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The Need for Quality Control in High Dose Rate Brachytherapy

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1. Introduction

Brachytherapy refers to the delivery of radiation directly into or onto the surface of the area to be treated. Radiation sources can be used in body cavities (e.g., the uterus, vagina, bronchus, esophagus, and rectum), can be placed on the surface of tumors in the skin or may be placed directly into a tissue by interstitial techniques such as those used in the head and neck region, prostate, and breast.

One of the main objectives of brachytherapy is to ensure an accurate and safe dose delivery to a target volume while avoiding unnecessary delivery to surrounding healthy tissue. [1]

In order to ensure the optimal treatment of patients, much effort is required during the commissioning phase of new brachytherapy equipment and during its clinical lifetime. The institution must therefore develop a suitable Quality Control (QC) program not only for brachytherapy sources and equipment but also for the physical and clinical procedures.

In 2000, the IAEA published its Report No. 17 entitled "Lessons learned from accidental exposures in radiotherapy". [2] Although brachytherapy is applied only in about 5% of all radiotherapy cases, 32 of the 92 accidents reported in this booklet were related to the use of brachytherapy sources. Errors in the specification of source activity, dose calculation or the quantities and units involved resulted in doses that were up to twice the prescribed dose. Some of the accidents were clearly related to human error. The same document demonstrates the need for well-designed QC programs for brachytherapy. For the conception of such programs, one must consider the consistency in the management of each individual treatment, the realization of the clinical prescription, and the control of safe execution of the treatment with regard to the patient and to others who may be involved with, or exposed to, the sources during treatment. [3, 4]

As a result of several accidents recently reported involving the use of advanced technology in radiation oncology, QC programs involving independent quality audits are also seen as a preventive action. [5,6,7,8]

The consequences of errors that are bound to occur in a radiation oncology clinical environment may be caused by the radiation oncologist, physicist, dosimetrist or radiation therapist. Of these errors, the most grievous to the patient are the systematic errors made by the physicists without his or her perception.

Therefore, the type of mistakes made by each staff member is different, as is the magnitude of the impact to the patient, as specified below:

- if a physician makes a mistake, it usually affects one patient;
- if a dosimetrist makes a mistake, it affects one patient or one tumor location;
- if a technologist makes a mistake, it normally affects one fraction of the treatment;
- if a physicist makes a mistake, it may affect all patients in the clinic during a given period of time.

A sound QC program must be in place to reveal and prevent these mistakes and may include as an important component independent Quality Audits.

2. The brachytherapy technology

During the past 15 years, high dose rate ^{192}Ir sources have become available as an efficient substitute for ^{137}Cs sources. Several advantages have drawn attention to this new technique, among which are the possibility to treat several new clinical sites due to the small dimension of the source, the viability of out-patients treatment, the lesser number of treatment sessions required, the complete remote-controlled source management, which increases the staff safety, and a computerized treatment planning system that offers the 3D-volume dose calculation.

Fig. 1. Typical configuration of commercially available HDR treatment unit

Since there are several types of HDR sources available in the market, Table 1 presents some of the main physical characteristics that are useful for entry-independent calculation analytical and numerical calculation methods.

Model:	Active length	Active diameter	Total diameter	Distance from active edge to tip of the source	Encapsulation
MicroSelectron Nucletron (new design)	3.6	0.65	0.9	0.2	Stainless steel
VariSource	10	0.35	0.61	1	Ni-Ti
Varian	5	0.34	0.59	1	Ni-Ti
Buchler	1.3	1	1.6	1	Stainless steel
Gamma Med 12i	3.5	0.6	1.1	0.86	Stainless steel
Gamma Med Plus	3.5	0.6	0.9	0.62	Stainless steel
BEBIG	3.5	0.6	1.0	0.9	Stainless steel

Table 1. Specific characteristics of the ^{192}Ir high dose rate sources. Dimensions are in mm. Adapted from [3]

3. Main treatment sites

High dose rate machines may have clinical indications in the treatment of a variety of different organs either as a primary treatment or as a complementary therapy. As a result, there are a large number of applicators and accessories designed specifically to fit the geometrical needs of each treatment site.

