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PRACTICAL APPLICATION OF SUSPENSION CRITERIA SCENARIOS: RADIOTHERAPY

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In 2007 the European Commission (EC) commissioned a group of experts to undertake the revision of Report RP91 “Criteria for Acceptability of Radiological (including Radiotherapy) and Nuclear Medicine Installations” written in 1997. The revised draft report was submitted to the EC in 2010, who issued it for public consultation. The EC commissioned the same group of experts to consider the comments of the public consultation for further improvement of the revised report. The EC intends to publish the final report under its Radiation Report Series as RP162. This paper presents a selection of practical applications of suspension criteria scenarios in radiotherapy, mostly in brachytherapy, with special emphasis on the critical roles and responsibilities of qualified radiotherapy staff (radiation oncologists, medical physicists and radiotherapy technicians).

INTRODUCTION

Patient safety in general is a growing concern internationally. The European Commission published recommendations to improve patient safety in Europe in 2009⁽¹⁾. Among the key recommendations were establishing or strengthening reporting & learning systems and embedding patient safety in the education and training of healthcare workers. It was recognised that in the EU between 8 – 12% of the patients admitted to hospitals suffer harm from the health care they receive, and that much of that harm is preventable.

Safe treatment has always been recognised as the key issue in radiotherapy. To mention just two overviews, both from 2008, the World Health Organisation (WHO) published its “Radiotherapy Risk Profile”⁽²⁾, and in the UK the report “Towards Safer Radiotherapy”⁽³⁾ was published. The WHO states “There is a long history of documenting incidents and examining adverse events in radiotherapy. From the study of these incidents and the factors underlying them it has been possible to map the risks”, and further that “Radiotherapy is widely known to be one of the safest areas of modern medicine, yet, for some, this essential treatment can bring harm, personal tragedy and even death.” The UK document concludes that safe radiotherapy depends on

- an adequately trained professional workforce practising together in a multidisciplinary environment

- robust operational and management systems which facilitate safe and effective practice
- equipment which is designed with safety in mind and which is up to date and maintained to high standards.

The Medical Exposure Directive 97/43/EURATOM (MED)⁽⁴⁾ “on health protection of patients against the dangers of ionizing radiation in relation to medical exposure” establishes a number of measures to ensure that medical exposures are delivered under appropriate conditions. EU Member States must among other things ensure that “appropriate radiological equipment, practical techniques and ancillary equipment are used for the medical exposure”, that “appropriate quality assurance programmes including quality control measures” are in use, and that “specific criteria of acceptability to indicate when remedial action is necessary, including, if appropriate, taking the equipment out of service” are adopted.

Quality assurance (QA) in radiotherapy was for a long time purely “physics business”, related to the physical and technical aspects of equipment. Today, quality assurance in oncology is a comprehensive QA programme, a management system for the whole oncology process including radiotherapy; from the moment patients enter the department, until they leave, continuing into the follow-up period. The goal of the quality system is to guarantee to patients, and society, that each individual will receive the best available care for his disease.

A quality system (as defined in ISO 9001) defines the organisational structure, responsibilities, procedures, processes and resources (time, personnel,

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and capital investments) required for implementing QA. A quality system requires predefined quality standards, where local aims and standards of care must match local resources, manpower and expertise, as well as patterns of patient referral.

The MED requires that “all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices are taken, economic and social factors being taken into account”.

In 2007 the European Commission (EC) commissioned a group of experts to undertake the revision of Report RP91 “Criteria for Acceptability of Radiological (including Radiotherapy) and Nuclear Medicine Installations” written in 1997⁽⁵⁾. The revised draft report was submitted to the EC in 2010, who issued it for public consultation. The EC commissioned the same group of experts to consider the comments of the public consultation for further improvement of the revised report. The EC intends to publish the final report under its Radiation Report Series as RP162. The radiotherapy section of RP162 presents key parameters describing the performance of radiotherapy equipment and criteria of acceptability for these parameters; (see the paper “Introduction to suspension levels: Radiotherapy”). In clinical practice, it is common to use a remedial level (sometimes called “reaction level”) to follow, evaluate and maintain the performance of a piece of equipment. Thus, in an established quality system, planned remedial action is taken before the suspension level is reached.

