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Radiological protection issues in endovascular use of radiation sources

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February 2006

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FOREWORD

The use of radiation from radioactive materials for cancer treatment is well established. However, examples of uses of radiation therapy for benign conditions have been limited. Placing a radioactive source in the blood vessel so as to irradiate the surrounding inner periphery of the vessel has been attempted in recent years to prevent restenosis after percutaneous coronary and peripheral interventions. This kind of endovascular application provides treatment options that are less invasive for various vascular conditions compared with open surgery.

As a part of the International Atomic Energy Agency's (IAEA) function for providing for application of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) that were jointly sponsored by the IAEA, FAO, ILO, OECD/NEA, PAHO and WHO, the IAEA planned a coordinated research project (CRP) that was to start in 2002 on radiological protection problems in endovascular use of radiation sources. However, as experts soon realized that the interest in this modality was waning, the CRP was not initiated. Nevertheless, it was felt that it would be appropriate to compile the information available on radiological protection problems observed so far and their possible solutions.

This work was seen as part of a broader IAEA programme that covered accident prevention in radiotherapy. Publications on this topic have included, inter alia, Lessons Learned from Accidental Exposures in Radiotherapy (Safety Reports Series No. 17); Accidental Overexposure of Radiotherapy Patients in Bialystok; Investigation of an Accidental Exposure of Radiotherapy Patients in Panama; Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica; and Investigation of an Accidental Exposure of Radiotherapy Patients in Poland.

Keeping in mind that endovascular applications involve specialists such as cardiologists, angiologists and surgeons, all of whom might not have a comprehensive background in radiological protection, this publication has been kept purposefully simple: it is not meant to exhaustively review dosimetry techniques and quality assurance.

The IAEA officer responsible for this publication was M.M. Rehani of the Division of Radiation, Transport and Waste Safety.

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CONTENTS

1. INTRODUCTION

Endovascular application of suitable radiation sources is one of the treatment modalities to prevent restenosis after percutaneous coronary and peripheral interventions. By now, clinical trials have shown a significant decrease in restenosis rate, mainly in the case of in-stent restenosis, but also for de-novo lesions in coronary arteries and for lesions treated in femoro-popliteal vessels [1–5]. The procedure is highly interdisciplinary in nature, involving at least one interventionist (e.g. cardiologist, angiologist, radiologist, surgeon), a radiation oncologist and a medical physicist. The role of the radiation oncologist in the team is the one of an expert in radiation effects on human tissues due to the non-oncological therapeutic application of radiation. Quality assurance, dosimetry and radiological protection is performed and/or supervised by a qualified medical physicist.

Based upon the requirements in International Basic Safety Standards (BSS) for Protection against Ionizing Radiation and for the Safety of Radiation Sources [6], a safety report was brought out by the IAEA [7], which lists the lessons learned from accidental exposures in radiotherapy. Since endovascular use of radiation sources was not covered, there is a need to disseminate information on a number of incidents/events resulting in undue radiation exposure to personnel and patients, with a view to reducing the chances of similar recurrences, or in fact to prevent them. Learning lessons from accidental events is the prime goal of any educational activity and of this publication. This publication is primarily directed at physicians getting involved with the use of radioactive sources for endovascular interventions. It will also be useful for medical physicists, radiation oncologists and hospital administrators in getting to know the type of events that can happen in such applications. It is not aimed to be a comprehensive report on dosimetry techniques and quality assurance.

2. TECHNIQUE AND DEVICES

Brachytherapy stands for brachy (Greek word for near) and therapy (treatment), when the radiation source is close to the tissues to be treated (target volume). Endovascular brachytherapy is the application of radioactive sources in specially designed applicators inserted directly into blood vessels. In some countries, the term intravascular brachytherapy is used for the same procedure.

2.1. PERIPHERAL ENDOVASCULAR BRACHYTHERAPY

The pioneering work establishing endovascular brachytherapy in general started with the first human treatment of peripheral arteries (femoro/popliteal region) in the 1990's [1] followed by various clinical trials [2]. As the diameter of these arteries is generally more than 4 mm, high dose rate (HDR) brachytherapy is applied using standard remote afterloading devices with gamma-emitting radionuclides already available for cancer treatment. Peripheral endovascular radiotherapy is performed in dedicated shielded treatment rooms of a brachytherapy department.

It is possible to use a semiflexible lumen catheter with a closed tip, similar to the ones used for intraluminal brachytherapy (e.g. bronchus) for a long time. These endoluminal applicators are placed through an introducer sheath into the artery.

Improvement of the dose uniformity by reducing overdosage to the intimal layer and underdosage at the target depth on the opposite side can be achieved using a centring catheter. A centring catheter uses a balloon configuration to position the source channel in the centre of the vessel lumen. The balloon is inflated directly before radiotherapy. Most afterloading devices have integrated radio-opaque markers to visualize the most distal dwell position.

Recently, devices initially used for coronary brachytherapy with beta-emitting radionuclides, are also adapted for peripheral applications in clinical trials. Due to the limited penetration ability of beta rays, sources are centred using balloons filled with gas in order to avoid large attenuation within the applicator itself. These rare techniques are performed directly in the catheterization laboratory (see next paragraphs).

2.2. CORONARY ENDOVASCULAR BRACHYTHERAPY

In general, radiation sources have to be thin in order to fit into catheters positioned in coronary vessels, usually smaller than 4 mm in diameter. Furthermore, the curvature of coronary arteries makes it necessary to use very flexible source arrangements. Standard HDR remote afterloading devices as already used for oncology treatments are not applicable for coronary applications due to the very high source strength. Therefore it became necessary to design and build new types of devices and sources. During the last decade, several devices have been tested in clinical trials; some of them are now commercially available while others remain as prototypes.