Among the numerous applications [1] for HD brachytherapy, the three main areas are:

Prostate: Two techniques are in use: 1. Temporary implants using a stepping ^{192}Ir HDR source to deliver large single-dose fractions has gained acceptance with current radiobiological models that predict a low [alpha]/[beta] ratio for prostate cancer, and 2. Permanent implantation, mainly with small radioactive seeds of ^{125}I source with a half-life of 59 days is a second option. In some centers, the ^{121}Pd is also used. The latter is not in the scope of this chapter.

Breast: Two techniques for partial breast implant irradiation are in use: 1. multicatheter brachytherapy is used as a conventional brachytherapy to cover the tumor bed with a 2- or 3-plane interstitial implant, and 2. the single-catheter technique that uses a new applicator marketed as the Mammosite is essentially a single-line flexible HDR afterloading catheter with an inflatable balloon at the end. The latter is not in the scope of this chapter.

Gynecological: This is focused mainly on cancer of the endometrium and cervix using specific types of applicators, for instance a ring system that allows multiple source positions including in the upper vagina.

Fig. 2. Typical set of applicators, accessories, catheters and sleeves used for HDR treatments

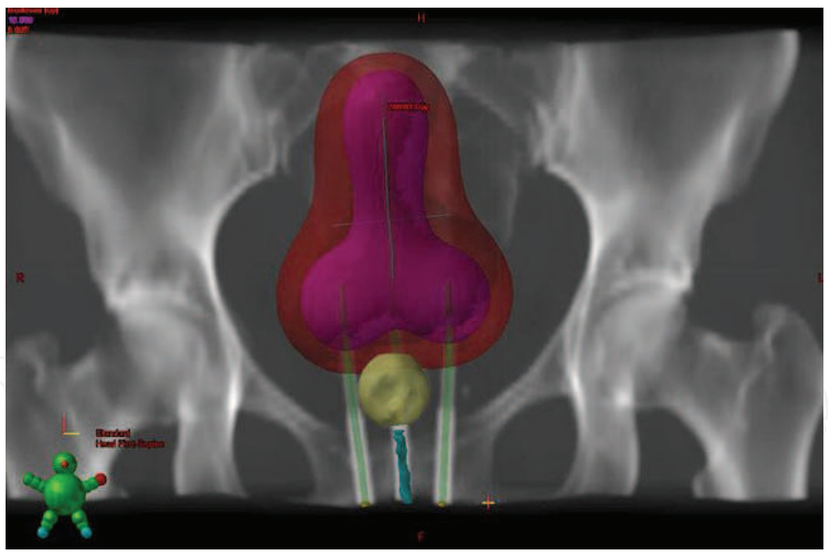

Fig. 3. Typical examples of a gynecological intracavitary treatment and a 3D-dose distribution around it

4. The scope of the quality control process

The emphasis in this chapter is to cover the physics aspects of a quality control program for HDR brachytherapy and to promote awareness of the tolerances and frequencies of the basic tests required. Those tests are based on the likelihood of a malfunction and the seriousness

or potential consequences of an unnoticed malfunction that would affect the patients and/or to the personnel involved in the clinical procedure if a malfunction occurs and is not identified during normal treatment applications. The purpose of the QC program is to guarantee that all operational procedures are being performed properly and in accordance with the licensing specifications.

The QC must consider the compliance aspects of planning through a comprehensive management plan, documentation of the actual operations, and the monitoring and reporting requirements. [8]

Tolerances and action levels

Performance within the tolerance level provides an acceptable degree of accuracy in any situation. If performance is outside the action level, it may demand an action to fix the situation.

A quality control test should use appropriate measuring equipment, which must itself have been subjected to maintenance and quality control. Irradiation conditions and measuring procedures should be designed to be suitable to each task, and they are expected to give the best estimate of the particular measured parameter. Because each measurement has an associated uncertainty that depends on several factors, the tolerances established must take that into account.

Action levels are related to tolerances but it may afford sufficient flexibility to monitoring and adjustment; for example, if a measurement indicates a result between the tolerance and action levels, it may be acceptable to allow clinical use to continue until this is confirmed by measurement the next day before taking any further action.