This paper presents a selection of practical applications of suspension criteria scenarios in radiotherapy, mostly in brachytherapy, with special emphasis on the critical roles and responsibilities of qualified radiotherapy staff (radiation oncologists, medical physicists and radiotherapy technicians).

LINEAR ACCELERATORS

Three examples of practical applications of suspensions of linear accelerators from clinical use are given.

- (a) The field size on one linear accelerator increased slowly from day to day; this problem was caused by unstable electronic components on one circuit board. When the deviation reached the suspension level specified in the quality system, treatments with small field sizes were stopped until the field size was readjusted by the service personnel. The relevant patients were moved to another linear accelerator.
- (b) For one linear accelerator, one out of several electron energies changed due to faulty variations of the bending magnet current. The error was detected at the weekly depth dose measurements in a water phantom. The patients treated with this

specific electron energy were transferred for treatment on another linear accelerator until the problem was resolved.

- (c) The isocentre circle exceeded the specified suspension level during rotation of the gantry for one linear accelerator. The stereotactic patients were treated on a second linear accelerator until the error was corrected by mechanical readjustments of the gantry.

BRACHYTHERAPY

Intra-operative ultrasound-guided high dose rate interstitial temporal prostate brachytherapy

Event 1: Loss of power.

The patient is under anaesthesia during the whole procedure, which takes place in the high dose rate brachytherapy (HDR BT) treatment room: this includes patient positioning, positioning of ultrasound (US) equipment (stepper, US probe in rectum, template for needle insertion), 3D US imaging, target volume definition, treatment planning, needle insertion, needle position verification (ultrasound and fluoroscopy), interactive adaptation of treatment plan, acceptance of the definitive treatment plan and finally treatment using remote controlled after-loading technique (¹⁹²Ir source) (see Fig 1). Dedicated treatment planning software on a laptop computer is used for planning and the definitive treatment file is sent by network transfer to the after-loader control computer before treatment. The total time for treatment, including tests of all channels/needles before treatment, is 20-30 minutes, and the total radiation time 5-20 minutes. The anaesthetised patient is monitored during treatment from the operator’s room.

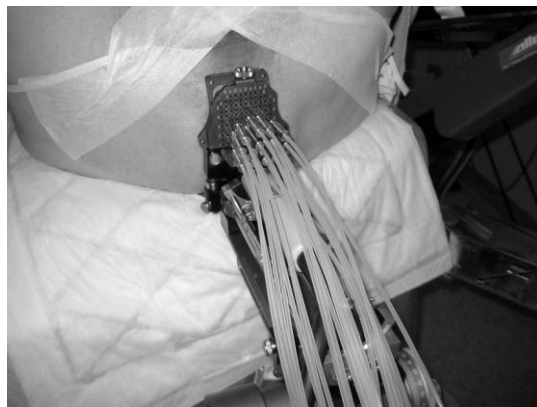


Figure 1. HDR interstitial prostate BT ready to start, showing the patient in the treatment position, the stepper with the US probe in place in the rectum, the template to guide needle insertion and the needles connected to the after-loader using source guide tubes

To ensure patient safety, the HDR BT after-loading treatment equipment as a whole was connected to a battery back-up system or uninterruptible power supply (UPS). The task of the UPS was to guarantee continuous power supply, in the event of central power loss (which has happened).

Halfway through this specific treatment “everything went black”. The whole system, the control computer, after-loader, printer, all powered via the UPS, had lost power. The experienced team, oncologist and medical physicist, were at hand as required. Primary physics checks confirmed that the source had retracted into the after-loader using its back-up battery (functionality check – part of QA) and the situation was “safe”.

As the patient was under anaesthesia, time was essential. To interrupt the treatment halfway through was not an acceptable clinical option; think first – act appropriately. A consultation between oncologist-physicist-anaesthesiologist resulted in the decision to extend the anaesthesia, fix the problem (physicist task), and finish the treatment. The control computer, after-loader, and printer were disconnected from the UPS and connected directly to the standard power network (extra time was required to replace all UPS specific connector plugs). The “system” was restarted and the treatment protocol recovered from the after-loader (recovery procedure correct – after-loader battery back-up functionality – part of QA), showing a correct recording of treatment already given (also verified by the oncology nurse). Decision of the oncologist-physicist: safe to restart and finish the treatment.