2.3. DELIVERY PROCEDURES

2.3.1. Afterloading devices

After the catheter has been positioned at the site of the treatment, the radioactive source has to be brought in. There are number of ways by which the source can be moved in and out of the treatment area, some manual, others using automatic devices. The afterloading unit stores the radioactive source in a shielded container and has the ability to deploy and retract the source into/from the delivery catheter. Additional lumina may be present in this catheter to hold the guide wire, a canal for a hydraulic circulatory system or a lumen to inflate centring devices. The major advantage of afterloading is the possibility to position the delivery catheter without any radiation to the vessel. It is a safe methodology, which is already established for decades in radiation therapy.

The mechanism to move the source can either be manually by pushing a wire (drive cable) on which the source is mounted or mechanically using a hand crank system or hydraulic pressure.

Automatic afterloading devices use a motor driven wire to move the source. This mechanism can also perform automatic stops at defined positions (dwell positions) over certain time periods (dwell times). Such systems can perform movements with a given step size in order to achieve a programmed active length with one smaller active source. In addition, the remote controlled afterloading devices used for HDR brachytherapy in radiation oncology and peripheral endovascular brachytherapy have a separate control unit outside of the treatment room.

2.3.2. Sources

Different types of sources may be used for afterloading procedures. The wire source consists of a radioactive core encapsulated with an outer metallic cylinder. It is directly welded to the drive cable of the afterloader. Seed sources are small capsules of radioactive material encapsulated in stainless steel. Several seeds can be arranged in seed ribbons where a nylon tubing fixes the seed spacing or in seed trains with no spacing in-between. Seed trains can be arranged in a loose configuration or stitched together in a jacketed form.

Afterloading devices are usually equipped with dummy sources in order to check the catheter for obstructions prior to the treatment with the active source. Dummy sources should be of the same geometry as the active source using the same type of delivery device in order to simulate the treatment. Automatic afterloading devices have built-in dummy sources. The dummy source can also be a separate wire which is at least of the same diameter as the source to check the functionality of the delivery catheter.

2.3.2.1. Liquid or gas filled balloons

Similar to the afterloading technique the applicator is first positioned at the target position inside the vessel lumen. The applied applicator is a balloon catheter like the one used

for dilation of the stenotic artery. In shielded systems, a syringe containing radioactive fluid or gas is connected to the proximal end of the balloon catheter. The balloon can be filled with radioactive material in order to achieve a homogeneous dose distribution within the surrounding vessel wall tissue. After the treatment the fluid is extracted from the balloon volume back into a shielded syringe.

2.3.2.2. Coated balloons

In contrast to afterloading devices and radioactive filled balloons, the coated balloon is always equipped with radioactivity. During the production process the radioactive material is filled between the layers of the balloon shell. The device is provided under sterile conditions. After insertion and placement into the vessel lumen to be treated, the balloon is inflated, pushing the radioactive layer directly on to the vessel wall. After deflation and removal of the balloon, it has to be put into a disposal container.

2.3.2.3. Radioactive stents

In case of radioactive stents, the wire mesh is coated or impregnated with suitable radionuclides. It is placed in the target region as a permanent implant. In general the total activity of this device is low compared to the activity of temporary applications since the dose is cumulated over the time of decay of the radioactive material. Based on the results of several clinical trials this type of application is currently being phased out of clinical routine [8].

2.4. GROUPS OF NUCLIDES

As the target volume is assumed to be located within parts of the arterial wall (media and/or adventitia) at a depth of 0 to 3 mm from the endothelial surface, low-energy gamma emitters or high-energy beta emitters show a good depth dose characteristic [9,10]. The choice of the radionuclide is limited by the possibility to build small sources with adequate specific activity. In general there are the following types of nuclides available [11]:

Gamma-emitting nuclides with a mean energy > 100 keV

e.g. Iridium-192, Caesium-137, Cobalt-60

Low-energy photon emitters with a mean energy < 100 keV

Sealed radionuclides with gamma energies < 100 keV, e.g. Palladium-103, Iodine-125 and stepping miniature X ray sources with maximum energies < 50 keV

Beta-emitting nuclides

e.g. Phosphorus-32, Strontium-90/Yttrium-90, Rhenium-188, Rhenium-186, Cerium-144, Xenon-133.

The physical characteristics of the most important nuclides are summarized in tables I and II. For $^{188}W/^{188}Re$, $^{90}Sr/^{90}Y$ and $^{106}Ru/^{106}Rh$ the emissions of the short-lived daughter are

in equilibrium with the long lived parent. Further, in these cases, only the beta energy of the daughter is of importance, because the relatively low energy beta particles of the parent are absorbed by the source encapsulation.

TABLE I. PHYSICAL DATA ON PHOTON EMITTING SOURCES (from [12])

Isotope	Half-life (days)	Traceability to a Primary Standard Dosimetry Laboratory (PSDL)
^{125}I	59.41	Yes
^{103}Pd	16.99	Yes
^{192}Ir	73.831	Only for LDR, none for HDR
^{137}Cs	11019.6	Yes
^{60}Co	1925.4	Yes

TABLE II. PHYSICAL DATA ON BETA RAY SOURCES (from [12])

Beta emitter	Maximum energy (MeV)	Average energy (MeV)	Half-life (days)	Traceability to a PSDL
^{133}Xe	0.346	0.100	5.243	Yes
^{32}P	1.71	0.695	14.26	Yes
^{188}W/^{188}Re	2.12 (^{188}Re)	0.766 (^{188}Re)	69.4 (^{188}W)	Yes
^{90}Sr/^{90}Y	2.28 (^{90}Y)	0.933 (^{90}Y)	10512 (^{90}Sr)	Yes
^{106}Ru/^{106}Rh	3.54 (^{106}Rh)	1.42 (^{106}Rh)	373.6 (^{106}Rh)	Yes

3. INFRASTRUCTURE

Endovascular brachytherapy for coronary arteries is a technique usually performed in catheterization laboratories (cath lab). These rooms were initially not designed to handle radioactive material. Normally the wall thickness and shielding facilities are appropriate for X rays. The existing configuration may often be sufficient in case of beta source applications. However, in the case of gamma-emitting sources, additional requirements are always needed. The need for additional shielding of the cath lab to protect the staff and the public depends mainly on the configuration of neighbouring rooms. It is possible to do the design based on occupancy factors and the related dose constraints to individuals without any need of expensive constructions [13]. Furthermore a dedicated room with appropriate shielding and lock mechanism is required to store the sources in a secure place. However, in most cases such a safe room is already available at a radiotherapy department and may be used for endovascular brachytherapy sources.

