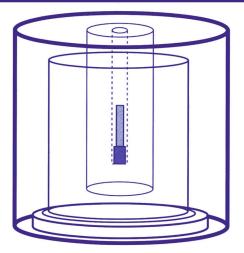
MEDICAL SCIENCE SERIES

# ACHIEVING QUALITY IN BRACHYTHERAPY B R THOMADSEN





## ACHIEVING QUALITY IN BRACHYTHERAPY

#### Other books in the series

Medical Physics and Biomedical Engineering B H Brown, R H Smallwood, D C Barber, P V Lawford and D R Hose

Biomedical Magnetic Resonance Technology C-N Chen and D I Hoult

Rehabilitation Engineering Applied to Mobility and Manipulation R A Cooper

Physics for Diagnostic Radiology, second edition P P Dendy and B H Heaton

Ultrasound in Medicine F A Duck, A C Baker and H C Starritt (eds)

Linear Accelerators for Radiation Therapy, second edition D Greene and P C Williams

Health Effects of Exposure to Low-Level Ionizing Radiation W R Hendee and F M Edwards (eds)

Monte Carlo Calculations in Nuclear Medicine M Ljungberg, S-E Strand and M A King (eds)

Introductory Medical Statistics, third edition R F Mould

The Physics of Medical Imaging S Webb (ed)

The Physics of Three-Dimensional Radiation Therapy: Conformal Radiotherapy, Radiosurgery and Treatment Planning S Webb

The Physics of Conformal Radiotherapy: Advances in Technology S Webb

The Design of Pulse Oximeters J G Webster (ed)

Of related interest:

Prevention of Pressure Sores J B Webster (ed)

Limited availability:

**The Physics and Radiobiology of Fast Neutron Beams** D K Bewley

**Radiation Protection in Hospitals** R F Mould

RPL Dosimetry-Radiophotoluminescence in Health Physics J A Perry

Medical Science Series

# ACHIEVING QUALITY IN BRACHYTHERAPY

Bruce Thomadsen

Departments of Medical Physics and Human Oncology, University of Wisconsin-Madison



CRC Press is an imprint of the Taylor & Francis Group, an informa business

#### © IOP Publishing Ltd 2000

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without the prior permission of the publisher. Multiple copying is permitted in accordance with the terms of licences issued by the Copyright Licensing Agency under the terms of its agreement with the Committee of Vice-Chancellors and Principals.

Institute of Physics Publishing and the author have made every possible attempt to find and contact the original copyright holders for any illustrations adapted or reproduced in whole in the work. We apologize to copyright holders if permission to publish in this book has not been obtained.

#### British Library Cataloguing-in-Publication Data

A catalogue record for this book is available from the British Library.

ISBN 0750305541

#### Library of Congress Cataloging-in-Publication Data are available

Series Editors: C G Orton, Karmanos Cancer Institute and Wayne State University, Detroit, USA J G Webster, University of Wisconsin-Madison, USA

Production Editor: Al Troyano Production Control: Sarah Plenty and Jenny Troyano Commissioning Editor: Kathryn Cantley and Ann Berne Editorial Assistant: Victoria Le Billon Cover Design: Jeremy Stephens Marketing Executive: Colin Fenton

Published by Institute of Physics Publishing, wholly owned by The Institute of Physics, London

Institute of Physics Publishing, Dirac House, Temple Back, Bristol BS1 6BE, UK

US Office: Institute of Physics Publishing, The Public Ledger Building, Suite 1035, 150 South Independence Mall West, Philadelphia, PA 19106, USA

Typeset in LATEX using the IOP Bookmaker Macros

The *Medical Science Series* is the official book series of the International Federation for Medical and Biological Engineering (IFMBE) and the International Organization for Medical Physics (IOMP).

#### IFMBE

The IFMBE was established in 1959 to provide medical and biological engineering with an international presence. The Federation has a long history of encouraging and promoting international cooperation and collaboration in the use of technology for improving the health and life quality of man.

The IFMBE is an organization that is mostly an affiliation of national societies. Transnational organizations can also obtain membership. At present there are 42 national members, and one transnational member with a total membership in excess of 15 000. An observer category is provided to give personal status to groups or organizations considering formal affiliation.

#### Objectives

• To reflect the interests and initiatives of the affiliated organizations.

• To generate and disseminate information of interest to the medical and biological engineering community and international organizations.

• To provide an international forum for the exchange of ideas and concepts.

• To encourage and foster research and application of medical and biological engineering knowledge and techniques in support of life quality and cost-effective health care.

• To stimulate international cooperation and collaboration on medical and biological engineering matters.

• To encourage educational programmes which develop scientific and technical expertise in medical and biological engineering.