This type of event was not anticipated; loss of power due to “failure” of the UPS, the back-up battery system with the role of ensuring a continuous power supply. After discussions with an extended BT team, it was decided to permanently bypass the UPS.

- Problem: The power supply safety system failed.
The back-up battery of the UPS itself had not been replaced at the periodical maintenance as scheduled.
- Lessons learned: Periodic maintenance is essential, protocols must be followed.
An experienced treatment team is invaluable.
Thorough knowledge of the whole treatment process and the treatment equipment is of great value in dealing with unexpected situations.

Event 2: Applicator problem - needles.

This was a very large patient with a large prostate, requiring many needles close to each other with the needles pushed “all the way in”; only the connector

parts of the needles were outside the template. The standard procedure adopted requires that all needles are checked with the dummy source before the actual treatment starts, to ensure correct connections for all needles-channels. All channels were checked as correct and the treatment started.

However, during the actual treatment the dummy source stopped short in needle number 10 (9 needles had been treated) with an error message indicating that the dummy had stopped 185 mm before the end of the 200 mm long needle. The treatment was automatically interrupted with the source returning to the safe position. Both the oncologist and medical physicist were at hand as required. Inspection showed that needle number 10 had “kinked” due to strain where the connector was welded to the needle. To stop the treatment halfway through was not an acceptable clinical option; think first – act appropriately. The experienced oncologist-physicist team decided, after consultation also with the anaesthesiologist, to extend the anaesthesia and fix the problem with the broken needle in order to finish the treatment. The following procedure was adopted:

- (a) Disconnect and take out some needles already treated, especially needles close to needle 10
- (b) Disconnect and take out kinked needle 10
- (c) Insert a new needle 10
- (d) Verify correct needle positions with fluoroscopy and US – verification OK
- (e) Connect needle 10 and restart treatment

There was now no strain on needle 10, the treatment was restarted and finished as planned.

- Problem: The needle was too weak for the strain applied at the needle-connector junction.
- Lessons learned: “Needle strain” can be a problem. Use longer needles (not available at the time of the event) and try to avoid needles too close to each other.

An experienced treatment team is invaluable.

Thorough knowledge of the whole treatment process and the treatment equipment is of great value in dealing with unexpected situations.

Intra-operative ultrasound-guided low dose rate interstitial permanent prostate brachytherapy

The procedure for intra-operative ultrasound-guided low dose rate (LDR) interstitial permanent prostate BT is similar to the corresponding temporal procedure described above. Small ^{125}I seeds (30 – 100 seeds) are permanently implanted into the prostate using an interactive procedure and a dedicated treatment planning system. Once a seed has been implanted into the prostate, it cannot be removed and the only way to change a dose distribution is to add extra seeds.

It is of the greatest importance, and required by law in the EU ^(4, 6), to keep records of all sources, both of

their type, strength and location. Seeds are normally ordered specifically for each patient, with the number of seeds and seed strength depending on the size of the prostate. Source documents and source labelling must be checked and verified at delivery.

Written protocols for the implant procedure are required, in which the responsibilities of the members of the whole implant team are clearly defined. The overall aim is to perform an optimal implant for the patient, keeping track of all seeds used and not used. Seeds can get stuck in needles, seeds can be dropped, and all seeds must be accounted for before the implant procedure is finished.

Event 1: Incorrect sources delivered.

The incorrect source seeds, wrong strength and/or number, could be delivered. As a consequence, a patient implant could have to be suspended.

- Problem: Incorrect source delivery can and has happened
- Lessons learned: Keep a signed record of sources ordered (date, number and strength), source order verified (date) and sources received (date, number and strength), as well as a standard source inventory. Sources should not be delivered on the implant day

Event 2: Seed not accounted for during the implant procedure.