Endovascular treatment of peripheral vessels (e.g. femoro-popliteal artery) is currently mainly performed using standard brachytherapy equipment for oncological treatments. The use of these high dose rate (HDR) gamma sources is usually restricted to dedicated HDR treatment rooms. Radiation safety recommendations are directly applicable from endoluminal brachytherapy. However, if there are new methods such as using beta sources for peripheral endovascular brachytherapy, it is possible to perform directly in the cath lab.

As endovascular brachytherapy is interdisciplinary it is recommended to plan, introduce and perform this treatment modality using a close cooperation between a medical physicist, radiation oncologist and the interventionist (e.g. cardiologist, angiologist). In general a radiotherapy department already uses most of the equipment to perform quality assurance (QA) and to store and handle radioactive sources.

A description of the equipment needed for dosimetry, quality control (QC) procedures and radiological protection can be found in detail in reference [11] and more generally in references [9, 10, 14]. The medical physicist has to ascertain the calibration of the source. Therefore a dosimetry system (e.g. a plastic scintillator, well type chamber and electrometer or radiochromic film) should be available. Additional equipment is necessary to verify relative dose distributions (depth dose curve, longitudinal homogeneity), leakage radiation and contamination. All these quality assurance procedures are usually performed in appropriate rooms. Most suitable are shielded work places of brachytherapy departments or treatment rooms.

An appropriate emergency container has to be available in the cath lab during every treatment. While a plastic shielded container is usually sufficient for beta radiation, a lead shielded container is required for gamma sources.

In the case of beta-emitting sources, the use of afterloading techniques may require perspex shielding around the source, whereas overall infrastructure can remain the same. For gamma-emitting sources additional requirements of shielding may be necessary, but may be avoided if the workload is highly limited and regulations allow it.

4. EVENTS

During the use of radioactive sources for therapeutic applications there is always the possibility of unintended events that may cause accidental exposure. The terminology is described in Annex I and can also be found in references [7, 15, 16]. Annex II gives the requirements as given in the BSS.

There are also detailed descriptions and human factor evaluations of abnormal occurrence reports related to brachytherapy. Many of the reported events are related to the loading of sources in manual afterloading brachytherapy, dose calculation errors and insufficient training of personnel. The general problem with accidental exposures is the lack of information. Very few countries have a system like the USA of reporting such events and thus many reported events are from the USA. It can be assumed that such events occur similarly at other countries as much as is reported in the USA.

In general, such events are also possible in endovascular brachytherapy. However, to date the number of reported abnormal occurrences is very small. This may be related to the fact that so far this new type of brachytherapy has been mainly performed in controlled and supervised conditions. The use of afterloading devices in radiotherapy has been well established for many decades. Therefore training and experience of the involved personnel was appropriate for the use of these new devices. However, in order to achieve the optimum amount of protection for the patient and the personnel the following section provides an overview of possible events related to endovascular brachytherapy. A few comments are given about handling these events. Avoidance of errors can be achieved by performing QA methods already described in various reports and recommendations. These methods are discussed briefly. However, the reader is referred to the literature for detailed information [9-11, 14].

4.1. EVENTS RELATED TO DEVICE MALFUNCTION

4.1.1. Source not transferable to the target position

4.1.1.1. Issue

After initiating the source delivery mechanism, the source arrangement or the radio-opaque markers indicating the source position may not be angiographically visible at the target position. Source movement is obstructed mainly by kinks of the delivery catheter, closed haemostatic valve of the guiding catheter or production failures of the source channel inside the delivery catheter.

Example from US Nuclear Regulatory Commission (USNRC) reports:

A coronary brachytherapy of the intermediate artery was performed with a ^{90}Sr, 40 mm source train. The written directions called for a treatment time of 2 minutes and 52 seconds, which would result in a total dose of 18.4 Gy. The catheter had a kink near the proximal marked location which caused the source train to get stuck before the

distal portion of the catheter. This caused an unintended treatment of an area proximal to the treatment site. The source was observed out of position by panning the table and using the fluoroscopy tube, at this time the source was retracted. The source was in the patient for 2 minutes and 32 seconds, resulting in a total dose of 16.4 Gy.

Additional examples of the same type are reported by the USNRC. In one case, where radiation oncologist and cardiologist were not certain they could see the radio-opaque markers of the source the physicist performed a radiation survey and confirmed that the source train was in fact in the patient's chest. Only after an additional check by sending the source and opening the fluoroscopy field of view was the source train observed to be stuck at a bend in the patient's aortic arch.

4.1.1.2. Handling

The actual position of the source has to be verified by fluoroscopy. Documentation is possible with cine angiography. It is not possible to locate the source accurately with a radiation survey outside of the patient. In case the disagreement between actual to planned position cannot be corrected by further source movement, the source should be retracted into the delivery device. If using automatic controlled afterloading devices, the internal safety mechanism should retract the source automatically when encountering any resistance. Afterwards, there should be an inspection for possible obstructions in the delivery catheter. In case of visible kinks with the possibility of damage to the catheter, further treatment using the same catheter should be avoided, as there may be the possibility of its breaking.

