system consists of a motor-driven source transport system for automatically transferring radioactive material between a shielded safe and the treatment applicator (AAPM, 1993). These systems were first designed for use in gynaecological brachytherapy, but microsource models were designed for broader applications.

(22) Overall requirements for an infrastructure can be found in IAEA (1998, 2001). This section will focus on operational and clinical aspects of an infrastructure.

Fig. 4.1. High-dose-rate (HDR) brachytherapy suite. A C-arm fluoroscope is used to position the guidance catheters or endoscopy equipment prior to source insertion. Other equipment for a minor operating room is also present. The HDR machine itself is not shown here.
4.1. HDR suite

(23) An adequately shielded room for the remote afterloading device, the necessary imaging equipment, and a separate room for the operators are required to avoid direct exposure of the operators. This allows all components of the treatment to take place without moving the patient. Some institutions split the functions of placement, simulation, and verification in different rooms, thus increasing the risk of errors.

4.2. HDR unit

(24) HDR remote afterloading systems should comply with international standards of safety and quality, such as those of the International Electrotechnical Commission (IEC, 1989) and International Standards Organisation 9000 (ISO, 2000). Commercially available HDR afterloading units consist of a number of components.

4.2.1. HDR source

(25) A radioisotope with a high specific activity was required to simultaneously achieve an HDR and a small source size required for intracavitary and interstitial brachytherapy. $^{192}$Ir was selected for HDR brachytherapy because of its relatively low gamma energy (average 0.4 MeV) and short half-life (74 days), and the ability to produce high specific activity (330 MBq/mm$^3$) sources. A new method of source specification has been proposed in brachytherapy: the Reference Air Kerma Rate (RAKR) (ICRU, 1985, 1997).

(26) The RAKR of a brachytherapy source is the air kerma rate (‘in vacuo’) at a reference distance of 1 m from the source centre. This quantity is expressed in Gy/s at 1 m (or a convenient multiple of this unit such as microgray/h at 1 m). For $^{192}$Ir, the RAKR is 0.116 microgray/h at 1 m/MBq (apparent activity).

(27) In practice, three to four sources are required each year per machine to achieve clinically acceptable dose rates.

(28) Microsource HDR remote afterloaders use a single $^{192}$Ir source with an activity of approximately 370 GBq (10 Ci). The encapsulated source is about 5 mm long and less than 1.5 mm in diameter; these dimensions vary with different commercial models. For example, one brand of source is made by drilling a hole in a nickel-titanium alloy wire, inserting two 0.35 x 2.5 mm iridium pellets, and welding an end cap to the end of the wire. The total length of the source is then 5 mm. A different brand of source has a single 0.65 x 3.6 mm iridium pellet in a stainless steel capsule that is welded to a metal plug and a stainless steel cable.

(29) While it is convenient to think of HDR sources as point sources, they are clearly longer than they are wide. The dosimetry of such sources has been studied using the Monte Carlo simulation code with attention to the dose rate distributions in the centimetre and millimetre distance ranges. Radial dose functions do not depend significantly on source and encapsulation geometry, and agree within 2% with that of a point source (Papagiannis et al., 2000).
(30) The source is welded to the end of a drive cable, transferred to programmed
locations within the applicators (dwell positions), and held in place for the pro-
grammed duration (dwell times) using a motor-driven system.

4.2.2. Afterloader device (treatment unit)

(31) An afterloader unit contains:

- a shielded safe (source container) to hold the source when not in use;
- a stepping motor;
- a source transferring and positioning system;
- several channels for source transport;
- an indexer to allow automatic transfer of the source cable among the different
  transfer tubes;
- transfer tubes to connect the device to the applicators;
- a safety system to ensure safe operation of the device, including:
  - automatic path-check of the applicator and transfer tube with a check cable,
  - means of sensing the source position and timing of its motion,
  - a built-in Geiger-Muller counter to check that the source has returned to the
    safe, and
  - backup batteries to withdraw the source in the event of power failure and for
    saving treatment data; and
- emergency systems to withdraw the source into the safe.

(32) These units are mobile and take up little floor space. A detailed description
and specification for an HDR afterloading device is available in IAEA (2001, Appen-
dix G.3).

4.2.3. Control console

(33) The control console located outside of the treatment room operates the after-
loader, shows the source position on the display as the treatment progresses, and
prints out a report of the treatment. The treatment plan can be transferred to the
control console through a direct link with the treatment planning computer, a floppy
disk or a program card (for older machines). It has a microprocessor to automati-
cally correct the dwell times for decay. The control console should be simple to
operate.

4.3. Applicators

(34) Almost all applicators designed for LDR manual afterloading have been
adapted for HDR use with a mechanism to connect them to a transfer tube from
the afterloader device. Typically, the applicators for HDR brachytherapy have thiner
 tubes. The connection has mechanical interlocks to prevent wrong connections.
The applicator, transfer tube, and afterloader device are a closed system to avoid the
possibility of the source becoming dislodged in the patient or exiting before reaching the target region. Some examples are shown in Fig. 4.2.

(35) There are four types of applicators: intracavitary, intraluminal, interstitial, and moulds. Each type employs a specific connector or transfer tube to link with the treatment unit.

(36) Intracavitary applicators utilise transfer tubes for each channel. These are designed to be the same overall length. Different interlocks are used for each channel to avoid connection errors. These applicators may be made of plastic, metal (radio-opaque), or radiolucent carbon graphite.

(37) Intraluminal applicators usually connect directly to the treatment unit using a specific adapter. These applicators can be 5 or 6 French diameter, blind-ended, flexible tubes (disposable) or they can have a specific design (e.g. oesophageal applicator).

(38) Interstitial applicators can be rigid or flexible. Rigid stainless steel needles are of different lengths and require specific transfer tubes. The needles can be re-used after sterilisation. Using a template for implantation with a fixed predetermined

Fig. 4.2. Examples of common applicators with retractors in use for gynaecological high-dose-rate brachytherapy showing the possibility of fixed geometry and the thinness of the applicators.
geometry allows use of standard dose distribution. Thin, flexible, disposable plastic tubes require different transfer tubes.

(39) Mould applicators also use thin flexible tubes embedded in plastic material to form an applicator that is applied to the patient’s skin or mucosa instead of being inserted into tissue.

4.4. Treatment planning system

(40) The treatment planning system should be fast, versatile, and specific to the remote afterloader. Planning cannot be performed on conventional brachytherapy planning systems. A treatment planning system is supplied as part of an afterloading treatment unit. It completes the treatment planning in a few minutes and transfers the program to the control console via a direct link, a floppy disk, or a program card (for older machines).

4.4.1. Preplanning

(41) The simplest treatment planning uses a single catheter with a single-site position, as in the ‘MammoSite’ applicator, whereby a dose at the surface of a balloon is delivered with a single dwell position. Equally simple is a line arrangement of dwell positions where the dose is prescribed at a specified radius, as used in treating cancer of the oesophagus. Fixed geometry intracavitary applicators with retractors using a standard treatment plan are next in complexity.

4.4.2. Individualised planning

(42) Intracavitary treatment with non-fixed geometry applicators requires patient-specific treatment plans optimised for the tumour configuration. Multiplane rigid interstitial application with optimised treatment planning is used for breast or rectum. Prostate interstitial applications are usually performed with online intra-operative optimised treatment planning.

(43) Multiplane, flexible, interstitial application with optimised treatment planning is the most complicated. Optimally, clinical examinations supplemented by one or several imaging modalities [computer tomography (CT), magnetic resonance imaging (MRI), ultrasound] are used to define the target volume and optimise the treatment plan to deliver a high dose to the tumour while minimising the dose to normal tissues. General requirements for a treatment planning system can be found in IAEA TECDOC 1040, Appendix C (IAEA, 1998).

4.5. Associated safety devices

(44) It is of the greatest importance to be in permanent contact with the patient as he may experience pain, discomfort, or anxiety and the radiation oncologist and nurse need to be able to speak to the patient without interrupting the treatment delivery. Closed circuit television and audio equipment can be used for this purpose.
Some cases are treated under sedation and medical supervision is required, so all communication equipment has to be kept in perfect condition and verified before each procedure.