#### Activities

The IFMBE has published the journal *Medical and Biological Engineering and Computing* for over 34 years. A new journal *Cellular Engineering* was established in 1996 in order to stimulate this emerging field in biomedical engineering. In *IFMBE News* members are kept informed of the developments in the Federation. *Clinical Engineering Update* is a publication of our division of Clinical Engineering. The Federation also has a division for Technology Assessment in Health Care.

Every three years, the IFMBE holds a World Congress on Medical Physics and Biomedical Engineering, organized in cooperation with the IOMP and the IUPESM. In addition, annual, milestone, regional conferences are organized in different regions of the world, such as the Asia Pacific, Baltic, Mediterranean, African and South American regions.

The Administrative Council of the IFMBE meets once or twice a year and is the steering body for the IFMBE. The Council is subject to the rulings of the General Assembly which meets every three years. For further information on the activities of the IFMBE, please contact Jos A E Spaan, Professor of Medical Physics, Academic Medical Centre, University of Amsterdam, PO Box 22660, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands. Tel: 31 (0) 20 566 5200. Fax: 31 (0) 20 691 7233. E-mail: IFMBE@amc.uva.nl. WWW: http://vub.vub.ac.be/~ifmbe.

#### IOMP

The IOMP was founded in 1963. The membership includes 64 national societies, two international organizations and 12 000 individuals. Membership of IOMP consists of individual members of the Adhering National Organizations. Two other forms of membership are available, namely Affiliated Regional Organization and Corporate Members. The IOMP is administered by a Council, which consists of delegates from each of the Adhering National Organization; regular meetings of Council are held every three years at the International Conference on Medical Physics (ICMP). The Officers of the Council are the President, the Vice-President and the Secretary-General. IOMP committees include: developing countries, education and training; nominating; and publications.

#### Objectives

• To organize international cooperation in medical physics in all its aspects, especially in developing countries.

• To encourage and advise on the formation of national organizations of medical physics in those countries which lack such organizations.

#### Activities

Official publications of the IOMP are *Physiological Measurement*, *Physics in Medicine and Biology* and the *Medical Science Series*, all published by Institute of Physics Publishing. The IOMP publishes a bulletin *Medical Physics World* twice a year.

Two Council meetings and one General Assembly are held every three years at the ICMP. The most recent ICMPs were held in Kyoto, Japan (1991), Rio de Janeiro, Brazil (1994) and Nice, France (1997). The next conference is scheduled for Chicago, USA (2000). These conferences are normally held in collaboration with the IFMBE to form the World Congress on Medical Physics and Biomedical Engineering. The IOMP also sponsors occasional international conferences, workshops and courses.

For further information contact: Hans Svensson, PhD, DSc, Professor, Radiation Physics Department, University Hospital, 90185 Umeå, Sweden. Tel: (46) 90 785 3891. Fax: (46) 90 785 1588. E-mail: Hans.Svensson@radfys.umu.se.

This book is dedicated to Lucille DuSault, who taught me that the care of the patient always comes first, and Arthur Sweet, who taught me the value of quality.



### CONTENTS

	PREF	FACE		xiii
1			ONSIDERATIONS IN QUALITY MANAGEMENT IN	1
DK	АСН 1.1	(THERAPY		
	1.1	nce of quality assurance	1	
	<ul><li>1.2 Principles of quality assurance</li><li>1.3 Error</li></ul>			2
	1.5	1.3.1	Sustantia	8
		1.3.1	· · · · · · · · · · · · · · · · · · ·	8
	1.4		Random error	8
	1.4	Error re		8
		1.4.1	Error prevention Error detection	8
		1.4.2		11
	1.5			12
	1.5	Training		13 16
		Staffing		
	1.7 Items not covered			
	1.8 1.9	85		
		Sources for information		
	1.10		performance implications for quality management	20
	1.11	Summa	ry	20
2	QUA	LITY M	ANAGEMENT FOR MANUAL LOADING,	
LOW DOSE RATE BRACHYTHERAPY SOURCES				
	2.1	Sources	for a permanent inventory	21
		2.1.1	Acceptance tests	21
		2.1.2	Periodic tests	33
	2.2	Sources	ordered for particular patients	36
		2.2.1	Integrity	37
		2.2.2	Linear uniformity-wire (not seeds, which are too short	
			to matter)	37
		2.2.3		37
		2.2.4	Penetration and dose distribution	40
	2.3 Summary			