4.1.1.3. QC methods

According to related reports and recommendations, the catheter integrity should be visually inspected prior to the catheter positioning and checked by test run using dummy source(s) [9, 10, 11, 14].

4.1.2. Source not retractable by standard mechanism with the necessity to use the emergency retraction system

4.1.2.1. Issue

In case of afterloading devices with an automatic source movement or a hand crank system, the breakdown of power backup, failures of the mechanism or obstructions in the catheter may prevent the return movement of the source.

4.1.2.2. Handling

Use the built-in emergency source retraction system to position the source inside the storage container of the delivery device. Every person not directly involved in the emergency procedure (e.g. nurses) should leave the room.

4.1.2.3. QC methods

Perform test of the emergency source retraction system including interrupt button, power backup and manual retraction facility [9,10,11,14].

4.1.3. Source lost inside the catheter with no possibility to retract it by any emergency retraction system

4.1.3.1. Issue

The source is located inside the catheter but all retraction facilities failed.

Example [reported by Univ. Dept. of Radiotherapy and Radiobiology, Vienna]:

> After performance of a coronary brachytherapy applying 18 Gy at 1 mm vessel depth with a treatment time of 3 minutes and 49 seconds, the 60 mm seed train was not retractable from the treatment position. An obstruction at the position of the proximal catheter marker prevented the source train from the return movement. The catheter was removed by the cardiologist, passed to the radiation oncologist who deposited it into the emergency container handled by the physicist. The catheter was picked up only at the most proximal part. Based on the reading of the treatment timer, the period between end of the treatment and closing of the emergency container was about 30 seconds. Personal dosimeter readings of the personnel involved showed no significant increase of the monthly dose.

4.1.3.2. Handling

The position of the sources should try to be located using X ray angiography. The catheter should be removed from the patient and placed inside the emergency container. Care should be taken to avoid touching the catheter near the active source. Emergency equipment (e.g. forceps, tongs and tweezers) should be used to move the catheter. Every person not directly involved in the emergency procedure (e.g. nurses) should leave the room.

4.1.3.3. QC methods

The same quality control procedures should be performed prior to the radiation treatment as described in the last two cases. A regular check of the emergency equipment functionality is recommended together with the advice to establish written radiological protection instructions and the need to practice these emergency procedures [9,10,11,14].

4.1.4. Source or parts of it lost inside the cath lab

4.1.4.1. Issue

The possibility of losing sources is present in case of malfunction of the coupling mechanism between delivery device and catheter or in case of a break in the delivery catheter or delivery device.

4.1.4.2. Handling

Use the emergency equipment (e.g. tweezers, tongs) to collect the missing parts of the source and put it into the emergency container. A careful survey of the whole room is essential to find any part of the source. Every person not directly involved in the emergency procedure (e.g. nurses) should leave the room. However, care should be taken of unintended movement of source parts outside of the room (e.g. monitor each person leaving the room).

4.1.4.3. QC methods

Catheter integrity should be checked and the missing catheter interlock mechanism performed on a regular basis [9, 10, 11, 14].

4.1.5. Source or parts of it lost inside the patient

4.1.5.1. Issue

In this worst-case scenario, the source is lost inside the blood circulation after break and leakage of the transfer mechanism and delivery catheter. This event has only a very low theoretical possibility. In case of cable driven afterloading devices there has to be a break of the cable and a leakage in the delivery catheter. In other cases the delivery catheter has to be severely damaged by applying high forces. A special case of this type of occurrence is contamination related to leakage of radioactive coated or filled balloons which is discussed in detail in section 5.

4.1.5.2. Handling

Highest priority is to prevent any occlusion of blood vessel by using intervention techniques performed by the interventionist. If surgery is the only solution to get the source, the radiological protection officer should supervise the radiological protection measures to be taken.

4.1.5.3. QC methods

Catheter integrity should be tested as outlined in the previous paragraphs.

4.1.6. Error of the dwell time calculation and the timer by integrated software

4.1.6.1. Issue

Some systems are equipped with internal utilities to calculate the treatment time based on the current source strength, the vessel diameter and the prescribed dose related to a certain vessel depth. In case of wrong basic data or software errors the treatment calculated and performed may be incorrect. Failures of the timer may result in wrong treatment times, too.

4.1.6.2. QC method

During the acceptance test, the dwell time calculation should be verified for various input parameters using a hand calculation based on the radial dose function provided. Timer accuracy and linearity is checked according to standard afterloading equipment [14].

4.2. EVENTS RELATED TO TREATMENT PLANNING

4.2.1. Mistakes during communication of relevant treatment parameters

4.2.1.1. Issue

In endovascular brachytherapy, the time between determination of the treatment parameters, treatment planning and application is very short compared to conventional brachytherapy for oncology treatments. Errors can be introduced by using unclear documentation and communication between different members of the team.

Example from USNRC:

> USNRC has received three misadministration reports involving overexposure caused by using improper dose calculation parameters. A brief summary of one of the three reported misadministrations, representative of them all, is provided below.

The patient's coronary artery was treated with the intra-vascular brachytherapy (IVB) device. The intended dose was 8 gray (Gy). During a review of dosimetry and physicians records, the licensee discovered that the diameter of the artery was used in the dose calculation, instead of the required radius of the artery. The licensee estimated that the dose to the outer portion of the patient's coronary artery was 14.6 Gy rather then the intended 8 Gy.

For each of the other misadministrations, a similar error resulted in estimated delivered doses of 12.5 Gy and 14.3 Gy for intended doses of 8 Gy.

Part of the following discussion provided by USNRC:

> Licensees are encouraged to consider whether potential for misadministration resulting from improper dose calculation parameters being used for IVB procedures exists at their facilities. If the potential does exist, one suggestion for reducing it would be to verify and clearly indicate, on forms used in treatment planning and/or written directives, whether the radius or diameter of the artery to be treated should be used for the dwell time (dose) determination.