(45) Radiation monitors (gamma alarms fixed and mobile) need to be present due to the use of very high activity sources. Warning lights are also an integral part of safety devices. Miscellaneous items such as a storage container and long forceps are mandatory. During the description of the events, their use will be very evident.

4.6. Building

4.6.1. Infrastructure required for applicator/catheter placement (procedure room)

(46) This room should function like an outpatient surgery room and should be suitable for various procedures such as endoscopy, percutaneous insertion of catheters, or gynaecological applicator placement. The factors to be considered include the availability of:

- sufficient space for both the brachytherapy team and any other medical or surgical teams that will be involved in the procedure;
- an adjustable and mobile table with stirrups, ideally x-ray compatible;
- instruments for minor surgery;
- a cart with disposable supplies;
- a storage cabinet for HDR applicators and other accessories;
- surgical lights, anaesthesia equipment, and patient telemetry (desirable); and
- a clean water supply and a sink.

4.6.2. Infrastructure required for localisation radiographs

(47) Ideally, dedicated x-ray equipment should be installed. Portable x-ray machines can be used but a fixed C-arm x-ray machine is preferable, as described in Section 4.7. If the treatment room is separate from the applicator placement room, the size of the shielded treatment room should be adequate to allow localisation radiographs to be obtained on the treatment table in order to minimise patient movement.

4.6.3. Infrastructure required for the treatment planning room

(48) The hardware for treatment planning can be placed in a separate room or adjacent to the control console. The only requirements are the space and the power supply. A device for an uninterruptable power supply with a voltage regulator should be considered as part of the hardware. It is desirable to have the treatment planning system placed close to the treatment room, as this improves efficiency and communication.
4.6.4. Infrastructure required for the treatment room

(49) An appropriately shielded room should be used for an HDR unit. Generally, concrete equivalent to 4 cm of lead, i.e. 35 cm thick (14 inches), is required but the precise thickness depends on the room design, the workload, and the local regulations. Note should be made that the required shielding of the treatment room will be significantly greater if $^{60}$Co is utilised as the source instead of $^{192}$Ir. Entrance doors should have electrical interlocks.

(50) There should be direct vision of the patient or a closed circuit observation system. The control console should be just outside the treatment room. An uninterruptable power supply is desirable. Requirements for the treatment room are given in IAEA (1998), NCRP (1976), and Stedeford et al. (1997).

4.7. Imaging

(51) Reconstruction and dosimetry of treatment depend on the system used for obtaining images. Three methods can be defined although the most simple (the first) is appropriate in most clinical situations.

4.7.1. Level 1: conventional radiology

(52) X-ray films can be obtained by using mobile equipment inside the shielded room or equipment fixed to the ceiling or walls (C-arm fluoroscopy unit). This produces semi-orthogonal films as used in LDR brachytherapy. Without isocentric equipment, reconstruction methods require a device (simulation box) that permits semi-orthogonal reconstruction to permit taking nearly orthogonal films (not exactly 90° position). If this technique is used, high kV equipment, which allows side exposure of the pelvis for gynaecological treatments, is necessary.

4.7.2. Level 2: simulator

(53) Having a simulator for external radiotherapy permits not only the taking of films as mentioned in the technique of conventional radiology, but also trustworthy orthogonal films. In addition, other (easier) reconstruction techniques such as isocentric and variable angles, which may be required under special circumstances, can be used.

4.7.3. Level 3: CT and MRI

(54) Axial cuts from a CT scan or MRI permit not only the reconstruction of the source position, but also the reconstruction of the anatomical volumes of interest in dosimetry. In the first two methods, it is possible to get the reconstruction of the applicators, but not their relationship to the soft tissue structures.
4.8. Equipment for radiation safety and source handling

(55) Every brachytherapy facility should have the following equipment:

- a storage container in the treatment room to serve as an emergency source container in case of failure of the afterloader in retracting the source;
- long-handled forceps; and
- a portable radiation monitor instrument and an area radiation monitor (IAEA, 1998).
5. PERSONNEL REQUIREMENTS AND TRAINING

5.1. Personnel requirements

(56) A major prerequisite for the development of an HDR brachytherapy facility is adequately trained staff. A multidisciplinary team should be organised. A radiation oncologist, a medical physicist, a technician, and a nurse are the minimum personnel required. Depending on the workload, a dosimetrist, more nurses, radiation oncologists, and technicians may be added. Introduction of an HDR machine leads to the treatment of a wider spectrum of malignant disease and a considerable increase in work load. Thus, a proportional increase of personnel is required to satisfy the incremental work load.

(57) The HDR brachytherapy procedure flow has been described elsewhere (IAEA, 2001; Kubo et al., 1998).

5.1.1. Radiation oncologist

(58) The radiation oncologist is responsible for the overall procedure, as brachytherapy is a medical treatment. He/she should be properly accredited according to each country’s regulations. Specific responsibilities of the radiation oncologist are (Kutcher et al., 1994):

- patient evaluation;
- patient selection;
- treatment protocol selection;
- treatment prescription;
- applicator insertion(s);
- imaging review;
- selecting tumour, target, and treatment volumes;
- treatment plan approval;
- applicator(s) removal;
- evaluation of tumour response and side effects; and
- patient follow-up.

5.1.2. Medical physicist

(59) The medical physicist should be accredited in dosimetry according to each country’s regulations and is usually responsible for radiation safety. Specific responsibilities of the medical physicist are:

- testing equipment at the time of acceptance of new equipment or after major repairs;
- verification of calibration of sources;
- performing source exchange if necessary;
• checking the treatment unit – verifying source positioning, indexing, internal gamma alarm, etc.;
• checking patient set-up including applicator positioning;
• supervising imaging;
• checking treatment planner;
• treatment planning and calculations; and
• supervising treatment administration by the technicians.

(60) The medical physicist should participate in preparation of the patient after the applicator has been inserted and prior to getting the aforementioned images, since it is during such preparation that the dummies (x-ray marker wires) are to be positioned in the applicators (as required by the technique used). If catheters are used, it is necessary to measure and identify them. It is also necessary either to select the angles of the radiographic images or to select planes in the event of CT or MRI.

5.1.3. Technician/brachytherapy technologist

(61) The technician is in charge of:
• checking applicators and specific accessories;
• daily checking of the treatment unit;
• assisting the radiation oncologist during implantation (alternatively nurse);
• obtaining images for localization;
• using treatment planning under the medical physicist’s supervision;
• delivering treatment;
• monitoring each treatment from the console; and
• recording treatment on appropriate documents.

5.1.4. Nurse

(62) The nurse is in charge of assisting the physician during each procedure. Specific responsibilities are:
• daily checking of the treatment room;
• ensuring supplies of disposables, gynaecological packs, etc.;
• scheduling of patients;
• receiving patients and sending them home; and
• assisting the radiation oncologist during implantation.

5.2. Is there a need for special training for HDR procedures?

(63) Personnel need to be trained adequately on the specific model of HDR remote afterloading system acquired in order to avoid possible confusion leading to errors, and to promptly identify and correct any errors that may occur. Having previous experience in LDR brachytherapy does not preclude the requirement of specialised training.
5.2.1. Radiation oncologist training

(64) Even if the radiation oncologist has experience in LDR brachytherapy, additional training is required in HDR-specific features such as applicators, insertion techniques, HDR radiobiology, and emergency procedures. HDR intracavitary, intraluminal, or interstitial applicators are similar to those used in LDR; however, the radiation oncologist needs to become practiced and familiar with their use. The radiation oncologist should be trained to place the applicators quickly and precisely. Radiobiology knowledge needs to be updated to select the appropriate treatment protocols and fractionation. The radiation oncologist should be trained in all clinical and physical emergency procedures.

5.2.2. Medical physicist training

(65) The medical physicist should be trained in the use of the HDR planning system (a necessary tool in the use of HDR equipment) and should become thoroughly familiar with applicator image reconstruction. Training in equipment use, security systems, and emergency procedures is mandatory. Medical physicists should also be trained in the basic principles and procedures of radiation protection.

(66) Preferably, the radiation oncologist and the medical physicist should be trained at a brachytherapy centre that treats similar types of cancers using the same model of HDR unit. ‘Hands-on’ training is highly desirable. During the initial phase of working with HDR brachytherapy, the support of an experienced physician and physicist is very useful for achieving the objectives with confidence and for good QA.