The accepted treatment plan for this patient required 78 seeds. When nominally 60 seeds should have been implanted, it was discovered that the number of “not implanted” seeds were 19 instead of 18, thus only 59 seeds instead of 60 were actually implanted at this stage of the procedure. This situation was verified with fluoroscopy. It was not at this point possible to reconstruct what had happened, and to determine which specific seed was missing; most probably a needle with 2 seeds had been implanted when a needle with 3 seeds should have been used. The detriment to the patient was determined as “minimal” by the oncologist; i.e. 77 seeds were implanted with 1 seed missing out of the 78 planned. No attempt was made to add the “undefined missing seed”.

- Problem: The standard procedure for performing an implant had not been followed.
- Lessons learned: Procedures/protocols are not enough – they have to be followed.

Event 3: Broken ultrasound probe.

The patient position in relation to the US probe must remain constant during the implant procedure, i.e. first for the imaging for treatment planning and

subsequently for the implant itself. This means that the patient must be immobilised for the entire procedure.

- Problem: The anaesthesia had not been deep enough and the patient moved, i.e. lifted his buttocks, in the middle of the implant. As the position of the US probe is fixed relative to the patient table (except for rotation and retraction), this movement of the patient caused the US probe to break. When the patient relaxed, the break in the probe closed. Stopping the implant halfway through was to be avoided, if possible. It was regarded safe to continue the implant procedure with the broken probe in the “closed position”. The US images were unaffected, and it was verified that the patient had regained his initial position. The implant procedure was finished according to plan. The probe was discarded after the implant.
- Lessons learned: The whole team must understand the requirements for a successful procedure. An experienced oncologist-physicist-anaesthetist team is invaluable.

Ring applicator for cervix cancer brachytherapy

The standard applicator used for HDR BT for cancer of the cervix was the ring applicator, a geometrically stable steel applicator available in several sizes and provided with plastic spacers. The applicator must be sterilised before each patient treatment and sterilisation has to be performed at the central Sterilisation Department. This department does not know or understand the requirements for applicators for BT.

When the physicist checked the verification films for treatment planning for this particular patient, it was noticed that the applicator was deformed; the angle of the ring part of the applicator had changed and the straight probe was no longer centred in the ring (see Fig 2).

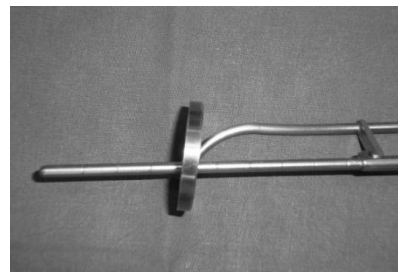


Figure 2. Geometrically stable steel ring applicator used for HDR BT for cancer of the cervix, without spacers. The applicator is deformed; the straight central probe should be at a right angle relative to the ring and centred.

This deformation of the applicator had not been noticed by the nurses preparing the BT procedure or by the oncologist, who unpacked the sterile applicator and verified correct applicator size and correct assembly of the ring and probe. Treatment with the deformed applicator, using the dose distribution planned for the non-deformed applicator (i.e. the source stop positions and dwell times), would have given a very different dose distribution, with both cold and hot spots in the target volume and organs at risk.

The procedure was stopped after a consultation between the oncologist and the physicist, and the applicator removed. Another applicator was selected, checked carefully, and the patient received her treatment.

In order to deform this steel applicator as shown, a considerable force must be applied. Just dropping the applicator does not change the configuration. What could have happened in the sterilisation department? Did someone drop the applicator, which was subsequently run over by a truck? No feedback was given to the BT department from the sterilisation department.

The applicator was discarded permanently from clinical use, but kept for educational purposes.

- Problem: Deformed applicator returned after sterilisation.
No information about the incident given to the BT department.
Deformed applicator inappropriate for clinical use..
- Lessons learned: Awareness is crucial.
Train your eyes to notice anything unusual.
Experience is invaluable.
Very unanticipated events can occur.

Verification of source strength – high dose rate brachytherapy

A dosimetry study was made in 2007 by the Swedish Secondary Standard Dosimetry Laboratory, SSI, in which all Swedish clinics with remote after-loading equipment participated (both HDR and pulsed dose rate (PDR) equipment with ^{192}Ir sources) ⁽⁷⁾. The study covered source strength measurements made independently at the hospitals over a number of years, measurements of reference air kerma rate (RAKR) following standard written protocols using the hospital equipment: calibrated well-type ion chambers, electrometers, thermometers and pressure gauges. Measurements were also made with the SSI equipment at each hospital. The results were overall acceptable. (Verification of source strength for all HDR/PDR sources is mandatory.)