As a normal procedure, the action levels must be activated depending on each particular situation, such as;

- if a daily measurement is within tolerance, no action is required;
- if the measurement falls between tolerance and action levels, this may be considered acceptable until the next daily measurement;
- if the measurement exceeds the tolerance level, immediate action is necessary and the machine may not be used clinically until the problem is corrected and verified by measurement;
- if repeated measurements remain consistently between tolerance and action levels, adjustment is required;
- any measurement that is outside the action level requires immediate investigation and, if confirmed, rectification.

As in general, action levels are set at about twice the tolerance level, while some critical parameters may require tolerance and action levels to be set much closer to each other or even at the same value.

Test frequencies must be considered in the context of the acceptable variation during a treatment course and also the period of time over which a parameter varies or deteriorates. Frequencies may be modified in the light of experience of the performance and stability of a given piece of equipment, initially setting a nominal frequency that may be subsequently reviewed in the light of observation. As machines get older, this may need further review.

The staff resources available to undertake the tests may limit what can be checked, which may have an effect on the structure of the quality control program. Tests should be designed to provide the required information as rapidly as possible with minimal time and equipment.

Whenever available, quality control protocols developed by national organizations should be applied. The following sections provide some examples of parameters, test frequencies, and tolerances currently used for different items of radiotherapy equipment.
For consistency, the values listed are based on the AAPM TG 40 [9] and ESTRO [3], and in some cases, on recently published additional reports on quality control in radiotherapy [10]. In any case, those protocols should be referred to for more details and adapted for local circumstances.

5. General concepts

It is essential that the performance of treatment equipment remain consistent within accepted tolerances throughout the clinical life of the equipment, as patient treatments will be planned and delivered on the basis of the performance measurements made during the equipment acceptance and commissioning tests.
An ongoing quality control program shall include regular checks beginning as soon as the equipment is commissioned. This program should be able to identify departures from expected performance and to activate corrective actions, and it shall consider the following points:

- the parameters to be tested and the tests to be performed;
- the specific equipment to be used to perform the tests;
- the geometry of the tests;
- the frequency of the tests;
- the staff group or individual performing the tests, as well as the
- individual supervising and responsible for the standards of the tests and for actions that he or she may deem necessary if problems are identified;
- the expected results;
- the tolerance and action levels;
- the actions required when the tolerance levels are exceeded

6. The quality control program

The organization of a program requires as a foundation that the institution is willing to be prepared for organizational rearrangements if needed in order to lay down very clearly the duties and responsibilities of each staff member.

The institutional organization

It is important to clearly describe not only the general aspects of the institutional position in the organization chart, but also the interaction with similar departments, the legal aspects and services provided, and the formal delegation of individual tasks to the staff. It is also crucial to detail the information flow, scheduling, list of staff members involved in the treatment, information given to the patient, and the radiation protection equipment and procedures in the treatment area.
A set of recommendations is proposed to be an integral part the patient file in order to promote appropriate treatment, to help the reviewing process. [3].
Patient ID, all documents, films, prints, plots provided with treatment, source strength matched with its decayed value, identification of the customizing file and source library, correct use of magnification factors and source-film distances, the position of sources or

applicators on the plots with radiographs compared with treatment (volume) prescription, correct use of units for all quantities, correct use of shielding or other correction factors, correct use of treatment parameters, such as step size, catheter length, begin- and end points along the catheters, consistent use of prescription criterion and optimization routines, according to the physician's intent and the possibilities of the implant geometry, statement about the dose uniformity and the dose differentials, dose and dose per fraction clearly stated according to prescription, dose to normal structures, high dose areas, constraints clearly fulfilled, identification of position of reference points, patient points, applicator points on the plots, match with those measured on the film, step size, catheter length, dwell times on treatment unit according to plan and for subsequent treatments program card, stored standards, or equivalent settings matching the first treatment.

Clinical procedures

It is of fundamental importance to clearly specify the control points (as described in Table 2) related to each of the procedures currently in use, including the procedures for CT and MRI imaging acquisition protocols, imaging reconstruction techniques, data transfer to the treatment planning system (TPS), dose validation methods involving the patient simulation and treatment, the frequency of each test, training, chart rounds, peer review, and incident reports.