3	QUALITY MANAGEMENT FOR A TREATMENT PLAN				
	3.1	Evaluating whether the plan contains errors			
		3.1.1	Direct checks on the input data	42	
		3.1.2	Does the plan make sense?	52	
		3.1.3	Indirect checks on the input data	53	
	3.2	Evaluating the appropriateness of the plan			
		3.2.1	Concerns in evaluating the appropriateness of a treatment		
			plan	55	
		3.2.2	Tools	59	
	3.3	Summa	ary	76	
4	QUA	LITY M	IANAGEMENT FOR MANUALLY LOADED,		
LC	W DO	DSE RAT	TE APPLICATIONS	78	
	4.1	Applica	ations involving sources from a standing inventory	78	
		4.1.1	Source loading	78	
		4.1.2	Calculation of the removal time	80	
		4.1.3	During the treatment	81	
		4.1.4		82 t 82	
	4.2	Applications involving temporary sources ordered for the treatment			
		4.2.1		82	
		4.2.2	Calculation of the removal time	86	
		4.2.3	During the treatment	87	
		4.2.4	At the removal	88	
	4.3	Applications involving sources ordered for a permanent implant		88	
		4.3.1	Source strength check	88	
		4.3.2	Source position checks	89	
	4.4	Implants using radium or caesium needles			
	4.5	Summa	агу	95	
5	QUALITY MANAGEMENT FOR HIGH DOSE RATE UNITS 9				
	5.1	Periodi	c evaluations (at the beginning of each treatment day)	98	
		5.1.1	Safety checks	99	
		5.1.2	Dosimetry checks	101	
	5.2	Initial of	checks	114	
		5.2.1		114	
			Dosimetry checks	115	
		5.2.3	Ancillary device checks	117	
	5.3		ance testing and commissioning	119	
		5.3.1	Operation	119	
		5.3.2	Detection of obstructions	119	
		5.3.3	Source retraction—automatic (emergency)	120	
		5.3.4	Source retraction-manual	120	
		5.3.5	Loss of source	120	

		Contents	xi	
	5.4	Checks during treatment	120	
	5.5	Checks after treatment		
	5.6	Summary		
			121 122	
6	QUALITY MANAGEMENT FOR HIGH DOSE RATE TREATMENT			
PL	ANS		126	
	6.1		127	
			128	
			128	
			128	
	6.2		128	
		1 1 ,	129	
			144	
			145	
	6.3		147	
		, , , , , , , , , , , , , , , , , , , ,	147	
			150	
			152	
	6.4		155	
	6.5	•	157	
		Appendix 6A. Some recommendations from the report of Task		
		Group 59 of the American Association of Physicists in Medicine	158	
7		LITY MANAGEMENT FOR LOW AND MEDIUM DOSE RATE		
RE			161	
	7.1		162	
		1 1	163	
	7.2		166	
	7.2		168	
			170	
			171	
		7.2.3 Procedural quality considerations with basic remote	174	
			174	
		reported operational problems with EDR remote	175	
	7.3		176	
	7.4		176	
	7.5		178	
8	QUA	LITY MANAGEMENT FOR BRACHYTHERAPY APPLIANCES	179	
	8.1		179	
			180	
	8.2	Intraluminal applicators	192	

	8.3	8.3 Interstitial equipment				
	0.5	8.3.1	Source-holding needles	193 193		
		8.3.2		196		
				200		
		8.3.3		200		
		8.3.4				
	8.4			204		
		8.4.1	-7-11	205		
		8.4.2		206		
		8.4.3	Intraoperative applicators	207 207		
	8.5	Summary				
9	OUA	LITY N	IANAGEMENT FOR DOSIMETRIC TREATMENT			
PL		NNING				
	9.1	Localization		211		
		9.1.1	Radiographic localization	212		
		9.1.2	Sectional localization	218		
		9.1.3	Ultrasound localization	221		
		9.1.4	Source simulation	222		
	9.2	Dose calculation		225		
		9.2.1	Digitization	227		
		9.2.2		228		
		9.2.3	Dose calculation	228		
		9.2.4	Plan output	235		
	9.3	Summ		237		
			dix 9A	237		
	REF	REFERENCES				
	INDEX					
	INDI	CA		247		

Planning is important. Planning is important. The plan is useless, but the planning is essential.

Dwight D Eisenhower

#### Is this a quality assurance manual or isn't it?

Certainly this book is a quality assurance manual. As such, it provides the reader with the steps for establishing a functional quality assurance programme in brachytherapy. However, those steps begin well before a check-off list of what to do for what type of case. The most important, and efficacious, steps address determining what the reader's particular facility really needs in terms of quality control and quality assurance-that is, creation of a quality management programme. No one has time and resources for a totally comprehensive quality control and assurance programme. Fulfilling the recommendations of some professional organizations would take sizeable increases in the staffing of many radiotherapy departments. Handling the job without abandoning other equally important tasks requires an analysis (and recognition) of a given facility's weaknesses, and building a programme to complement those areas, putting resources where they are most likely to prevent errors. Unfortunately, many regulatory bodies require practitioners to perform quality control procedures checking systems that have never failed, simply because they seem like important checks. The abstract and isolated list of checks may prevent some mistakes, but most erroneous treatments (that are noticed) happen in the face of a quality assurance programme. The problem usually is that the programme fails to address the realities of how the particular department functions. Related to the quote above, when things go astray (as they will), the plan, even the plan for what to do when things go wrong, usually is worthless. However, having gone through the planning gives an understanding of the situation that allows one insights for dealing impromptu with unexpected problems. Instead of simply giving lists of items to check (the reader can find those in the Task Group reports of the American Association of Physicists in Medicine listed in the references), this book suggests an approach to quality management, and provides discussion of the means and techniques for execution of a programme of quality control and assurance.