5.2.3. Technician and nurse training

(67) The technician and nurse can be trained in HDR brachytherapy procedures by the radiation oncologist and the medical physicist. Radiation safety instruction and emergency procedures are essential elements to be covered.

5.2.4. Emergency procedures

(68) Emergency procedures are described in IAEA (1998, 2001). These procedures should be practised periodically and the information should be displayed prominently in the treatment room and control room. The items required to perform emergency procedures should be available on the HDR brachytherapy suite.
6. QUALITY ASSURANCE

(69) QA in radiation therapy is essential for obtaining good results, avoiding unnecessary side effects, and performing HDR brachytherapy accurately and safely. In HDR brachytherapy, QA is extremely important because the treatment is delivered in a short time period, with little or no opportunity for correction other than alteration of subsequent fractionation – a deviation from prescription.

(70) The QA programme should include physical, clinical, and organisational aspects applicable to this modality. The details of a QA programme are beyond the scope of this report and the reader is referred to FAO et al. (1996), IAEA (1998, 2001), and Kutcher et al. (1994).

6.1. Clinical quality assurance

(71) Clinical QA begins with the patient selection criteria for HDR brachytherapy. Patient evaluation includes the patient’s general condition as well as tumour characteristics. It is followed by dose determination, prescription, specification and fractionation, quality of insertions, tumour volume, and treatment volume definition. Follow-up is mandatory to determine the outcome in terms of survival and quality of life – the ultimate yardstick of QA. A significant number of unreported ‘errors’ probably occur due to inadequate imaging for determination of the tumour volume.

6.2. Physical quality assurance

(72) The physical aspects of dosimetry include checks of imaging for planning and treatment verification; target volume; computer planning system; information input, source strength, and dose modelling; QA of the treatment unit for accuracy of source position and dwell times; and the integrity of the applicators. New sources should be measured in a calibrated well chamber to verify the manufacturer’s reported activity.

6.3. Organisational quality assurance

(73) The procedures surrounding patients (identification, communication by closed circuit television and audio equipment etc.) and documentation of organisational forms (treatment prescription and recording, misadministration recording) need to be performed in a rigorous manner (FAO et al., 1996; IAEA, 2001; Kutcher et al., 1994).

6.4. Specific quality assurance related to HDR units

(74) Computer-controlled microsource HDR afterloaders require the radioactive source to be changed three or four times per year because of the relatively short half-life of $^{192}$Ir (74 days) and concern over the integrity of the weld connecting the source to the drive cable.
6.5. Special requirements for interstitial brachytherapy

(75) All systems of treatment application should be closed at the end of source travel. This is to prevent the inadvertent egress of the source outside the applicator or entry of contaminants into the source path.
7. EXPOSURES, EVENTS, AND ACCIDENTS

(76) Many radiation events have been reported since the introduction of HDR brachytherapy technology (NRC, 2002). Generally, it is thought that under-reporting of all radiation accidents has been common. As HDR brachytherapy delivers a very high dose in seconds and a mistake in an individual fraction cannot be easily rectified, a very high standard of QA is mandatory.

(77) The events have different origins:

- the handling and transport of the sources;
- inadequate shielding;
- sources in transit (sources remaining in the safe, in the patient, or along the transfer tubes);
- treatments given to wrong patients; and
- incorrectly prescribed or delivered doses, or repeated treatments to the same patient.

(78) Failure of radiation oncologists, medical physicists, and technical staff to adhere to a strict QA programme can lead to unacceptable rates of adverse events. With stricter adherence to reporting criteria, the list would probably be longer.

7.1. Events related to packing and transport

(79) When sources are replaced, they are returned to the producer. Thus each source is transported twice. Due to the number of sources involved (more than 5000 a year) and their high activity, special care has to be taken at every step. Each year, 10,000 source shipments occur. Sources should be installed properly and secured adequately in the shielded position for transport, and international regulations apply. Events due to non-compliance have resulted in accidental damage to the container and unnecessary exposures of the driver, handling operator, administrators, and the public. Accidents may also arise from intentional actions, such as theft of the vehicle with the radiation sources. Illustrative cases are given in Appendix A.

7.2. Exposures to personnel and the public

(80) Events related to source exchange resulting in exposure to people involved in the operation have been reported, and include backward connection of the transfer guide. Public exposure in a waiting area in the second floor above the bunker has been reported as a consequence of flaws in the bunker design.

7.3. Events during operation

(81) Analysis of event reports show that more events, such as misadministrations and/or accidents, occur during actual operation of the machine. Some are related to mechanical problems but the majority are due to human error.
7.3.1. Reported mechanical and computer events

(82) The reported mechanical events are related to the HDR control unit, the computer, the source cable, the catheter, and the applicators. The following are selected examples of mechanical events.

- Loss of power to the control unit stopped its operation, which necessitated manual means to interrupt the treatment.
- During treatment, the stop button in the console did not retract the wire source.
- Power failure with subsequent failure of the computerised security program, which allowed incorrect calculation after wrong data entry.
- The source cable either became disconnected or kinked or the interlock failed and the source stayed in the exposure position with resultant clinical consequences. Also, premature and abrupt termination of treatment has been reported.
- Displaced/dislodged applicators have resulted in thigh irradiation when vaginal treatment was intended; during treatment of lung cancer, another unrelated lung area was treated.
- Blood contaminating the source tube and the source during use of open-ended catheters. The use of these catheters is at variance with the recommendation that only closed systems should be used.

7.3.2. Reported human errors

(83) Human errors include incorrect medical indication, patient identification, diagnosis or area of treatment, prescription, data entry, catheter, or applicator. There are reports in which failure to identify the patient properly resulted in delivery of an incorrect treatment; for example, a patient with nasopharyngeal cancer received treatment on the lip with a lip mould.

(84) There have been instances where the correctly identified patient has received the prescribed treatment in an incorrect location. For example, a patient with uterine cancer received treatment with the correct applicator, but to the vulva because the default distance from the end was entered in millimetres instead of centimetres. Similarly, a patient with oesophageal cancer received gastric irradiation because the tube extended into the stomach as a result of an incorrect default entry. A second error that may have a similar result is incorrect entry of the overall delivery tube length. A patient designated for bronchus treatment with a 150-cm tube received irradiation to his cheek when a 120-cm tube was used. A recommendation that would help to minimise this occurrence would be to keep all tubes outside the body as distant as possible from the patient's skin; for example, in the previous example, the tubes were placed parallel to the cheek. Had the tubes been distant from the cheek, the patient would not have received the dose. Manual insertion of a homemade test wire with a mark at the programmed treatment length before each treatment is a recommendable practise to avoid these mistakes.

(85) There are reports of patients receiving double doses because of a change in personnel, with the first group finishing treatment to a patient and the next shift
repeating the treatment. Patients have received an increased dose because of failure to immediately calibrate a replacement source, receiving therapy using dwell times based on a 161-GBq source that had been replaced by a 355-GBq source.

(86) In the reported cases, many errors were part of fractionated treatment. As such, these errors are seldom fatal and may be compensated for by eliminating one of the fractions or adjusting the subsequent doses per fraction.

(87) Errors have been reported in dwell time programming, either by introducing the data inversely or by programming the steps incorrectly, e.g. in 10-mm steps instead of 5-mm steps. In these cases, the doses needed to be adjusted. It is recommended that the step size in a particular centre should be kept constant (e.g. 5 mm) for all treatments in order to avoid errors of incorrect step size. Cases have been described in which a treatment was delivered even though discrepancies in dose and distribution had not been resolved by the staff because of patient discomfort.