Item	Material and Methods	Frequency
Test of outcome of HDR calculation	Apply the methods developed at the institution for specific clinical cases	each patient
Treatment protocols	All types of applications should be described in detail	each patient
Standard forms	To be developed for each application	each patient
Independent check	Ensure that a second person checks the work of the first planner	each patient

Table 2. Simple guidelines to be considered as part of the design of the treatment operational flux for each patient. Adapted from [3]

Physical procedures

The control points defined for the QC program shall also include the physical data either taken from tables, publications, guidelines, measurements involving the machine acceptance and commissioning, source calibration, patient data (protocols for imaging acquisition and data entry to the treatment planning system), dose calculation for the patient, dose validations or patient chart checks.

The early detection of errors in the operational process following the steps proposed in Table 3 is very important in order to allow the elimination of errors and to promote the necessary modification of the routine procedures.

Item	Material and Methods
Patient identification	All documents, films, prints, plots provided for a treatment
Dose prescription	Delivered dose vs. prescribed dose, evaluation of uniformity of the dose, location of prescribed dose, dose distribution/differentials in dose, begin and end positions correctly along the catheter
Dose to normal structures	Identification of the location of high-dose areas, location of normal structures and constraints to be fulfilled
Program identification	Identify the algorithms used, version number, shielding and correction factors
Program verification	Identify the source strength, step size and tip length
Transfer of data	Identify the correct position of each dwell position, dwell time, total time and correct channels

Table 3. The main sources of detectable errors and preventive actions recommended in orderto avoid unnecessary sources of errors. Adapted from [3]

Safety aspects

Protection of the patient and the staff is the most important objective to be considered in the proper treatment to the patient. One shall consider the physical conditions and the calibration certificates of the physics equipment and review the current procedures performed, as well as the emergency procedures, drills, source storage disposal issues, posting, surveys including the results of the wipe tests and its appropriate register.

In addition, one must consider items such as electrical interlocks, source exposure indicator lights on the after loader, control console, viewing and intercom systems, emergency response equipment, radiation monitors, timer accuracy, clock (date and time) in unit's computer and decayed source activity in unit's computer.[8]

A set of minimum requirements for specific actions are presented in Table 4, including the frequency of verification of the most important parameters related to the safe operation of the clinical procedures.

It is the physicist's task to inspect the performance history of the system meticulously, using the data in the logbook noted during the clinical lifetime of the equipment.

An important component of safety is the proper training of the staff to deal with unexpected situations. The knowledge of the equipment design and its components, including access to the emergency knobs, buttons and tools as shown in Fig.4, may help to speed the resolution of a particular incident.

Description	Minimum requirements	
	Test frequency	Action level
Safety systems		
Warning lights	Daily/3M*	-
Room monitor	Daily/3M*	-
Communication equipment	Daily/3M*	-
Emergency stop	3M	-
Treatment interrupt	3M	-
Door interlock	W	-
Power loss	3M	-
Applicator and catheter attachment	W	-
Obstructed catheter	W	-
Integrity of transfer tubes and applicators	3M	-
Timer termination	Daily	-
Contamination test	A	-
Leakage Radiation	A	-
Emergency equipment (forceps, survey meter)	Daily/3M*	-
Practicing emergency procedures	6M	-
Hand crank functioning ***	A	-
Hand-held monitor	3M/A**	-
Physics parameters		
Source calibration	SE/3M	>5%
Source position	Daily/3M*	>2 mm
Length of treatment tubes	6M	>1 mm
Irradiation timer	6M	>1 %
Date, time and source strength in treatment unit	Daily	-
Transit time effect	3M	-

(3M–quarterly; 6M–biannual; A–annual; SE–source exchange; W=weekly Adapted from [3] *Daily checks are assumed to be an implicit part of normal operation and registered in a logbook. ** Verify the proper function of the hand-held monitor, e.g., with a known source of radiation. "Action level" reflects the upper limit in clinical conditions

Table 4. Recommended types, frequencies and tolerances of the quality control tests. Adapted from [3]