4.2.1.2. Handling

Endovascular brachytherapy is based on a close cooperation between interventionists and experts from radiotherapy. The use of a common language is therefore highly recommended during the treatment and also for recording and reporting. Each person involved should know the definitions of the important parameters (e.g. intervention length,

margin for planning target length, reference isodose length, active source length, reference vessel diameter, reference depth and lumen dose [10]). An overview of the essential longitudinal parameters of some commercially available devices can be found in Ref. [17]. A written form for the dose prescription is to be filled by the authorized user prior to the initiation of irradiation [9].

4.2.2. Errors in treatment time calculation or the use of a look-up table

4.2.2.1. Issue

Treatment time can be calculated manually in the cath lab, taken from a look-up table which is prepared in advance or automatically by a computer assisted treatment planning system. Errors can be introduced by using wrong parameters as source strength, half-life, dates or mistakes during manual calculation.

Example from USNRC:

> During treatment of a patient 10.9 Gy of Ir-192 was administered to the patient, instead of the prescribed 8 Gy. It appears the misadministration was a direct result of the licensee utilizing an inaccurate decay chart to calculate dose.

4.2.2.2. Handling

In the case of manual afterloading devices without additional treatment planning software, dwell times are calculated manually. The calculation should be independently verified and signed by two different individuals [9,10]. In order to avoid calculation errors a look-up table can be used. This look-up table should be based on the vessel diameter, the prescribed dose at a certain depth and the activity. For short-lived nuclides these tables have to be printed out with the current source strength on each treatment day. However, the treatment time taken from a look-up table should be verified by a second person [10].

In case of treatment planning systems the recommendations for standard equipment used in radiotherapy are applicable (e.g. [14,18]).

4.3. EVENTS RELATED TO CALIBRATION AND DOSE DISTRIBUTION OF THE SOURCE

Accidental exposure can also be based on errors related to dosimetric errors as the calibration of the source, the homogeneity of the dose distribution and the actual depth dose curve. The recommendations given in Refs [9,10,11,14] provide detailed information on definitions, measurement methods and tolerance levels. In general tolerance levels are higher compared to conventional radiotherapy due to steep dose gradients and uncertainties of dose measurements close to the source (e.g. at 2 mm reference distance from the source axis). Especially, dosimetry of beta sources is not straightforward. Therefore tolerance levels for dose specification below +/- 10% (2SD) seem not to be achievable at present.

5. SPECIFIC ISSUES WITH UNSEALED SOURCES

A concept developed later during the introduction of new radiation devices for endovascular brachytherapy is the use of unsealed radioactivity with liquid-filled balloons. It allows homogenous dose delivery to the vessel wall in contrast to the use of wires where careful centring is essential. Centring of balloon occurs during inflation even in vessel bends. This approach combines the advantages of optimal energy transfer to the vessel wall and radiological protection aspects [19]. A number of radionuclides have been used (^{186}Rb, ^{133}Xe, ^{188}Re and ^{166}Ho); among these, a useful radionuclide is rhenium-188, which is available from the ^{188}W/^{188}Re generator system [20, 21]. Bone and bone marrow seeking radionuclides like ^{90}Y and ^{32}P cannot be used because of the high radiation absorbed dose to bone and bone marrow that would occur in the event of balloon rupture.

A disadvantage of the balloon technique is the occlusion of the vessel, which will be tolerated only for a limited time in the case of coronary arteries. However, the balloon can be easily deflated and irradiation can be fractionated depending upon the clinical status of the patient.

The main disadvantage is the risk of balloon rupture with resultant contamination of the patient. There is very low probability (<0.1%) of balloon rupture [22]. To minimize the radiation exposure in the event of balloon rupture, chelation with mercaptoacety-triglycine has been proposed, as this will ensure rapid renal elimination [23]. The total body absorbed dose is reduced to 10% by the chelation. Use of perchlorate has also been recommended. It has been shown that perchlorate will discharge perrhenate from the thyroid and the stomach resulting in reduction of effective dose to 38% compared with unblocked state [24]. Forced diuresis can further decrease the absorbed dose. Such combined therapy with perchlorate and forced volume diuresis has been used in a reported accidental radioactive ^{188}Re balloon leakage [25]. Due to a manufacturing defect at an adhesive joint on the catheter shaft just proximal to the balloon, 4 mCi ^{188}Re were released through a slow leak to the patient. Total body dose and individual organ dose estimated by the Committee on Medical Internal Radiation Dose (MIRD [26]) were 18 mGy or 10 mGy when calculated by using a kinetic model for ^{99m}Tc [24]. With the use of perchlorate, the chelating procedure may be unnecessary in view of effective discharge from the critical organs.

6. EXPOSURE LEVELS

In general, the exposure to the personnel during an endovascular brachytherapy is low compared to the exposure due to the X ray angiography. During treatments with a gamma-emitting source, the personnel usually leave the cath lab. Therefore the exposure to the personnel involved is limited to small time periods when deploying and retracting the radioactive source. Total effective dose per procedure was reported to be less than 10 μSv [27, 28, 29].

In case of beta-emitting sources, the bremsstrahlung generated inside the afterloading device is present during storage, transportation and handling of the device. Lead aprons usually worn in the cath lab provide some protection, except to the hands during handling of the device. The exposure due to beta particles is limited to a short time period when the source is travelling from the delivery device into the part of the catheter inserted into the introducer sheath [29]. The ambient dose equivalent is expected to exceed 1 mSv/h at locations of the involved personnel, but the time period is rather short, not exceeding a few seconds. However, according to the optimization principle, during this time period it is recommended to keep as large a distance as possible from the catheter [10]. Furthermore, this potential hazard has to be kept in mind in case of malfunction during the radiation treatment.