#### xiv Preface

Most of the work presented in this text comes from other excellent persons devoted to achieving quality in brachytherapy. Notably, as seen from entries in the references, this author owes much to Jeffrey Williamson, Gary Ezzell and Eric Slessinger. Sankara I Ramaswamy spends his time working on quality instead of writing about it, and shared important pearls with me. In the compilation of this book, several companies provided figures that helped to clarify the sometimes rambling prose: Best Medical International, Medical Radiation Devices, Inc., Bill Kan, Mick RadioNuclear Instruments, Nucletron, Standard Imaging, 3M Company and Varian Associates. Much of my interest in the subject comes from interactions with co-workers who investigate cases with very serious shortages of quality: Judith Stitt, Barrett Caldwell, Rebecca McConley, Tonia Anderson, Partick Learnmerich and Andrew Kapp. Bhudatt Paliwal lent encouragement and expertise during this writing. Of paramount essence in the production of this book was the support, most of all, of my wife, Dr Nancy Thomadsen. I would particularly like to thank my father-in-law, Arthur Sweet, the former Quality Control Supervisor with the State of Wisconsin, who inspired me to learn the difference between quality control and quality assurance, and their basic principles.

> Bruce Thomadsen Madison, WI, September 1999

### **CHAPTER 1**

### GENERAL CONSIDERATIONS IN QUALITY MANAGEMENT IN BRACHYTHERAPY

#### 1.1. IMPORTANCE OF QUALITY ASSURANCE

Chances are that the reader, having picked up this book and gotten this far, needs no convincing that quality assurance, QA, serves an indispensable role in preventing patient injury and minimizing down time for the equipment used. Appreciation for the value of QA frequently follows some disaster that easily could have been avoided by a simple check beforehand. In many facilities, the quality assurance programme for brachytherapy seems driven by compliance with governmental regulations. Such a focus misses the opportunity to customize the programme to the individuality of the clinical practice, and may well fall short in important items not covered by laws and rules.

This text discusses programmes for assuring the quality of patient treatments in brachytherapy in considerable detail. Perhaps not all points discussed apply to all practices. The discerning readers will consider each point and decide the relevance in their own situation. Probably no institution will include all evaluations in this text in its routine procedures: doing so would simply consume too many resources and take too much time. The economics of the real world limits the efforts toward assuring quality and assuring that the treatment execution follows the therapeutic intentions. However, one mistake may cost a hospital millions of dollars in both legal fees and settlements, while a small fraction of this cost directed into effective quality assurance could avoid the expenses and detrimental publicity of such an event.

Values inherent in an effective quality assurance programme often evade monetary determination, but include peace of mind for the participants in the clinical procedure and mean that the treatments patients receive seldom deviate far from the ideal.

#### 1.2. PRINCIPLES OF QUALITY ASSURANCE

Medical physicists generally have definite ideas about what quality assurance means. However, quality assurance constitutes a major field of study itself, outside the medical physics arena. Only of late have general quality considerations and the principles of quality assurance invaded medical practice, but they have done so in a major way, frequently applying quality control measures from industry in inappropriate manners. A familiarity with the more general conceptions regarding quality helps persons crafting a programme for application in their facility.

Terminology plays an important part in sorting out the various facets of this topic. Below follow some common terms:

#### Quality management

'All activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance, and quality improvement ...' (ISO 1994). The goal of quality management is to achieve a desired level of quality.

#### Quality assurance

"... The activity of providing the evidence needed to establish confidence... that the quality function is being effectively performed' (Gryna 1988). Equivalently, 'quality assurance is: all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfil requirements for quality' (ASQC 1998). The goal of quality assurance is to demonstrate quality.

#### Quality control

'The operational techniques and activities used to fulfill requirements for quality' (Gryna 1988). Quality control (QC) consists of the tools used to meet the desired level of quality. QC follows the general process of (Juran 1988, p 2.9):

- (1) Evaluating actual operating performance.
- (2) Comparing actual performance to goals.
- (3) Acting on the difference.