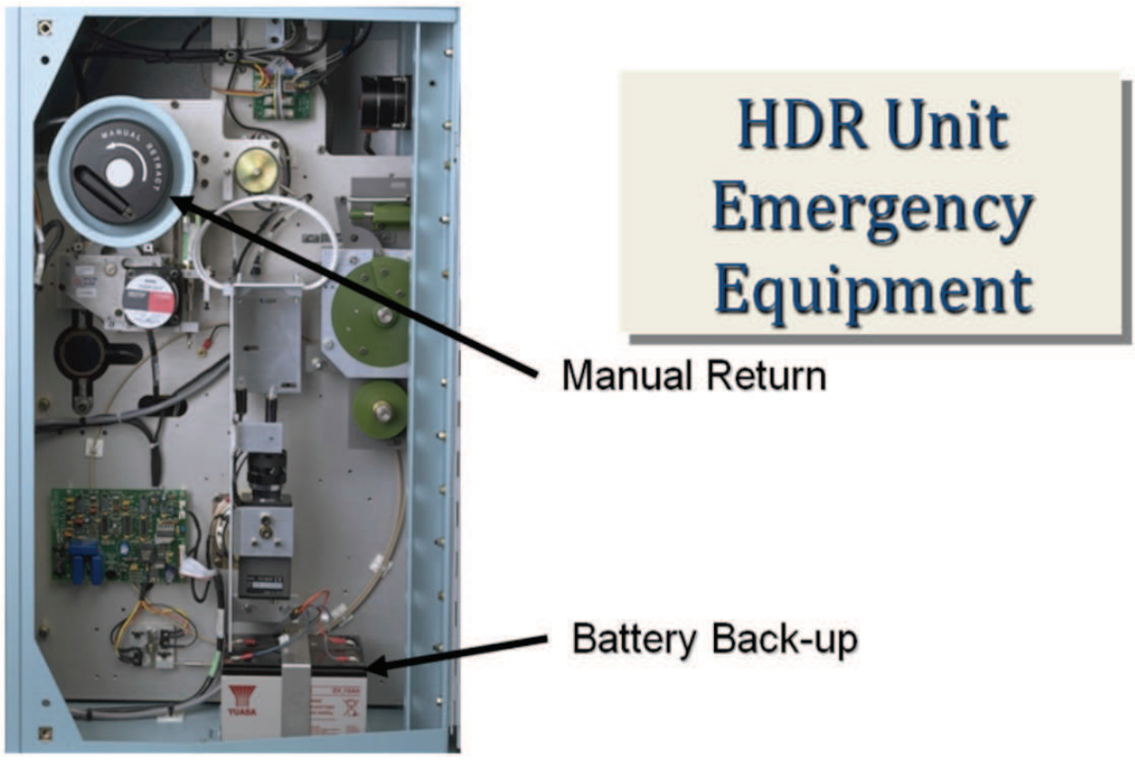

Fig. 4. An inside view of one of the machines available on the market illustrating a manual system to retrieve the source and the battery back-up that keeps the equipment operational in case of a power failure

7. Dose calculation

The dose calculation algorithm of the treatment planning systems uses the TG 43 data [11,12], which is the best approach at the present time. This step should include a review of the patient identification data, the imaging acquisition protocols, the data transfer to the TPS and the results of the independent checks.

Two important steps must be considered to validate and periodically control this parameter; first, the basic dose calculation steps as described in Table 5, and second, the dose volume histograms, including optimization, as shown in Table 6. Both tables contain parameters of significant relevance to allow a correct clinical decision for treatment and long term follow-up.

In brachytherapy, it is not redundant to reinforce that the concept of recommended tolerance levels should be interpreted such that when the tolerance level is reached, it is essential that appropriate actions be taken.

By all means, the treatment unit should not be used clinically when the tolerance level is exceeded unless after careful consideration by the medical physicist and with the agreement of the radiation oncologists and radiation technologists, a joint decision is made to carry on.

For medical physicists in this position, it is essential that they possess the awareness and skills necessary to make a sound judgment based on all available information and following an appropriate assessment of the risks involved. This type of approach may also help with a better understanding the concept of tolerance levels.