Comparisons were further made between the source strengths as measured by the hospitals and as given on the source certificate by the vendors, and presented as “hospital/vendor” ratios of RAKR. This ratio has the

potential of showing changes in measurement protocols and calibrations at the hospital or vendor site, changes that would have been hidden in the uncertainty of the RAKR values themselves. The “hospital/vendor” RAKR ratios were found to be mostly around unity to within $\pm 1.5\%$, but some larger deviations were found. As an example of such a deviation, it was found that the RAKR ratio for a certain source type decreased steadily over a period of time. When the deviation reached the value -3% the source vendor was contacted. It was established, that the reason for the deviation was an erroneous pressure gauge at the vendor site.

- Problem 1: Increasing deviation in “hospital/vendor” RAKR ratio. Vendor contacted; pressure gauge problems identified.
- Lessons learned 1: It is useful to follow RAKR ratios; they provide a way of detecting problems with equipment or measurement techniques at the hospital or at the vendor site.
- Problem 2: A 5 % too high RAKR value measured for one source. Vendor contacted.
- Lessons learned 2: Use your established protocol for specifying source strength in your treatment planning system.

Dosimetry equipment – brachytherapy

Education and practical training is part of the programme at a university hospital, and students are allowed to use clinical radiotherapy equipment for their studies under the supervision of experienced clinical staff. Extra provisions must be taken when clinical equipment is used for education and training.

The standard dosimetry equipment for determination of BT source strength is the well-type chamber, used for both ^{192}Ir after-loading sources and for ^{125}I seeds for permanent implants. At Lund University Hospital a second dosimetry system, based on standard thimble chambers, is also used for the ^{192}Ir sources. The two dosimetry systems are calibrated independently. Both systems are used for source strength verification for all ^{192}Ir sources, giving extra security to source strength verification. Both systems are also used in education and training.

The clinical HDR well-type chamber was accidentally dropped during a HDR source exchange, and had to be taken out of use and replaced. The independent thimble chamber system was intact, and the source strength verification could proceed without delay. The dropped well-type chamber was later tested, and no noticeable changes in dosimetric characteristics were actually found. This chamber was specifically dedicated to student exercises, to be used also as an extra back-up. (A special thimble chamber was also dedicated to student exercises.) When LDR BT with permanent ^{125}I seed implants started, a new well-type

chamber was acquired dedicated to ^{125}I seed strength verification. Both clinical well-type chambers are today calibrated for all types of BT sources used, and cross-calibrated with the student chamber.

- Problem: Loss of the well-type chamber.
- Lessons learned: Back-up systems are valuable.
Two independent systems give extra security in source strength determination.

CONCLUSIONS

As long as people are involved in delivering patient care, mistakes will never be eliminated. Today, safety and value have become the “watchwords of accountability” in health care.

Most recommendations for quality systems in radiotherapy focus on QA and equipment operation, and equipment failure and inadequate equipment design have been central in some very high profile events. But, it is also recognised, that most radiotherapy events result from human performance failures rather than equipment failures.

Hospital administrators and heads of radiation therapy departments should be aware of the importance of a strong safety culture⁽⁸⁾, and provide a work environment that encourages “working with awareness”, maintains concentration and avoids distraction. This also includes an attitude of learning from experience, including systematic reporting of near misses and unexpected events in order to find weak points before an accident occurs. Examples of publications on accident prevention and lessons to be learned are the reports from ICRP⁽⁹⁻¹³⁾ and IAEA^(8, 14).

RP 162 is designed to help ensure patient safety by providing objective test criteria which radiological equipment in its normal use should be able to pass. The scenarios presented in this paper also indicate the importance of the experienced radiotherapy team, being able to handle unanticipated situations.

It is in the nature of all QA recommendations that they remain incomplete at any point in time and need to be continually updated. The traditional prescriptive device orientated approach is still valid and valuable for “current technologies”, but new approaches must be developed for “developing technologies”⁽¹⁵⁾. These new approaches should be risk- and evidence-based, process-oriented, resource- and risk-optimised and flexible.

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