Much of what medical physicists call quality assurance falls more in the realm of quality control by these definitions. The American Society of Quality Control (1998) notes, '... often, however, "quality assurance" and "quality control" are used interchangeably, referring to actions performed to ensure the quality of a product, service, or process.' In fact, the Standards for Laboratory Accreditation of the College of American Pathologists (CAP 1987) include requirements for a 'Quality Assurance program to monitor and evaluate quality and appropriateness... [and]

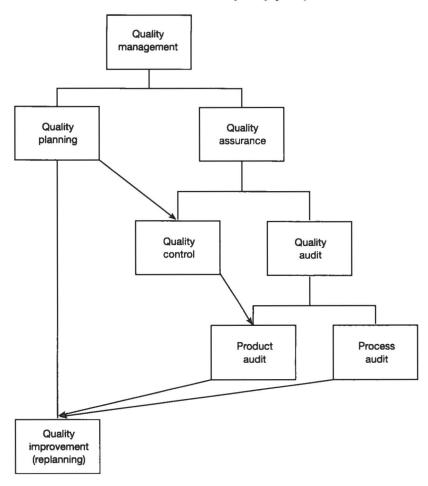


Figure 1.1. A diagram of a sample quality management programme.

identify and resolve problems,' and 'Quality Control that demonstrates the reliability of data'. Obviously, the two concepts share many features, and it often becomes unclear whether a particular action serves to control or demonstrate quality. To a great extent, the confusion obscures distinctions that clarify organizing processes. Since any discussion hinges on understanding the terminology, this text will try to follow the definitions above, where applicable.

A sample organization for quality management (QM) might look like figure 1.1. The first step, and one essential to the success of the process, consists of quality planning, setting out the methods and procedures to lead to high quality treatments.

#### 4 General considerations in quality management in brachytherapy

Part of this planning process includes deciding how to define 'high quality treatments'. Defining 'quality' proves challenging at best. Contemplation of this question drives Phaedrus, a college instructor who wants to teach his students quality, to a nervous breakdown in *Zen and the Art of Motorcycle Maintenance* (Pirsig 1974). Phaedrus notes that, while quality evades definition, everyone has a sense for what things are high quality and what are low. Unfortunately, trying to establish procedures for ensuring quality without clearer ideas of a target goal could drive us crazy also. Juran, observing that quality has multiple meanings, suggests two as most applicable in this context:

- 'Quality consists of those product features which meet the needs of the customer...'.
- (2) 'Quality consists of freedom from deficiencies' (Juran 1988, p 2.6).

He also observes that some define quality as conformance to standards or specifications. For brachytherapy, these lead us to defining quality as meeting the needs of the patient<sup>1</sup>, remaining free from errors and satisfying the prescription, both as explicitly written and as implied.

Quality planning begins with decisions for each patient or type of patient regarding the needs for adequate and accurate treatment. The dose accuracy required varies with the tumour type and target site, and often with the treatment approach. These deliberations obviously require input from the physician involved with the treatment, but to a great extent rest with the medical physicist. Task Group 56 of the American Association of Physicists in Medicine (AAPM TG56 1997) recommends the following tolerances for brachytherapy delivery:

Positional accuracy:  $\pm 2$  mm with respect to the appliance.

*Temporal accuracy*:  $\pm 2\%$  for remote afterloaders (although all do much better, and manually loaded low dose rate cases have no problem in bettering this by a factor of 10).

Source-strength calibration accuracy:  $\pm 3\%$ .

Dose calculation accuracy:  $\pm 2\%$ .

Dose delivery accuracy: 5-10%.

The next step in quality planning entails developing the quality control procedures necessary to ensure both generation of a treatment plan that satisfies the patient needs, as reflected in the prescription, and accurate delivery of the plan. While the prescription serves as the primary documentation of the ideal objectives for the treatment plan, the physician probably desires more than actually written. Details of uniformity of the dose distribution, limits on doses to neighbouring structures

<sup>&</sup>lt;sup>1</sup> While the medical physicist's customer in the business sense may be the physician, the view of quality management through this book focuses on the quality of the therapy delivered to the patient. The truly business aspects of quality management, as addressed in most of the quality management literature, will be left to other texts.

and dose gradients near the edges of the target volume often arise in discussion or follow some understanding derived through previous interactions between the physician and the medical physicist. Limitations on the whole treatment process, such as maximum times patients remain under anaesthesia, may play major roles in the treatment system. Part of quality planing includes establishing mechanisms by which all these parameters that delimit the treatment find accounting in the planning and delivery process.

Along the way through the treatment process, there should be tests and checks to assess that the process is proceeding properly and headed toward the correct outcome. Such tests include checks on the sources or equipment used for an application and evaluations of treatment plans. In part, these checks form quality control because they help direct the individual treatment to the successful outcome; however, they also become part of quality assurance since they demonstrate the correctness of the treatment.