Item	Material	Frequency
Point dose calculation	Identify relevant dose points around the source for which a dose rate table is available, compare results, tolerance level is at ±2%, analyze in detail if deviations are > 5%	Initially and with software updates
Source selection	Check that the system performs the source selection from the library properly	Initially and with software updates
Check dose distribution calculated by TPS	Clinical benchmark cases shall be used	Initially and with software updates
Check dose distribution calculated by TPS of multiple source geometries	Compare with previously selected clinical benchmark cases	Initially and with software updates
Shielding	Check dose distribution of sources near the applicator shielding	Initially and with software updates

Table 5. The main steps involved in control of the basic dose calculations

Item	Material	Frequency
Volume calculation from 3-D imaging data	Calculate the volume of well-defined "organs"	Initially and with software updates
DVH of an isotropic point source	Cumulative differential and natural dose volume histograms	Initially and with software updates
Anisotropic sources	Calculate the DVHs with anisotropy correction	Initially and with software updates
Clinical examples	Calculate DVHs for benchmark clinical cases	Initially and with software updates

Table 6. The critical parameters related to dose volume histograms and their optimization. Adapted from [3]

- Treatment-planning system

In addition to the computer itself, the major hardware devices associated with a planning system are the digitizer and the plotter. Their accuracy should simply be routinely checked with a benchmark case that checks the overall accuracy of source reconstruction, including translation from film to Cartesian coordinates, rotations, and corrections for magnification. [13,14].

The frequencies should follow those described in Table 9.7

- The consistency between quantities and units

A main source of error in dose distribution calculations is the incorrect use of quantities and units required by the dose calculation software. It is essential to verify the correct labeling of the input and output quantities and units. The strength of the sources (activity) may be specified in one of several alternative units, and the user should pay particular attention to this important parameter. Inconsistent use of units could lead to severe errors in the treatment and possibly compromise the expected treatment outcome.

- Computer versus manual dose calculation for a single source

The computer-calculated dose distribution around one linear source must be compared with published dose rate values for a similar source or with manually calculated values using the Sievert integral. Additional tests may include summing of the dose for multiple sources and the check of decay corrections with a proper choice of units.

- Source Tests

An important topic to be considered is the check of a new incoming source that is usually changed 3-4 times a year, its comparison with the institutional data and the data provided by the manufacturer.

- Wipe tests

All sources that are maintained in a permanent inventory are required to be wipe-tested for any leakage of radiation.

Radiation levels should be measured and recorded both at the surface and at a 1-m distance. Individual encapsulated sources should be wipe-tested for possible leakage or contamination. A source is considered to be leaking if ~200 Bq (~5 nCi) of removable contamination using a cotton swab is measured in a GM counter or a scintillation well counter.

- Calibration process and its metrological traceability

Due to still some unresolved issues regarding the absolute standardization of the calibration procedures of ^{192}Ir HDR sources [15,16], several methods (using the interpolative approach) are still being used, though traceable to the calibration laboratories. [17].

Fig. 5. A typical well-type ionization chamber, including a tool to performs tests of source positioning within 0.3 mm, timer accuracy, and consistency of source activity

It is recommended that brachytherapy sources have their source strength calibrations traceable to a national standards laboratory by using a calibrated well-type ionization chamber such as the one shown in Fig. [18]
The activity of all sources should be measured on receipt with a local well-type chamber and compared with the manufacturer's certificate of source strength. In case it is above the tolerance level, another measuring system should be used until the reason for the deviation is fully explained.

- Constancy check of a calibrated dosimeter

The consistency of the response of the dosimetric system (electrometer, cable and chamber) may be checked by periodic measurement using a source with long half-life, such as ^{137}Cs placed inside the chamber in a reproducible position. Alternatively, one may use a radiation beam from a Linac or a Cobalt teletherapy unit fixing the irradiation parameters such as field size, geometry, distance source to surface of chamber and number of MU. [16].

- Regular check of the source positioning.

The source positioning the catheter is a very important control point before each treatment is conducted. A very simple device may be used with the dummy source as shown in Fig.