(88) Only one reported death is on record related to administration of HDR brachytherapy. The patient had received pelvic teletherapy for anorectal cancer. She had flexible tubes inserted transperineally to the anorectal region for an interstitial implant. One of the planned treatments was aborted because of source transfer ‘problems’. The patient was returned to the nursing home and did not re-attend. A flexible tube fell from the patient 4 days later and was placed in a waste container. The patient died the subsequent day. After the source was noted to be missing, it was tracked through the patient to the waste incinerator. This case is further described in Chapter 8 as the most severe case, but for its characteristics, we can consider it as an event that illustrates equipment, human, and organisational errors. The failure of the weld between the transfer wire and the source was the initial precipitating event. Subsequently, the staff ignored the machine and room radiation monitors that registered the failure of return of the source to the safe, and the external monitors that identified residual radiation after treatment. These external monitors had malfunctioned previously but had not been repaired or replaced. The staff had failed to monitor the patient for radiation emission after treatment.
8. EXAMPLES OF REPORTED EVENTS

(89) Even though it is estimated that accidents or events are greatly under-reported, more than 500 HDR events have been recorded. For illustration, a few examples are described. The most frequent cause is human error. Malfunctions of hardware and errors by software applications have also been reported, as well as defective parts or maintenance, problems in transport and handling, and even problems in building. The reports given below may appear incomplete but provide the information almost verbatim from the official government accident reports.

8.1. The most severe case

(90) The licensee performed an interstitial HDR treatment for anorectal cancer at one of its regional treatment centres. The treatment was terminated early because of the inability to get the source into one of the treatment catheters. The patient was sent back to her nursing home where she died 5 days later. The catheter containing the source had fallen out of the patient on the day prior to her death, and was disposed of in a biohazard waste container. The waste container was picked up by a commercial medical waste disposal company 5 days later and taken to an incinerator where the radiation was detected. The entire shipment was returned to the waste disposal company. The disposal company performed a search of the waste and notified the treatment centre that radioactive material had been picked up at the nursing home. The treatment centre retrieved the source and reported the loss. An investigation was initiated.

8.2. Transport and package

8.2.1. Source placed outside the transport safe and not secured

(91) The licensee reported a transportation event involving a GammaMed source changer containing 185 GBq of $^{192}\text{Ir}$. The radiation level in one small area of the top surface of the package was 3.8 mSv/h. The level at 1 m from this surface was 30 μSv/h. Subsequently, the source was moved to its shielded position and radiation levels were reduced to normal levels. The GammaMed source changer (for transporting $^{192}\text{Ir}$ for HDR remote afterloaders) was prepared for shipment at the licensee’s facility. The package was then shipped on 14 March 1997. Prior to shipment, the package was surveyed and indicated $1 \times 10^{-8}$ C/kg/h at 1 m and $5.3 \times 10^{-7}$ C/kg/h or less on contact with the package.

8.2.2. Returned source not inserted in safe: failure to survey

(92) A shipping package containing a depleted $^{192}\text{Ir}$ HDR afterloader source was received by Omnitron from a shipper in South Korea. Radiation levels significantly exceeded permissible levels specified in Department of Transport regulations. The
package was one of two packages. Each package contained an $^{192}$Ir source in the form of a wire that had an activity of approximately 16,650 MBq, and a radiation level of 37 mSv/h at the surface and 1.4 mSv/h at 1 m from the side of the package. The source was not secured in the safe or completely shielded position. This suggests improper installation for shipment and failure to perform a proper survey. There was no indication of damage or any reason to suspect that the source had changed position during transport. The investigation determined that at least 32 people were probably exposed to excessive radiation from the package. The maximum dose received by an Alliance driver was 5.82 mSv, the maximum dose received by an American Crating employee was 46.13 mSv over a period of several hours, and the maximum dose received by a Federal Express driver was 0.84 mSv. Approximately 24 members of the public received exposures above the recommended requirements of 1 mSv/year.

8.2.3. Damage in transit

(93) A licensee reported that one of its HDR units had damage to its overpack when it fell off a conveyor during shipment. The unit was transported from the USA to Holland. The licensee sent a new overpack and the shipment continued.

8.3. Exposures to personnel and the public

8.3.1. Inadequate shielding of bunker

(94) During an inspection of the licensee’s new HDR afterloading facility, the inspector concluded that the facility’s shielding was inadequate in that the dose rate limit of 20 µSv/h for unrestricted areas was exceeded. With the Nucletron HDR unit’s 218-GBq $^{192}$Ir source exposed, radiation levels of 260 µSv/h were identified on the floor of the public waiting area above the facility. This was due to the contractor’s failure to install shielding over the facility’s ceiling vent. The licensee failed to determine that the shielding was missing prior to the initial operation of the facility. A review of the licensee’s records of facility usage indicated that the maximum likely unrestricted area dose was approximately 470 µSv/h. On 4 April 2000, the licensee reported that their medical physicist had placed temporary shielding over the ceiling vent. On 10 April 2000, the original contractor was called back for permanent installation of the missing shielding. Following installation of the shielding, survey results showed that no unrestricted area received more than 20 µSv/h.

8.3.2. Faulty connection from transport container to HDR safe

(95) The licensee reported that a radiological engineer received an extremity overexposure while performing a quarterly change of the source in a GammaMed III HDR unit. The engineer was transferring a 315-GBq $^{192}$Ir source from a shielded safe to an isotopen tecknik GammaMed II-I automated HDR afterloader, and inadvertently connected the transfer guide tube backwards. The engineer briefly
(0.25 s) touched the guide tube to return the source and received the overexposure. The root cause of the overexposure was that the engineer did not follow the established order of procedures for this task. The engineer received 1 mSv to the whole body, 21 mSv to the left thumb and index finger, and 419 mSv to the tip of the left index finger.

8.4. Mechanical events

8.4.1. Source cable separated from drive unit

(96) MDS Nordion in Kanata, Ontario, Canada issued a bulletin to notify all users of GammaMed models 12i and 12it HDR afterloader units of a defect in the GammaMed brachytherapy units. MDS Nordion had been notified of four incidents involving GammaMed HDR afterloader units in which the source cable became separated from the driving mechanism. In each of these incidents, the source remained in an exposed position, and required intervention to place the source in a shielded position. MDS Nordion investigated these incidents and concluded that the cause was attributable to a specific batch of cable used in the production of these sources by the source manufacturer. The source cable wire was not sufficiently stiff to resist looping when the source was being retracted to the shielded position, and became disengaged from the drive wheel assembly causing the $^{192}$Ir source to remain exposed. These sources had only been installed in the USA and Canada. Thirty-seven GammaMed HDR afterloader model 12i customers had source changes since April 1999 with the potentially defective source cable wire, which could affect the source drive mechanism. All affected customers were informed by telephone of the potential defect on 12 August 1999. MDS Nordion recommended that these afterloader units should not be used until the wire/source assembly was replaced. MDS Nordion worked with the source assembly manufacturer to expedite replacement.

8.4.2. Source stuck (unknown reason)

(97) A licensee reported that an HDR afterloader source had stuck in the extended position during phantom visual step indicator testing. The Gamma Med HDR (model 12i, serial #709) containing a 166.5-GBq $^{192}$Ir source was located in the radiation oncology 4-MeV vault. Three hospital staff entered the vault for approximately 1.5 min each in order to manually crank the source back into the stowed position. The Radiation Safety Officer estimated that the brief exposure time in the 2-mSv/h field resulted in a dose of approximately 0.05–0.1 mSv to each individual. Personnel film badges were processed to confirm this estimate. The service company dispatched a technician to return the source to the stowed position. This particular device was scheduled for a source change on 9 August 1999, but was completed on 6 August 1999. MDS Nordion issued a bulletin recommending that these afterloader units should not be used until the wire/source assembly was replaced.
8.4.3. Undersized transfer cable diameter

(98) A licensee reported that the GammaMed HDR afterloader unit $^{192}$Ir sources could not be retracted into their shielded position, and this problem was apparently due to the new wire shipment that they had received recently. The licensee decided to purchase their wire directly from the supplier instead of through the device manufacturer. The licensee received a wire that was 0.0762 mm smaller than 1.19 mm, but still within specifications. The licensee believed that this difference in wire diameter might have caused the wire to slip off the two wheels that protract and retract the source. The manufacturer recommended that these afterloader units should not be used until the wire/source assembly was replaced.