For liquid beta-emitting sources, the staff doses may be significantly higher, since one has to start with a higher activity of about 10 GBq for achieving 1 GBq in the balloon. This is because of remaining fluid in the connecting tubing and syringe. Thus, there is a need to ensure protection from bremsstrahlung as well as to have mechanisms to contain any spill of radioactive liquid. The latter is crucial since any spilled liquid will deliver substantial surface doses due to the beta activity [22] and can result in closure of the cath lab for a significant period of time. General recommendations for occupational radiation protection are given in [30].

6.1. DOSE LEVELS IN THE ROOM

The measurement of dose and dose rate (in terms of ambient dose equivalent) in the case of gamma-emitting sources can be performed using standard equipment. However, in the case of beta-emitting sources, radiological protection dosimetry is not straightforward. The Deutsche Gesellschaft fur Medizinische Physik (DGMP) recommends performing area dose rate measurements with ionization chambers, which after taking off the protective and/or build-up cap can also measure beta radiation. In order to react appropriately in case of emergency, it is also stated to have an operational, directly indicating, electronic dose/dose rate measuring device and a contamination monitor available during every endovascular brachytherapy procedure [11].

The American Association of Physicists in Medicine (AAPM) recommends monitoring the exposure levels around the patient/room during the procedure and to perform a radiological protection survey at the end of the procedure as mandated by state/federal regulations [9] in the USA. In the European Society for Therapeutic Radiology and Oncology

(ESTRO) recommendations, it is emphasized to perform such radiation surveys of the patient, the room and the delivery catheter before and after the treatment [10]. One measurement prior to the procedure determines the background level, which can be often increased due to the radiopharmaceutical existing in the patient from nuclear medicine imaging recently performed.

6.2. OCCUPATIONAL EXPOSURE

The occupational exposure monitoring involved in IVB is primarily done by personal dosimeters. The ESTRO and DGMP reports emphasize that partial body dosimeter (finger ring dosimeter) may be required in case of direct manipulation, emergency or handling devices with high dose rates on the device housing, in addition to the mandatory dosimeter for estimating whole body dose.

6.3. EXPOSURE OF THE PATIENT

Calculations described in the literature show a mean effective dose to the patient from gamma endovascular brachytherapy, which is comparable to the radiation dose from angiography [31]. The dose to organs at risk is also at the same order of magnitude as from the angiographic procedure. In case of proper use of endovascular brachytherapy the dose to the patient is comparable to the dose from angiography for gamma sources and much smaller for beta sources, respectively [29]. Although there is an additional radiation exposure to patients by this single treatment, the values are much smaller than those caused by second angiography in case of restenosis treatment.

7. EXISTING GUIDELINES RELATED TO DOSIMETRY AND RADIATION SAFETY

The first recommendations related to endovascular brachytherapy were published in 1999 in a report of the AAPM TG 60 (American Association of Physicists in Medicine Radiation Therapy Committee Task Group 60) [9]. This report is mainly focused on the physics related problems giving an overview of dosimetric studies available at that time, introducing a concept for dose specification and normalization and listing recommendations on quality assurance and safety aspects.

In the year 2000, the Netherlands Commission on Radiation Dosimetry (NCS) issued a report on quality control in brachytherapy including an overview of the current practice and minimum requirements [14]. A dedicated chapter deals with recommendations related to endovascular brachytherapy. It recommends detailed minimum test frequencies for safety aspects and physical parameters.

The endovascular (EVA) GEC (Groupe Européen de Curietherapie) ESTRO (European Society for Therapeutic Radiation Oncology) Working Group published in 2001 detailed recommendations on prescribing, recording and reporting endovascular brachytherapy treatments [10]. It introduces a concept for a common language in order to specify dimensions and dose of an endovascular brachytherapy treatment. Treatment planning and reporting is organized in a three level concept including basic requirements, advanced state of the art and developmental concepts for research purposes. In addition it covers quality assurance and radiation safety recommending general requirements. A dedicated section introduces a detailed concept of tasks and responsibilities of the different professions in endovascular brachytherapy.

A working group of the German Association for Medical Physics published in 2001 the DGMP (Deutsche Gesellschaft für Medizinische Physik) Report No.16 on Guidelines for Medical Physical Aspects of Intravascular Brachytherapy [11]. The content covers a detailed overview on prerequisites, radiological protection, quality management, treatment planning and documentation. In contrast to the previous reports it introduces more detailed regulations on requirements and procedures mandatory to perform endovascular brachytherapy.

Details related to calibration of photon and beta sources used in endovascular brachytherapy can also be found in the IAEA-TECDOC-1274 [12] and a forthcoming ICRU Report on ‘Dosimetry of beta ray and low energy photon brachytherapy sources’.

8. PERSONNEL, RESPONSIBILITIES AND TRAINING

Endovascular brachytherapy is a very multidisciplinary treatment. AAPM and ESTRO recommendations describe the working team for endovascular brachytherapy including (i) an interventionalist (e.g. interventional cardiologist, radiologist, angiologist), (ii) a radiation oncologist, (iii) a radiotherapy physicist and (iv) assisting personnel as radiation technologist, nurse and coordinator. Furthermore a health physicist or radiation safety officer is required, which may be the same person as the radiation physicist. It is his responsibility to inform and train all participants in the catheter lab about radiation emergency and radiological protection procedures. The physical aspects of the quality assurance programme should be followed under the direction of a qualified medical physicist [9]. The GEC-ESTRO recommendations present a concept for task and responsibilities for all the different professions [10]. The responsibility of the radiation oncologist for the procedure does not necessarily mean that he has to personally perform it in every application. Under well-defined conditions in routine applications some tasks may be delegated to co-workers. However, the physical presence of the radiation oncologist in the cath lab may be required by national regulations.