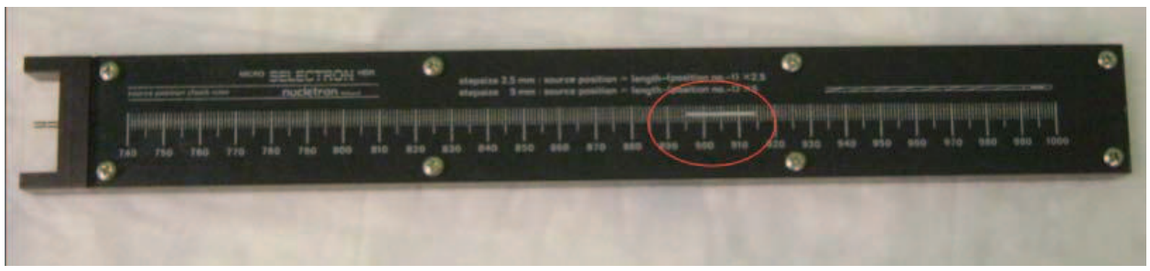

Fig. 6. The source position ruler showing the source in a red circle

- Regular checks of applicators

The applicators are used with very high frequency and go through severe handling, cleaning and sterilization processes.

Fig. 7. Typical Gyn intracavitary applicator ring type with an intrauterine tandem

Periodic inspection and radiographic evaluation of all applicators should be performed at some pre-established frequency as proposed by and described in Table 6.2

Gynecological appliances	Element to be tested	Frequency
Tandems	Flange screws function	Each use
	Curvature	Each use
	Closure caps function	Each use
	Plastic sleeve and rod fit and slide	Each use
Fletcher-type ovoids	Source carrier function	Each use
	Integrity of welds	Each use
	Position of shields	Semi-annually or after repair
	Identification markers	Each use
	Bridge integrity/thumb screws	Each use
Tandem-based cylinders and tandem checks	Flanges function	Each use
	Identification markers	Each use
	Cylinders fit snugly	Each use
Solid cylinders	Source carriers function	Each use
	Closure caps function	Each use
Intra luminal catheters	Integrity	Each use (after sterilization)
	Strength of tip	Each use (after sterilization)

Table 8. Quality control procedures for brachytherapy appliances

8. Independent auditing

Quality audits are now considered an essential component of a QC program, and there is a strong trend for these audits to become an operational requirement by the licensing authorities. The quality audit is a way of independently verify the correctness and effectiveness of an ongoing program. This may be performed by individuals with qualified proficiency or by an accredited organization or institution. The first program available was offered by the Radiological Physics Centre (RPC) [6,1], which has been funded by the National Cancer Institute (NCI) continuously since 1968 to provide quality auditing of dosimetry practices at institutions participating in NCI cooperative clinical trials. These services may or not include site visits when the discrepancies need to be resolved. Similar services are provided in Europe by the EQUAL, which is funded by ESTRO [7]. In Brazil, this activity is conducted by the LCR [8], and recently the IAEA promoted this conception worldwide as part of the QUATRO program [10].

Other institutions providing quality audits are the American College of Radiology and American College of Radiation Oncology. These two programs are more involved and include site visits to the radiation oncology department being reviewed [19,20,21,22].

9. Final remarks

Brachytherapy is indeed a very important treatment modality of several of the malignant diseases that allows conformal treatment without complex technological involvement.
Although the basic principles of brachytherapy have not changed much during the past 100 years of radiotherapy, the advent of remote after-loading made brachytherapy more efficient for the patient and much safer for staff from the radiation protection point of view.
In terms of human resources, brachytherapy treatment requires considerably more involvement than an average external beam patient.
Quality control programs must be flexible to permit additional testing whenever it seems necessary following repair, observed equipment behavior or indications of problems during the regular quality control tests. To diminish treatment interruption due to non-regular interventions or additional quality control measurements, it is essential to maintain the test and measurement equipment in good order and subject this equipment to its own quality control program, as well as to have alternate equipment readily available.

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The rich palette of topics set out in this book provides a sufficiently broad overview of the developments in the field of quality control. By providing detailed information on various aspects of quality control, this book can serve as a basis for starting interdisciplinary cooperation, which has increasingly become an integral part of scientific and applied research.

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