8.4.4. Treatment planning software error or human error

(99) A licensee reported a medical misadministration due to a problem with treatment planning software (TCS Version 1.20 upgrade) provided by Nucletron. A patient being treated for vaginal cancer was prescribed a dose of 4500 cGy (rad) by EBRT and 1000 cGy (rad) by an HDR afterloader (Nucletron MicroSelectron HDR, V2) with a sealed source containing 37.0 GBq of $^{192}$Ir. However, due to a problem with the treatment software, the patient also received a dose of approximately 2.4 Gy to a site outside the treatment area. The patient did receive the prescribed dose of 45 Gy by EBRT and 9.6 Gy of the prescribed 10 Gy by the HDR remote afterloader to the correct treatment site. The licensee will not administer the remaining 0.4 Gy of treatment to the patient. The treatment planning software error created an unexpected step size change in the treatment parameters. The patient and referring physician were informed of the misadministration. The licensee notified the software vendor of the anomaly and modified its procedures to require a pretreatment check that includes step size. All individuals who enter treatment data manually will be made aware of the defect and told to confirm their entries visually prior to printing the pretreatment report. The sequence of events leading to this misadministration began with the licensee encountering difficulty in electronically transferring the treatment plan for this patient from its Nucletron treatment planning system to their Nucletron MicroSelectron HDR treatment system. After several unsuccessful attempts at transferring the patient’s treatment plan to the treatment system electronically, the licensee elected to enter the treatment plan manually into the treatment system’s control station. This was accomplished without apparent difficulty. While making the required manual entry changes to edit the source dwell times, the keystrokes used in completing the data entry field changes caused the source step size to change from 2.5 mm to 10 mm. The licensee did not notice this change and the patient was treated using the incorrect step size. The licensee attributes this unintended and unnoticed change in step size to a software problem. However, had the licensee reviewed the complete final treatment plan properly, this misadministration could have been prevented. The review of the preliminary inspection information related to this misadministration indicated that there were two software problems that contributed to this event; one with the Nucletron Plato treatment system.
planning system, and one with the MicroSelectron HDR treatment control station. The MicroSelectron HDR treatment system problem was that unintended and unnoticed changes to the source step size could be made while editing an unrelated parameter. A service engineer investigated the cause of the transfer problem and found it to result from an undocumented limitation on the maximum number of combined patient and applicator points that could be transferred. Licensee corrective actions were as follows: (1) pretreatment procedures have been modified to include a check of treatment computer system step size after data entry; and (2) the brachytherapy quality management programme has been revised.

8.4.5. Kink in the applicator (needle)

(100) A licensee reported a misadministration of a dose that was greater than prescribed. At the end of an interstitial treatment, the source wire failed to retract to the shielded storage position. Members of the medical staff followed appropriate emergency procedures for removal of the needle containing the source wire from the patient. Once the source was outside the patient’s body, the Omnitron retracted the source to the shielded position. As a result of the incident, the dose in one treatment position was 17.3 Gy compared with the prescribed dose of 10 Gy (73.2% overdose), and another location received a dose of approximately 14 Gy compared with the prescribed 10 Gy (40% overdose).

(101) The licensee believed that the retraction failure was caused by a kink in the Omnitron needle through which the source travelled. The Omnitron needle had been inserted through a biopsy needle in the patient. A sudden movement by the patient apparently caused a kink at the interface between the Omnitron needle and the biopsy needle, and prevented the source from retracting. When the biopsy needle and the Omnitron needle were withdrawn, the pressure on the kink in the Omnitron needle was lessened somewhat, allowing the source to return to the storage position. There were no reported adverse effects to the patient from the misadministration.

8.4.6. Failure of retraction system

(102) A remote afterloading brachytherapy source failed to retract after a treatment. A technician was called in and corrected a problem with the take-up reel and the pressure regulator. The take-up reel was replaced.

8.4.7. Loss of connection between control panel and HDR unit

(103) A licensee reported a potential defect with a Nucleotron HDR MicroSelectron brachytherapy unit. While treating a patient, the unit malfunctioned when a technician bumped the table upon which the control unit was placed. The control unit temporarily lost communication with the remote afterloader unit. The source immediately retracted into the shield position, aborting the treatment. However, when the treatment tape was reviewed, the source dwell time had not been printed.
The medical physicist had been monitoring the console and was able to determine the dwell time by other means.

### 8.4.8. Optical interlock

(104) A licensee reported a defective treatment head of a Microselectron HDR unit manufactured by Nucletron-Odelft. During a Nuclear Regulatory Commission (NRC) Region I inspection, the inspector requested that the licensee file a report following the criteria of the US Code of Federal Regulations (CFR), specifically 10 CFR Part 21. The defect involved the failure of the treatment head to prevent the check source and the HDR source from driving past the optical interlock when no applicator was connected to the unit. The incident occurred during machine warm-up. There were no injuries to either patients or staff. A service call was placed to Nucletron. Later in the day of the event, a service engineer from Nucletron visited the licensee’s site. The problem could not be reproduced nor has it occurred since.

### 8.4.9. Open-ended source carrier

(105) A licensee reported that during treatment with a Nucletron HDR unit (model V2), blood and body fluids were seen leaking from the source exposure head after the HDR source had been retracted. Further examination of the patient indicated that an open catheter system had been used instead of the approved closed-end catheter. This resulted in fluids back-filling into the head of the Nucletron unit. The contaminated unit had to be returned to Nucletron in Holland. An investigation into this incident is ongoing.

### 8.5. Human errors

#### 8.5.1. Wrong patient: identification problem

(106) The licensee reported a brachytherapy misadministration involving dose to the wrong site. A patient was to receive brachytherapy treatment to his nose. The computer-controlled afterloader was loaded with treatment information for another patient. The medical physicist failed to check the patient’s identity and assumed that the packet corresponded to the patient. The patient received 73 rads to his lips instead of his nose. The licensee has stated that, in the future, no exceptions will be made to the training required for HDR unit users.

(107) It should be mentioned that the NRC requires all patients to be identified before treatment. We recommend that it should be done by at least two methods, e.g. verbal, bracelet, photograph, birth date, etc.

#### 8.5.2. Reverse order of entry of dwell positions

(108) A licensee reported a medical event involving a dose to an unintended area of a patient who had undergone HDR brachytherapy treatment for cervical
cancer. The treatment was performed using a GammaMed HDR (model 12I) and a tandem and ovoid applicator. The licensee discovered the error during a review of the patient’s treatment plan late on the day of treatment. However, the licensee did not determine that a reportable medical event had occurred until further review of the incident the following day. The licensee conducted an investigation and determined that the radiation sources remained in the patient at the wrong locations because the positions were entered into the treatment plan in reverse order and neither the radiation oncologist nor the medical physicist caught the error. As a result, the licensee’s treatment planning system calculated and optimised the treatment time for each of the source stopping positions in error, in that the correlation between the calculated treatment time and the dwell positions (X, Y, and Z co-ordinates) were not in accordance with the actual set-up of the applicator in the patient. The error also involved the offset of the treatment positions by 2 cm for the central tandem. The licensee determined that the dimensions of the treated volume varied from those of the prescribed volume in thickness, width, and length by 2 mm, 2 mm, and 12 mm, respectively. This resulted in the patient receiving an 8.0-Gy dose instead of the prescribed 5.0-Gy dose to the prescription point. The cause of the event was operator error during the digitisation of film data. In addition, the established second check procedures were inadequate to catch the error. A contributory cause was that the software in the treatment planning system is confusing and non-robust. Licensee corrective actions included: (1) modifying the annual retraining outline for radiation oncologists and medical physicists to include a discussion of the error for all future training; (2) modifying the procedure for the second physicist check to address the error; and (3) modifying the procedures for the physician check to address the error.

8.5.3. Inadequate default position for start of dwell sites

(109) The licensee reported a medical misadministration in which a patient being treated for cancer of the oesophagus received a radiation dose to an unintended area of the oesophagus during the first of two treatments using an HDR afterloading treatment device. The Isotope-Technik GammaMed (model IIi) afterloader containing a 0.37-TBq $^{192}$Ir source was not programmed properly; a 60-mm skip was not entered into the unit, causing the device to start the treatment 60 mm beyond the intended location. As a result, a 60-mm length of the oesophagus received an unintended 5.0-Gy dose, and only the lower 4 cm of the originally intended 10-cm length of the mid-oesophagus received the planned 5.0-Gy HDR treatment. The patient and the referring physician were notified of the event by telephone on 24 September 1999. The licensee intended to compensate for the underdose during the second treatment in the series. A medical consultant was contracted by the NRC to perform a review of the medical consequences of the misadministration. The root cause of the misadministration was the licensee’s failure to ensure that individuals operating the HDR unit were trained effectively and were knowledgeable about the operating parameters and set-up. Contributing to the event was the licensee’s policy of not verifying HDR programmed parameters against the
approved HDR planning and treatment record. To prevent recurrence, the licensee:
(1) revised the instructions for HDR safety checks to include a skip treatment; (2) revised the instructions for the monthly HDR QA test to include a required mock programme to provide for a skip treatment; (3) issued a memorandum of instructions on keying in skip treatments on the HDR unit; (4) revised the HDR treatment and planning record; (5) revised the instructions for two-way patient identification; and (6) revised the Quality Management Programme to include the use of pretreatment information to verify that the information agrees with both the console and the treatment record.