An important and underutilized part of quality assurance is the quality audit. The quality audit consists of an independent review of the quality management programme. The independence of the persons performing the review allows recognition of weaknesses in procedures that the persons involved cannot see. If the facility will not bring in an outside expert to review the programme, an internal review provides some information on the quality of the brachytherapy programme ... if the review looks with care at all aspects of the programme from the beginning to the end and compares each step to some generally accepted standard. Even with those provisos, an outside reviewer's perspective provides vastly superior recommendations (the inside team should have already implemented their ideas) and more credible support for establishing confidence in the quality of the programme (either by verifying the high quality of the programme or pointing to items needing improvement, or both). The auditors need the assistance and cooperation of the personnel at the facility, and the persons undergoing the audit should realize that, while receiving the critique may register as unpleasant, the audit facilitates improvement.

Aside from the external (even if conducted with internal personnel) quality audit as just described, the facility should also have an ongoing internal quality audit programme as part of quality assurance. This audit periodically reviews the quality control records of the treatments, looking for errors and trends indicative of potential for errors.

The quality audit contains two distinct parts: the process audit and the product audit. For brachytherapy the process audit entails analysis of the procedures followed through brachytherapy cases, covering all aspects of each type of treatment used. The auditor needs not only to be familiar with the customary approaches to the treatments, but also to understand the physics and clinical bases for the treatments to evaluate the justifications for, and ramifications of, deviations from customary procedures.

A product audit reviews a sampling of cases to assess whether the case achieved the objective specified. Such a review may involve an independent recalculation of doses, verification of treatment durations and inspection of prescriptions and inventory records. Depending on the activity of the facility under review, the review may look at all records or just a sampling. The aim of the product audit is to determine the probable 'failure rate', that is, the frequency with which the treatment differs from the intentions, and the seriousness of such discrepancies.

In figure 1.1, the plain lines connecting the boxes indicate the hierarchical relationships between the parts of the quality management programme. The arrows indicate where the output of a process becomes the input into a different process. As discussed above, part of quality planning entails determining the quality control procedures. Review of the quality control records forms an important part of the product audit. The results of the quality audits (both internal and external) provide the basis for quality improvement, i.e., quality re-planning to correct and amend the process to improve the quality of the treatments. Quality re-planning should include all players in the process: not that everyone's concerns can or should be met, but they should be considered.

The foregoing discussion has applied the concepts of quality management to brachytherapy. Of late, these concepts, as developed for industry, have found regulatory or accreditation organizations applying them almost directly to medical settings, frequently inappropriately. Several aspects differentiate the industry and medical situations.

• Goal

The goal, sometimes referred to as the mission, of an industry is to make a profit; the goal in health care is to relieve the pain and suffering of the patient. This difference in viewpoint changes the interpretation of the quality concepts. Some of the applications of quality management in medicine have been generated through health-care administrators, and, unfortunately, retain much of the profit-oriented aspects associated with industrial settings.

• Tolerance for error

In industry, as in medicine, quality comes with a cost. Figure 1.2 shows the relationship between the cost for a product and the assured quality for the product. In the figure, very poor quality comes with a high cost. In industry, these costs may correspond to replacement of parts in the field, liability and loss of customers. On the other side, extremely high quality also entails a high cost, from multiple inspections, production waste due to rejection or increased time in manufacture. The diagram implies that, for an industry, a minimum in the cost exists between the cost of failure and that of quality, and operating in that minimum maximizes profit. This approach considers a certain level of failure as acceptable. Brachytherapy procedures follow the same type of curve. Some level of error falls into the class of 'inconsequential', such as a 1 mm displacement in the dose distribution or a 1% discrepancy in the dose to a point. However, for the most part, medical procedures can accept very few failures, particularly as judged from the

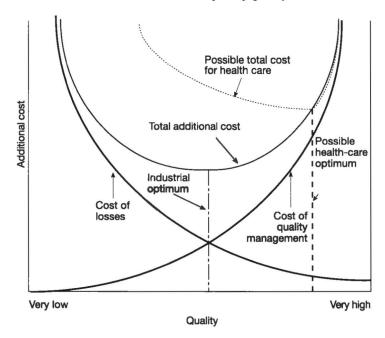


Figure 1.2. The cost in addition to that just to deliver health care due to losses secondary to poor quality and to provide quality management. The chain line (- - -) shows the optimum balance between the two additional costs appropriate for industry, while the dotted line falls at a balance more appropriate for health care.

perspective of the customer (patient). As a result, medicine operates far to the right on the curve, well above the minimum, and that, in part, accounts for the high cost of health care. Some analyses redraw the curve including litigation costs secondary to errors as the dotted line in the figure, arguing that medicine actually does operate in a minimum. This argument assumes that the only reason medical persons perform carefully is to avoid a lawsuit (or regulatory fines etc), ignoring that the parties involved enter the field to improve patient care. While no facility can afford to operate on the extreme right-hand side of the curve, medical operations find the balance differently than industry.

Separation of roles

Industries often consist of one team that produces the product, and a second team assigned to quality assurance. While this concept certainly plays an important role in medicine (as discussed under general quality control concepts), the same person often performs much of the quality control and quality assurance in medical settings.