The development of a programme to regularly provide education and training on radiological protection to all staff members involved, including physicians, nurses, and ancillary personnel is recommended in view of the possibility of accidental exposure in endovascular brachytherapy. For the medical physicist, the DGMP report demands special education in radiological protection in the field of endovascular brachytherapy [11]. The EVA GEC ESTRO group recommends training in endovascular brachytherapy for all persons involved including basic knowledge in angiologic/cardiologic applications for radiation oncologist and physicist, whereas the interventionist should know about basics of brachytherapy, radiation therapy physics, radiological protection and radiobiology. A training concept including dedicated teaching courses is recommended by the ESTRO group [10].

The IAEA has developed training packages in the form of CDs containing PowerPoint slides for trainers. The CDs also include practical exercises, a trainer's manual, reference publications, questions and resources. The CDs on "Radiation Protection in Radiotherapy" and "Accident prevention in radiotherapy" (the latter still to be published) can be obtained by writing to patient.protection@iaea.org. Although not exclusively directed at endovascular brachytherapy, the concepts of radiation protection in radiotherapy are well covered.

9. CONTROL OVER RADIATION SOURCES AND MANAGEMENT OF RADIOACTIVE WASTE

BSS requirements for control and management of radiation sources are:

"Sources shall be kept secure so as to prevent theft or damage and to prevent any unauthorized legal person from carrying out any of the actions specified in the General Obligations for practices of the Standards, by ensuring that:

(a) control of a source not be relinquished without compliance with all relevant requirements specified in the registration or licence and without immediate communication to the Regulatory Authority, and when applicable to the relevant Sponsoring Organization, of information regarding any decontrolled, lost, stolen or missing source;

(b) a source not be transferred unless the receiver possesses a valid authorization; and

(c) a periodic inventory of movable sources be conducted at appropriate intervals to confirm that they are in their assigned locations and are secure."

At the end of the useful life of radiation sources or in the event they become disused, arrangements need to be adopted to ensure their safe management. In most cases, the company providing the devices manages the disposal of radioactive sources. For return of the source, the national legislative regulations for the transport of sources have to be fulfilled. In the event that this is not the case, the sources should be transferred to a radioactive waste management organization as soon as possible. If no such organization exists they should be stored under conditions approved by the regulatory authority.

In the case where unsealed sources are used and radioactive waste is generated, its management should be undertaken by a person with the recognised competence have to be stored after the application. However, most of the nuclides used for filled or coated balloons have a rather short half-life (e.g. ^{32}P, ^{188}Re) so that safe storage to allow decay before clearance is the best option. More detailed safety guidance on the management of such waste can be found in Safety Standard WS-G-2.7 [32].

10. LEGISLATIVE PROVISIONS

Endovascular brachytherapy is an accepted form of radiation therapy. All basic principles and safety standards for radiological protection for medical exposure tom ionizing radiation are applicable. General requirements are provided in Appendix II of the BSS [6] and some excerpts are provided in Annex II of this document. Guidance on meeting these requirements is described in chapter 5 of reference [33]. The standards for the calibration of sources, clinical dosimetry and treatment planning, quality assurance and training are fulfilled by existing and forthcoming recommendations introduced in chapter 7.

Regarding the legislative provisions relating to the regulatory control of radiation sources used in endovascular brachytherapy, no new provisions need to be introduced. Guidance on the regulatory control of radiation sources (the legal basis, development of regulations and guidance documents or codes of practice, authorization of radiation sources, inspection of facilities using radiation sources, and enforcement) is provided in reference [34].

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ANNEX I

DEFINITION OF TERMS

The IAEA has a Safety Glossary which can be accessed on the website http://www-ns.iaea.org/standards/safety-glossary.htm. It is quite extensive and applies to a variety of nuclear safety situations. For the purposes of this report, the terms below are defined as follows, in line with the BSS[1].

Potential exposure is exposure that may result from an accident due to an event or sequence of events of a probabilistic nature; the probability, while not negligible, is significantly less than one.

Normal exposure is exposure which is expected to be received under normal operating conditions, including minor mishaps or errors whose probability of occurring is not significantly less than one.

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

Medical exposures are exposures incurred by individuals in the course of diagnostic examinations or treatment and exposures (other than occupational) endured knowingly and willingly by individuals helping in the support and comfort of patients undergoing diagnosis treatment. Medical exposure also includes exposures incurred by volunteers participating in programmes of biomedical research.

Accident refers to any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

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

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

[1] Reproduced from IAEA, Safety Reports Series No. 17 [7].

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

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

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

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

Disposal

1. Emplacement of *waste* in an appropriate *facility* without the intention of retrieval.

- Some countries use the term disposal to include discharges of effluents to the environment.

! In many cases, the only element of this definition that is important is the distinction between disposal (with no intent to retrieve) and storage (with intent to retrieve). In such cases, a definition is not necessary; the distinction can be made in the form of a footnote at the first use of the term disposal or storage (e.g. "The use of the term disposal indicates that there is no intention to retrieve the waste. If retrieval of the waste at any time in the future is intended, the term storage is used.").

- In some states, the term disposal is used administratively in such a way as to include, for example, incineration of waste or the transfer of waste between operators. In Agency publications, disposal should only be used in accordance with the more restrictive definition given above.

! The term *disposal* implies that retrieval is not intended; it does not mean that retrieval is not possible.

- Contrasted with *storage*.

direct disposal: *Disposal* of *spent fuel* as *waste*.

geological disposal: *Disposal* in a *geological repository.*

near surface disposal: *Disposal*, with or without engineered *barriers*, in a *near surface repository*.

sub-seabed disposal: *Disposal* in a *geological repository* in the rock underlying the ocean floor.

2. [The emplacement of *spent fuel* or *radioactive waste* in an appropriate facility without the intention of retrieval.]