8.5.4. Kink in catheter

(110) A licensee reported a brachytherapy misadministration involving dose to the wrong site. A sharp curve caused an HDR source to become lodged in the catheter, resulting in a portion of the trachea instead of the bronchi receiving a high dose.

8.5.5. Dwell position error

(111) The licensee reported a brachytherapy medical misadministration. A patient with cancer of the vagina was prescribed treatment with an HDR remote afterloader brachytherapy unit using a $^{192}$Ir source. The treatment plan specified seven source or dwell positions within the treatment site. Before the first treatment, all but one of the correct treatment parameters were entered. The treatment plan called for a step length of 2.5 mm, but a 5-mm step length was entered. When the step length was altered to the longer length, the length of the treatment volume was also longer. Therefore, the dose that was delivered was less than the prescribed dose. The first dwell position was actually located outside the treatment site while being in the cylinder. However, it was located 1’ from the patient’s perineum, which may have resulted in the patient possibly receiving a maximum dose of approximately 5 Gy to the skin at the thighs. The licensee and an NRC consultant do not expect any adverse effects to the patient. The licensee re-ran the treatment plan for that fraction and retreated the patient with the prescribed dose of 5 Gy +/- 5%. The licensee has determined that an inadequate procedure to transcribe the treatment parameters resulted in the misadministration. The medical physicist verified the accuracy of all the treatment parameters on the work sheet. However, the work sheet did not include the step length. The step length that had been used routinely in previous treatments was entered into the console inadvertently by the medical physicist. The error was noticed after treatment had commenced, when the dosimetrist verified the transcription on the treatment tape.

8.5.6. Wrong catheter

(112) A licensee reported a therapeutic misadministration to the wrong treatment site. The female patient was being treated with an HDR afterloading device
containing 0.13 TBq of $^{192}$Ir. On the day of the event, the patient had a catheter in the urethra for the HDR treatment, and a second catheter in the bladder for an unrelated medical procedure. The physician reportedly reviewed the films during the trial run for the treatment and determined that the HDR catheter was placed properly. The treatment was delivered. While removing the source, the licensee discovered that the HDR unit had been placed in the bladder catheter, which delivered the dose to the bladder, i.e. the wrong treatment site. This treatment was one of multiple treatments intended to deliver a total dose of 30 Gy. The patient was retreated at the correct site the same day. The licensee reportedly informed the physician and the patient of the misadministration.

8.5.7. Catheter of wrong length

(113) A patient received an unprescribed dose of 0.9–1.3 Gy to the right cheek due to the use of an incorrect sized catheter with a brachytherapy device. The patient was prescribed to receive a two-part radiation therapy to the bronchus of 120 Gy (6 Gy/treatment) using an Omnitron HDR unit with a 170-GBq $^{192}$Ir source. The source was to be placed using a 150.25-cm-long catheter, but a 125.25-cm catheter was used instead. The patient’s right eye also received a dose of 0.35–0.45 Gy. The physician notified the patient of the misadministration, which was caused by human error. The wrong catheter length was entered into the HDR’s computer treatment planning software. To prevent recurrence, the licensee added redundancy to its internal checklists to verify that the correct catheter length is entered in the HDR’s computer treatment software.

8.5.8. Wrong orifice

(114) A licensee reported a brachytherapy misadministration involving dose to the wrong site. The mistake was made while inserting the afterloader applicator in preparation for an HDR treatment. Patient discomfort and movement resulted in the applicator being inserted in the rectum instead of the vagina. The resulting dose to the vagina was half of that prescribed. The misadministration was discovered upon termination of treatment.

8.5.9. Wrong transfer tube

(115) A licensee reported to the state that eight patients, who received a total of 22 treatments, had received dose to parts of their bodies that were not scheduled to be treated. All patients were receiving gynaecological treatments as a boost treatment from a Nucletron Microselectron HDR remote afterloading brachytherapy unit using a 300-GBq $^{192}$Ir sealed source after receiving EBRT. The misadministration was caused by the use of a 1.5-m obstetrics/gynaecology
transfer tube/applicator combination length instead of a 1-m length. Seven of the eight patients were treated with a single transfer tube with an average dose per treatment of 36 mGy. The doses were administered approximately 50 cm from the intended site, outside of the patients’ bodies approximately 30–34 cm from the patients’ knee area. The licensee reported that no physical effects were observed or expected in these patients. The remaining patient was treated with four catheters and one transfer tube per treatment. Since the transfer tube used to treat the vaginal vault was longer than the four shorter catheters used to treat the interstitial tissues, the transfer tube was looped over the patient’s knee for comfort. This patient developed skin erythema around the knee area from a calculated dose of 40–60 Gy.

8.5.10. Failure to re-calibrate

(116) A licensee reported a brachytherapy misadministration involving a dose that was greater than prescribed. A 161-GBq $^{192}$Ir source in an HDR device was replaced with a 355-GBq $^{192}$Ir source, and a treatment was administered before re-calibration occurred, resulting in excess dose. The treatment called for 12 Gy to be delivered in two fractionated doses of 6 Gy. Instead, approximately 12.1 Gy was given in one dose. A state inspector is on site and a full investigation will be conducted by the state. To prevent recurrence, the licensee will enter the activity value of the new source at the time of source exchange into the console of the HDR treatment unit, and the treatment unit has been placarded with a warning. The patient was told that he had received approximately twice the amount of radiation that the physician had intended with his first treatment, and he would not receive a second treatment. Instead, an endoscopic examination would be performed to evaluate the effect. It was the physician’s expectation that there would be no adverse effects.

8.5.11. Dislodged applicator

(117) A licensee’s consulting medical physicist informed the NRC of a misadministration involving an HDR remote afterloading unit. Further discussion with the licensee indicated that a vaginal treatment of a patient with an HDR afterloader with an $^{192}$Ir source planned for 15 Gy (three fractions of 5 Gy) started early in March 1996. The licensee reported that on 12 March 1996, during the administration of the third treatment fraction, the vaginal applicator with the iridium source was dislodged from the treatment site and irradiated the patient’s inner thigh. The licensee reported that the patient called the hospital and complained about skin reddening and irritation of her inner thigh. The patient was examined by the prescribing physician and the licensee determined that approximately 4.4 Gy was delivered to the patient’s inner thigh when the source was dislodged.
9. RECOMMENDATIONS

9.1. General recommendations

- A written comprehensive QA programme is essential.
- Compliance with QA procedures will contribute to minimising the occurrence of errors, both in number and magnitude.
- While not necessarily required by regulation, a hospital radiation safety committee (QA committee) needs to exist and interact with regulatory and health authorities.
- Maintenance is an indispensable component of QA.
- External audits of procedures re-inforce good and safe practice, and identify potential causes of errors.
- All significant steps from prescription to final delivery of treatment should be checked and verified by a second competent person. The objective is to ensure that the correct patient receives the correct dose at the correct site.
- Peer review of each case improves quality.
- Every incident or accident should be reported as required to the appropriate authority.