#### 8 General considerations in quality management in brachytherapy

Many innovations that work well in some industrial settings would prove disastrous in medicine. Take, for example, 'just-in-time' supplies, where supplies for an industrial operation come to a station just as they are needed. This minimizes the cost of storage and maintaining an inventory of parts, but in medicine a failure in the system could leave a patient without life-supporting care. Cross training may serve a function in industrial flexibility, but treating patients requires great expertise and experience.

#### 1.3. ERROR

Any error can compromise the accuracy of treatment; an inaccuracy in treatment delivery results from an error. Errors generally fall into two categories: systematic or random.

#### 1.3.1. Systematic error

Systematic errors stem from mistakes or errors in the general operation of a process. In brachytherapy, such errors include inappropriate algorithms in the treatment planning system, incorrect distances measured for localization radiography equipment or mistakes in establishing the calibration factors for the well chamber used for assaying sources. Errors of this sort affect all patients. Acceptance testing and commissioning should uncover these problems. Failure to ensure the accuracy of all the basic systems leads to general degradation of quality through all treatments.

#### 1.3.2. Random error

Random errors include mistakes made during the process of an individual patient. Prevention of random errors follows the discussion below on error prevention. Almost all random errors stem from human errors.

#### 1.4. ERROR REDUCTION

The quality assurance programme should employ both approaches to error reduction: error prevention and error interception.

#### 1.4.1. Error prevention

For high dose rate brachytherapy (HDRB) treatment planning, error prevention amounts to reduction in the probability of errors in the input data entered into the treatment planning computer or treatment unit. The three techniques below help prevent errors from entering the data: *protocols, forms* and *a second person*.

*1.4.1.1. Protocols.* A protocol simply provides a formalized, standard set of expectations and procedures. When all persons involved follow a protocol, deviations from the protocol stand out as possible mistakes and items calling for investigation before proceeding to execution of the treatment. Some examples illustrate the variety protocols take.

#### Dose protocols

Doses prescribed for a given cancer often depend on the stage, grade or location of the disease. During treatment planning, the planner checks the prescribed dose and compares that dose to that listed in the protocol. For a cervical cancer treatment, for example, an application on a particular day may provide especially good separation between the uterus and the bladder and rectum. In response to such a good application, the physician might increase the dose for that day's fraction. However, such deviations from the expected value should lead the planner to question the prescription. The question not only entails whether the variant prescription accurately reflects the physician's intention, but how the physician determined the value, and how this prescription affects subsequent fractions. Unlike blindly fulfilling the prescription, the check on the correctness of the prescription provides protection for the physician against a mistaken prescribed dose.

#### Data-recording protocols

Endobronchial insertions using two catheters present the possibility that the identity of the catheters may at some time become confused or switched. As an example, faced with one catheter in the right lung and one in the left, there is no particular reason to expect the catheters to exit the patient from the nostril on the same side. The treatment for each catheter may fall at different locations along the catheter, with different length catheters, and possibly use different radial treatment distances or doses. To avoid confusion, the University of Wisconsin employs the following protocol for identifying the catheters:

- (1) If the two catheters fall on different sides, the one on the patient's right uses the marker set indicating catheter 1, and the one on the patient's left uses the marker set indicating catheter 2.
- (2) If the two catheters lead to bronchi on the same side, the more upper lobe catheter uses the marker set indicating catheter 1, and the more lower lobe catheter uses the marker set indicating catheter 2.
- (3) If the two catheters fall on different sides, and the one on the left is in a more upper lobe than the one on the right, differentiation with respect to patient's side takes priority.
- (4) The identity of the catheters is determined under fluoroscopy by inserting a marker train into only one catheter. The end of the identified catheter outside the patient is marked with tape and the appropriate catheter number. Then the correct marker trains are inserted into each catheter.
- (5) A second person verifies the identity of the two catheters.

#### 10 General considerations in quality management in brachytherapy

#### Variations from protocols

Not uncommonly, patients present with situations that fall outside normal expectations, and procedure specified in a protocol proves incompatible with the objectives of the treatment. Facilities must allow some freedom and flexibility to accommodate the realities of clinical operations. Even so, departures from protocols should follow a protocol on departures. Failure to provide guidance during variations and departures invites miscommunications, errors and injuries. For example, part of the protocol given above for identification for two-catheter endobronchial applications includes procedures to follow during deviations:

- (1) If the expected identification routine proves inadequate, inappropriate or infeasible to apply, the person performing the identification must contact another person knowledgeable of the identification procedure to verify the validity of, and witness, the procedure used.
- (2) The method of identification shall be written in the patient's chart.
- (3) The identity of the catheters shall still be verified under fluoroscopy, and the catheters marked with tape at the patient's nostrils.
- (4) The results of the identification shall be written in the patient's chart.
- (5) The person performing the identification shall discuss the variance in the identification procedure and the results directly with the person performing the treatment plan.