3. The act or process of getting rid of *waste*, without the intention of retrieval.

- The terms *deep sea disposal* and *seabed disposal* do not strictly satisfy definition (**1**) or (**2**), but are consistent with the everyday meaning of *disposal* and are used as such.

deep sea disposal: *Disposal* of *waste* packaged in *containers* on the deep ocean floor.

- As practised until 1982 in accordance with the requirements of the London Convention 1972.

seabed disposal: Emplacement of *waste* packaged in suitable *containers* at some depth into the sedimentary layers of the deep ocean floor.

- This may be achieved by direct emplacement, or by placing the waste in specially designed 'penetrators' which, when dropped into the sea, embed themselves in the sediment.

ANNEX II

MEDICAL EXPOSURE[2]

(Selected portions reproduced here)

II.1. Design considerations

II.1.1. General

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

(a) failure of a single component of the system be promptly detectable so that any unplanned medical exposure of patients is minimized; and

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

II.12. Registrants and licensees shall:

(a) take into account information provided by suppliers, to identify possible equipment failures and human errors that could result in unplanned medical exposures;

(b) take all reasonable measures to prevent failures and errors, including the selection of suitably qualified personnel, the establishment of adequate procedures for the calibration, quality assurance and operation of diagnostic and therapeutic equipment, and the provision to personnel of appropriate training and periodic retraining in the procedures, including protection and safety aspects;

(c) take all reasonable measures to minimize the consequences of failures and errors that may occur; and

(d) develop appropriate contingency plans for responding to events that may occur, display plans prominently, and periodically conduct practice drills."

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

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

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[2] Reproduced from the BSS (Appendix II, pp. 47-56) [6].

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

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

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

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

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

(g) exposure rates outside the examination or treatment area due to radiation leakage or scattering be kept as low as reasonably achievable." Requirements for radiation generators and irradiation installations for radiotherapy

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

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

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

(c) high energy radiotherapy equipment:

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

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

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

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

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

II.1.2. Calibration

II.19. Registrants and licensees shall ensure that:

(a) the calibration of sources used for medical exposure be traceable to a Standards dosimetry laboratory;

(b) radiotherapy equipment be calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions, e.g. following the recommendations given in IAEA Technical Reports Series No. 277[3];

(c) sealed sources used for brachytherapy be calibrated in terms of activity, reference air kerma rate in air or absorbed dose rate in a specified medium, at a specified distance, for a specified reference date;

(d) unsealed sources for nuclear medicine procedures be calibrated in terms of activity of the radiopharmaceutical to be administered, the activity being determined and recorded at the time of administration; and

(e) the calibrations be carried out at the time of commissioning a unit, after any maintenance procedure that may have an effect on the dosimetry and at intervals approved by the Regulatory Authority.

II.1.3. Clinical dosimetry

II.20. Registrants and licensees shall ensure that the following items be determined and documented:

(a) in radiological examinations, representative values for typical sized adult patients of entrance surface doses, dose-area products, dose rates and exposure times, or organ doses;

(b) for each patient treated with external beam radiotherapy equipment, the maximum and minimum absorbed doses to the planning target volume together with the absorbed dose

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Absorbed Dose Determination for Photon and Electron Beams, Technical Reports Series No. 277, IAEA, Vienna (1987).

to a relevant point such as the centre of the planning target volume, plus the dose to other relevant points selected by the medical practitioner prescribing the treatment;

(c) in brachytherapeutic treatments performed with sealed sources, the absorbed doses at selected relevant points in each patient;

(d) in diagnosis or treatment with unsealed sources, representative absorbed doses to patients; and

(e) in all radiotherapeutic treatments, the absorbed doses to relevant organs.

II.21. In radiotherapeutic treatments, registrants and licensees shall ensure, within the ranges achievable by good clinical practice and optimized functioning of equipment, that:

(a) the prescribed absorbed dose at the prescribed beam quality be delivered to the planning target volume; and

(b) doses to other tissues and organs be minimized.

II.1.4. Quality assurance for medical exposures

II.22. Registrants and licensees, in addition to applying the relevant requirements for quality assurance specified elsewhere in the Standards, shall establish a comprehensive quality assurance programme for medical exposures with the participation of appropriate qualified experts in the relevant fields, such as radiophysics or radiopharmacy, taking into account the principles established by the WHO[4,5,6] and the PAHO[7].

II.23. Quality assurance programmes for medical exposures shall include:

(a) measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter;

(b) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;

(c) written records of relevant procedures and results;

(d) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and

(e) as far as possible, regular and independent quality audit reviews of the quality assurance programme for radiotherapy procedures.

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[4] WORLD HEALTH ORGANIZATION, Quality Assurance in Diagnostic Radiology, WHO, Geneva (1982).

[5] WORLD HEALTH ORGANIZATION, Quality Assurance in Nuclear Medicine, WHO, Geneva (1982).

[6] WORLD HEALTH ORGANIZATION, Quality Assurance in Radiotherapy, WHO, Geneva (1988).

[7] PAN AMERICAN HEALTH ORGANIZATION, Publicación Científica No. 499, Control de Calidad en Radioterapia: Aspectos Clínicos y Físicos, PAHO, Washington, DC (1986).

II.1.5. Investigation of accidental medical exposures

II.29. Registrants and licensees shall promptly investigate any of the following incidents:

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

(b) any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels;

and

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

II.30. Registrants and licensees shall, with respect to any investigation required under para. II.29:

(a) calculate or estimate the doses received and their distribution within the patient;

(b) indicate the corrective measures required to prevent recurrence of such an incident;

(c) implement all the corrective measures that are under their own responsibility;

(d) submit to the Regulatory Authority, as soon as possible after the investigation or as otherwise specified by the Regulatory Authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the Regulatory Authority; and

(e) inform the patient and his or her doctor about the incident.

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