9.2. Specific recommendations

- Training at a centre with experience in HDR brachytherapy should commence prior to machine acquisition and should include the specific techniques to be used.
- Training should be directed towards ensuring a team approach involving a radiation oncologist, a medical physicist, a technician, and a nurse.
- Training and introduction of techniques should be sequential, commencing with simpler techniques before attempting more complex activities (e.g. multiplane flexible implant is not the way to start!). Fixed geometry applicators and implants are less likely to result in errors.
- Transport regulations should be adhered to. On site, the container should be inspected for damage. Removal of the old source, its transfer to the container, and installation of the new source into the safe should be performed by a factory-trained and -certified operator.
- New sources should be measured in a calibrated well chamber to verify the manufacturer’s reported activity, and the results should be entered into the software immediately. At this time, it is advisable to do a full commissioning (physics and mechanical QA checks).
- All delivery systems (catheters, needles, and fine tubes) should be closed ended.
- Manual insertion of a test wire (check cable) clearly marked at the programmed treatment length is recommended before each treatment to ensure that the total length of the transfer tube plus applicator equals the programmed treatment length. A manual check cable also helps to identify any kinks or obstruction in the catheter or transfer tube.
It is recommended that the step size in a particular centre should be kept constant (e.g., 5 mm) for all treatments to avoid errors of using the incorrect step size.

- Keeping all tubes outside of the body as far as possible from the patient's skin will help to minimise unintended doses.
- A dedicated self-contained brachytherapy suite housing all requirements is highly advisable. It is very important to make sure that the room shielding is adequate.
- Applicator positioning should be verified before each treatment. For this reason, a C-arm is considered to be an indispensable part of an HDR suite.
- So-called ‘false alarms’ and interlock ‘failures’ should be investigated thoroughly and appropriate action should be taken. Failure to do so may encourage the staff to ignore valid alarm signals.
- Survey of the patient by a portable radiation monitor is essential after each treatment.
- An emergency plan should be prepared and practiced with commencement of operations. A list of emergency procedures (both medical and radiation) should be displayed prominently within the suite. All necessary emergency equipment items should be readily available. Training for all personnel should be repeated regularly, especially when new personnel are introduced to the team.
- The person responsible for performing an emergency procedure should remain in the brachytherapy suite during the entire treatment. In some countries, it is a requirement that both a clinician and a physicist remain.
- One should be alert to the possibility of theft of an HDR source for use as a weapon (‘dirty bomb’) for nuclear terrorism. The HDR machine and source should be kept secure at all times, and particular attention should be paid if the facility or machine is decommissioned to prevent the source from ending up in a junk yard or included in scrap metal.
APPENDIX A. CLINICAL INDICATIONS

A.1. Cervical cancer

(A1) The incidence of cervical cancer in most developing countries is high, often exceeding 30/100,000. Gynaecological brachytherapy can account for up to 100% of the brachytherapy practice in some developing countries. Due to the anatomy and short treatment times needed, coupled with no requirement for anaesthesia nor a full surgical operating room, HDR machines are capable of treating large numbers of patients. Implementation of HDR should therefore be considered for developing countries with a high incidence of this disease.

(A2) EBRT and HDR brachytherapy are commonly integrated in the treatment of cervical cancer, with HDR brachytherapy beginning after about 2 weeks (20 Gy) of EBRT. Typically, the brachytherapy is performed once a week, while pelvic EBRT is continued (with a midline block in some centres) to about 40–50 Gy. Microsource HDR brachytherapy uses narrow applicators that can be inserted on an outpatient basis under intravenous sedation or without sedation. General or spinal anaesthesia is generally not used since little or no dilation of the cervical os is required. A variety of HDR gynaecological applicators (Fletcher, Ring, etc.) are available. The HDR dose used (usually prescribed to point A) is dependent on the stage of the disease and the dose of EBRT used. The ratio of EBRT to brachytherapy is dependent on stage, with more emphasis being placed on EBRT for the more advanced stages, which are commonly seen in developing countries. Although there is marked variation in the dose and fractionation employed, most centres are comfortable using a schedule of approximately 5–8 Gy per weekly fraction and three to six fractions (the smaller number of fractions is used by those using larger doses per fraction). While recognising that many efficacious HDR fractionation schedules exist, the American Brachytherapy Society (ABS) suggestions for treatment of early- and advanced-stage cervical cancer are given as a guide (Nag et al., 1999a, 2000). It is emphasised that care should be taken to ensure adequate bladder and rectal packing, especially if a high dose (>7 Gy) per fraction is used. While HDR brachytherapy allows optimisation, incorrect optimisation can be worse than no optimisation at all. Hence it is suggested that institutions begin by using the standard treatment plans with rigid (fixed) geometry applicators and fractionation schemes that have been proven in places with experience.

(A3) Analysis of worldwide reviews (retrospective studies as well as prospective randomised clinical trials) suggests that LDR and HDR treatments are probably equivalent in terms of survival, local control, and morbidity (Arai et al., 1992; Fu and Phillips, 1990; Nag et al., 1999a, 2000; Orton, 1998; Petereit and Pearcey, 1999; Shigematsu et al., 1983; Teshima et al., 1993; Wakabayashi et al., 1971).
A.1.1. Carcinoma of the endometrium

(A4) HDR brachytherapy is commonly used for adjuvant treatment of the vaginal cuff after hysterectomy in patients at intermediate and high risk of vaginal recurrence (high grade, deep myometrial invasion, or advanced stage). Additionally, brachytherapy may be used for primary treatment in inoperable endometrial carcinoma and for treatment of recurrences after hysterectomy (Nag, 1994, 1997).

A.2. Oesophageal cancer

(A5) Oesophageal cancer is common in developing countries around the Caspian Sea (Turkmenistan, Kazakhstan, Uzbekistan, and Iran), Southern Africa (Malawi, South Africa, Lesotho, and Botswana), and parts of China and Mongolia. As most of these cases are advanced, the results of radical treatment are dismal (5-year survival = 6%); hence, treatment is essentially palliative for the majority of cases.

(A6) HDR brachytherapy has been used for the treatment of oesophageal cancer, either alone or in combination with EBRT (Flores et al., 1994; Gaspar et al., 1997; Levin et al., 1997; Peterson et al., 1996; Sur et al., 1996a,b, 1997, 2002). The sequence of combination of EBRT and HDR brachytherapy appears to be unimportant. The microHDR technique is relatively simple since a single-line catheter is used. The insertion is performed with sedation after surgical dilatation and biopsy. Treatment is usually given using a special oesophageal applicator via an intra-oral or a nasogastric approach. The largest diameter applicator that can be inserted easily should be used to minimise the dose to the mucosa and to improve the dose at depth. The site to be irradiated is confirmed by fluoroscopy with contrast. The length treated includes the tumour and a margin of 2–5 cm. The dose is prescribed at 1 cm from the source, and doses of 5–15 Gy/fraction have been given for one to four fractions (Peterson et al., 1996; Sur et al., 1996b, 1997). HDR brachytherapy can be given before, concurrently with, or after EBRT. The advantage of giving brachytherapy after EBRT is that a more uniform dose can be delivered to the residual tumour after it has been reduced by treatment. The advantage of giving brachytherapy initially is rapid relief of the major symptom, dysphagia.

A.3. Head and neck cancer

(A7) Head and neck cancer is a common problem in some developing countries (e.g. nasopharyngeal cancers in China, oral cancers in India). HDR brachytherapy may be used in selected cases to reduce radiation exposure and permit optimisation. However, these advantages are offset by the need for multiple fractions, especially since the head and neck area does not tolerate a high dose per fraction (Nag, 1994).

A.3.1. Nasopharynx

(A8) The nasopharynx is easily accessed by an intracavitary HDR applicator. In Rotterdam, doses of 18 Gy in six fractions are delivered by a special
two-channel nasopharynx applicator to boost 46–60 Gy of EBRT (Levendag et al., 1994).

A.4. Other interstitial or mould applications

(A9) The use of HDR brachytherapy catheters in removable dental moulds allows highly reproducible, repeated, fractionated, outpatient brachytherapy applications to superficial tumours (Jolly and Nag, 1992). Doses of about 15–20 Gy in three to five fractions can be delivered in this manner to boost 45–50 Gy EBRT.

(A10) Data on the use of HDR brachytherapy alone as salvage in tumours recurrent after EBRT are sparse. Doses of 50–55 Gy at 3 Gy/fraction have been used.

A.5. Lung cancer

(A11) In industrialised countries, the lung is probably the most common site of HDR brachytherapy, particularly microsource HDR brachytherapy, at the present time. This is not the case in developing countries, probably because of the relatively low incidence of lung cancer. Even with aggressive therapies, locoregional failure occurs in a significant number of patients. The use of HDR brachytherapy is well established for the palliation of haemoptysis, endobronchial obstruction recurrent after EBRT, or in combination with EBRT for palliation of metastatic lung cancers (Mehta et al., 1994; Sur et al., 1995). According to statistics for non-small-cell lung cancer, persistence or local relapse after standard EBRT occurs in 60% of patients. Endobronchial brachytherapy significantly improves the quality of life of these patients. A review of the literature shows palliation rates over 65%.