1.4.1.2. Forms. The use of data forms serves several functions. The forms prevent lapses: omission of data due to momentarily forgetting what information the procedure requires. The guidance a form provides also helps prevent unintentional departures from protocols. By forcing the person taking the data to write information, the information, partially at least, is mentally processed. The act of writing makes the recorder more likely to challenge questionable data. Forms format information so all accessing persons know where to look and what to expect. Finally, forms can become part of a permanent record, facilitating reviews of the treatment in the future. Each type of treatment and often different parts of a treatment may benefit from a unique form. Using a form for procedures other than those that led to its creation frequently gives a false sense of security, believing that effective checks verify a treatment when in fact the forms may provide no control for the case in question. Frequent marginal notations on a form serve as one indication that a form conforms poorly in a given function.

The most indispensable form is the prescription. The description of the target site and dose distribution desired must be explicit enough to guide the dosimetry. While discussed in some detail in chapter 3, some information about the treatment becomes part of the prescription only by reference to the 'treatment plan'. The treatment plan, in this context, describes the brachytherapy application. The description should contain at least the following:

- A statement specifying whether the application is temporary or permanent, and if temporary, whether using high or low dose rate sources.
- The source material.
- A diagram of the implant, possibly showing different views as necessary to convey an understanding of its geometry. For multiple needle or catheter applications (including, for example, Heyman capsule packings), the diagram should label the needle tracks unambiguously. For treatments using remote afterloaders, the labels should relate to the treatment channel numbers.
- A description of the loading for each needle track or applicator part with respect to source strength and location. The description should be clear enough that any knowledgeable practitioner could duplicate the application exactly.
- The calculated dose distribution in as many planes as necessary to convey the shape of relevant isodose surfaces.
- The desired dose with specification of its relationship to the target (for example, as a minimal peripheral dose) and to the plotted dose distribution, and the time course of dose delivery.

This list does not apply to all applications. The process of customizing the list for a given treatment forms an important part of quality planning, and should precede the actual procedure.

1.4.1.3. Independent second person. An independent second person serves as one of the best error-prevention tools. A second person observing one who performs a function often sees mistakes the first does not, and allows immediate correction before the error propagates.

#### 1.4.2. Error detection

Despite intensive efforts to prevent errors from entering into the planning process, some mistakes or misinterpretations are likely to slip through. To prevent these from causing injuries to patients (or regulatory hassles) takes a second line of defence to discover the presence of errors and correct them before treatment execution. The basic approaches to error detection use *comparison to standards and expectations, forms* and *independent reviewers*. Forms serve the same function as with error prevention, basically to assist the person performing the check to remember all the important steps. An independent reviewer, as with error prevention, provides an unbiased vantage for the evaluation. The designation 'independent' eliminates the second person involved in error prevention from performing the role as independent reviewer for error detection.

The basis for the evaluation of quality revolves around comparison of the item under consideration (the 'product' in the foregoing discussion) to some standards or expectations established *before* the evaluation began, and based on some information *external* to the item. For brachytherapy treatment plans, for example,

#### 12 General considerations in quality management in brachytherapy

the standard may be dosimetry tables from some well established system. Subsequent chapters discuss appropriate standards or expectations in considerable detail. As the prescription served as an important form for error prevention, it provides several of the expectations for error detection.

#### 1.4.3. Guidance in the use of tools

Several concepts guide the development of the quality control tool.

#### Redundancy

Redundancy should not be equated with useless duplication. The duplication inherent in redundancy provides verification through matching the product of a second process to that of a first. The robustness of the verification strengthens as the two processes arrive at their answers by different paths. However, even if the two answers come from the same method, their agreement provides some check on random mistakes if the procedure at least produced the same result twice.

#### Forced attention

No technique forces an operator to pay attention. However, requiring interactions makes it less likely that the person performing a procedure mentally skips over important parts. Consider the design of forms used to guide a reviewer through an evaluation of a treatment plan. As a minimum, the reviewer needs to tick boxes indicating performance of the individual items in the review. Better yet, the reviewer should enter values into blanks on the form. Increasing still the attention required, the form could require the reviewer to enter the ideal value for a parameter, then enter the value from the plan, highlight the value on the plan and then enter the calculated difference between the two. Each entry forces the brain to partially process the value, and increases the probability of noticing a value out of range or unusual. Unfortunately, for frequently performed tasks, humans often slip into a mental mode of assuming things are correct and not paying the appropriate attention to warning signs.

#### Patient identification

While the prospect of treating the wrong patient seems remote to any facility that has never encountered such an event, this error happens not infrequently. In the United States, the US Nuclear Regulator Commission requires identification of the patient by *two* of the following methods:

- asking the patient his or her name;
- asking the patient for his or her address, and comparing that to the address in the patient's chart;