(A12) One or two catheters inserted through the working channel of a flexible bronchoscope are used. The dose and fractionation used vary widely, ranging from 15 Gy in one fraction to 4 Gy in five fractions (Sur et al., 1995). The ABS suggests using three weekly fractions of 7.5 Gy each, two fractions of 10 Gy each, or four fractions of 6 Gy each prescribed at 1.0 cm when HDR brachytherapy is used as the sole modality for palliation (Mehta et al., 1994). The benefits of fewer bronchoscopic procedures should be weighed.

A.6. Breast cancer

(A13) Breast cancer is the most common cancer in women of developed countries, and the standard treatment for early cases at the present time is conservative surgery followed by radiation. This is usually administered as a combination of EBRT and brachytherapy or electron beam therapy as a boost to the primary area (Clarke et al., 1994; Hennequin et al., 1999; Kuske et al., 1994, 1998; Manning et al., 2000; Nag and Orton, 1993; Perera et al., 1995, 1997; Polgar et al., 1999; Romestaing et al., 1997; Schmidt-Ullrich et al., 1993; Tessier et al., 1998).

(A14) New studies are being performed aiming to demonstrate that partial breast irradiation can be used in selected cases (e.g. HDR brachytherapy with the MammoSite applicator) to reduce the total duration of irradiation.
A.7. Prostate cancer

(C15) Currently, permanent implantation of $^{125}$I or $^{103}$Pd seeds is the most common type of prostate brachytherapy. However, several centres have used HDR brachytherapy, usually as a boost to EBRT (Borghede et al., 1997; Dinges et al., 1998; Kovacs and Galalae, 1997; Martinez et al., 2000, 2001; Mate et al., 1994, 1998; Rodriguez et al., 1999; Yoshioka et al., 2000), for the treatment of prostate cancer with encouraging results. One of the major advantages of HDR brachytherapy is that the dose distribution can be intra-operatively optimised by varying the dwell times at various dwell positions (Edmundson et al., 1995), potentially allowing reliable and reproducible delivery of the prescribed dose to the target volume while keeping the doses to normal structures (i.e. rectum, bladder, and urethra) within acceptable limits. Another potential advantage of HDR brachytherapy in prostate cancer is the theoretical consideration that prostate cancer cells behave like late reacting tissue with a low alpha–beta ratio and they should, therefore, respond more favourably to higher dose fractions than the lower dose rate delivered in LDR brachytherapy (Duchesne and Peters, 1999; Fowler et al., 2001).

(C16) Patients with stages T1b–T3b prostate cancers without evidence of distant metastases are candidates for HDR brachytherapy as a boost to EBRT. Patients with distant metastases, a life expectancy of less than 5 years, or those who are medically unfit for anaesthesia or in whom it is technically not feasible to implant the entire prostate should be excluded. Relative contra-indications include large gland size (>80 cc), recent transurethral resection of the prostate (TURP) within the previous 6 months, or large TURP defects, all of which increase the risk of urinary morbidity.

(C17) Standard fractionation EBRT (39.6–50.4 Gy) is given concurrent with, or within 2 weeks before or after, HDR brachytherapy. The minimum volume treated should include the entire prostate and seminal vesicles with a margin, with or without the pelvic lymph nodes.

(C18) The HDR brachytherapy dose is given in multiple fractions in one or two implant procedures. A variety of dose and fractionation schemes may be appropriate for same-stage disease. HDR fractions are generally given twice a day with a minimum of 6 h between fractions. The most commonly encountered acute genito-urinary morbidities include urinary irritative symptoms, haematuria, haematospermia, and/or urinary retention, similar to LDR permanent implants.

A.8. Soft tissue sarcomas

(C19) Excellent results are obtained with a combination of wide excision of the tumour and adjuvant EBRT. However, irradiation of large volumes after surgery gives rise to morbidity, especially normal tissue fibrosis. To minimise morbidity, a few centres have used LDR brachytherapy, either alone (Harrison et al., 1992) or with EBRT (Schray et al., 1990). A prospective randomised trial showed superior local control (80% at 5 years) in the group receiving brachytherapy compared with 62% in the group not receiving brachytherapy (Harrison et al., 1992). The major
problem with LDR brachytherapy of large volumes is the radiation exposure involved. Hence, a few centres are investigating the use of HDR brachytherapy for soft tissue sarcomas (Alekhteyar et al., 1994; Chuba et al., 1996; Crownover et al., 1997; Donath et al., 1993; Koizumi et al., 1999; Yoshida et al., 1996). HDR brachytherapy catheters are implanted along the tumour bed and radio-opaque clips indicate the margins. A 2–5-cm margin proximally and distally is used after gross excision of tumour. Optimised treatment planning can be used to deliver a more homogeneous dose. Doses of 40–50 Gy are given in 12–15 fractions if the HDR brachytherapy is given alone (Alekhteyar et al., 1994; Donath et al., 1993). If EBRT (45–50 Gy) is added, the brachytherapy dose is limited to 18–25 Gy in four to seven fractions (Nag et al., 1994). It is important to delay the start of brachytherapy for approximately 4–7 days to allow for wound healing. Nerve tolerance to high dose per fraction is poor, and HDR brachytherapy should be used with caution when catheters have to be placed in contact with neurovascular structures.

A.8.1. Soft tissue sarcomas in children

(A20) LDR brachytherapy has been used in children to reduce the deleterious effects of EBRT (Flamant et al., 1990; Fontanesi et al., 1991; Gerbaulet et al., 1989). However, LDR brachytherapy is difficult to perform in young children and infants because they require prolonged sedation and immobilisation with close monitoring, which increases the risk of radiation exposure to nursing staff and parents. HDR is therefore very appealing in infants and younger children, and is currently undergoing trials at Ohio State University (Nag et al., 1993, 1995, 1999b). The recommended dose for HDR brachytherapy as monotherapy is 36 Gy in 12 fractions given at 3 Gy (prescribed at 0.5 cm) twice a day (Nag et al., 1999b). The interval between fractions is at least 6 h. There are no published data giving any dose recommendations for HDR brachytherapy as a boost to EBRT. The linear-quadratic model (Nag et al., 1997a) can be used to calculate a fractionation scheme equivalent to that of an LDR implant boost dose of 15–25 Gy (prescribed at 0.5 cm). According to the Inter-group Rhabdomyosarcoma Study, the standard EBRT dose for paediatric soft tissue sarcomas is 40 Gy for microscopic disease and 50 Gy for gross disease. Intra-operative HDR brachytherapy allows a reduction in the dose of EBRT to 27–30 Gy so that concerns for impaired growth and organ function are greatly reduced (Nag et al., 1997b, 1999b, 2001). Although the long-term morbidity of HDR brachytherapy in young children is not fully known, one may expect preservation of organ functions similar to that seen with LDR brachytherapy (Flamant et al., 1990). Due to the complexities involved in paediatric HDR brachytherapy, it is recommended that its use in paediatric tumours should be limited to centres that have experience with paediatric implants.

A.9. Other sites

(A21) HDR brachytherapy has also been used to treat carcinoma of the vagina, bile duct, brain, skin, and rectum. The development of thin diameter sources allows
percutaneous interstitial brachytherapy through very thin needles (21 G). This may be of particular advantage for lip, nose, and eyelid tumours and for percutaneous, image-guided treatment of intrathoracic or intra-abdominal tumours.

A.10. Intra-operative use of HDR brachytherapy

(A22) One way to improve the therapeutic ratio of HDR brachytherapy is to deliver the irradiation during surgery while the patient is still anaesthetised. This technique (intra-operative HDR brachytherapy) allows radiosensitive normal tissues to be retracted or shielded during surgery, thus lowering the radiation dose to normal tissue (Perera et al., 1997). Additionally, since the irradiation is given under direct vision, the risk of a geographical miss is reduced. Maximum surgical debulking is performed in cases of advanced disease, and the brachytherapy is delivered to the micro- or macroscopic residual disease.
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