

TECHNICAL REPORT

RAPPORT TECHNIQUE

Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics

Appareils électromédicaux – Accélérateurs médicaux d'électrons – Lignes directrices pour les caractéristiques des performances fonctionnelles



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2008 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur.

Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: www.iec.ch/searchpub

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: www.iec.ch/online_news/justpub

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

- Electropedia: www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

- Customer Service Centre: www.iec.ch/webstore/custserv

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:

Email: csc@iec.ch

Tel.: +41 22 919 02 11

Fax: +41 22 919 03 00

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

- Catalogue des publications de la CEI: www.iec.ch/searchpub/cur_fut-f.htm

Le Catalogue en-ligne de la CEI vous permet d'effectuer des recherches en utilisant différents critères (numéro de référence, texte, comité d'études,...). Il donne aussi des informations sur les projets et les publications retirées ou remplacées.

- Just Published CEI: www.iec.ch/online_news/justpub

Restez informé sur les nouvelles publications de la CEI. Just Published détaille deux fois par mois les nouvelles publications parues. Disponible en-ligne et aussi par email.

- Electropedia: www.electropedia.org

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International en ligne.

- Service Clients: www.iec.ch/webstore/custserv/custserv_entry-f.htm

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions, visitez le FAQ du Service clients ou contactez-nous:

Email: csc@iec.ch

Tél.: +41 22 919 02 11

Fax: +41 22 919 03 00

TECHNICAL REPORT

RAPPORT TECHNIQUE

Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics

Appareils électromédicaux – Accélérateurs médicaux d'électrons – Lignes directrices pour les caractéristiques des performances fonctionnelles

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX

XB

ICS 11.040.50

ISBN 2-8318-9893-5

CONTENTS

FOREWORD.....	3
INTRODUCTION.....	5
1 Scope.....	7
2 Normative references	7
3 General, type tests	7
3.1 Format of Annex A of the disclosure standard with suggested functional performance values	7
3.2 Rationale for functional performance values suggested by the Working Group.....	30
3.2.1 Introduction	30
3.2.2 IEC 60976, Clause 6.....	30
3.2.3 Suggested functional performance values.....	30
4 Acceptance tests	39
4.1 General.....	39
4.2 Summary of suggested test methods for MEDICAL ELECTRON ACCELERATOR acceptance.....	41
4.3 Acceptance test conditions	50
4.4 Suggested equipment for acceptance tests and for subsequent periodic tests	59
4.4.1 Introduction	59
4.4.2 Item description	59
5 Periodic tests	59
5.1 Introduction	59
5.2 Suggested set of periodic test methods and test conditions.....	61
5.3 Suggested frequency for periodic tests during working life of the ELECTRON ACCELERATOR.....	66
Bibliography.....	68
Figure 1 – Cumulative errors in beam displacement.....	39
Figure 2 – Phantom position	41
Figure 3 – DOSE MONITORING SYSTEM proportionality.....	43
Table 1 – Summary of major tolerances in routine X-RAY THERAPY	38
Table 2 – Suggested set of periodic test methods and test conditions.....	61

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –
MEDICAL ELECTRON ACCELERATORS –
GUIDELINES FOR FUNCTIONAL PERFORMANCE
CHARACTERISTICS**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC 60977, which is a technical report, has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1989 and its Amendment 1 (2000). It constitutes a technical revision.

This second edition likewise follows on the issue of a second edition to the disclosure standard IEC 60976 in 2007. It includes the addition of performance guidelines relating to several relatively new technologies introduced within the last few years, including dynamic beam delivery techniques, such as moving beam radiotherapy, INTENSITY MODULATED RADIATION THERAPY (IMRT), IMAGE GUIDED RADIOTHERAPY (IGRT), and PROGRAMMABLE WEDGE

FIELDS (PWF). Also included are STEREOTACTIC RADIOTHERAPY (SRT)/STEREOTACTIC RADIOSURGERY (SRS) and the use of certain ELECTRONIC IMAGING DEVICES (EIDs).

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62C/424/DTR	62C/439/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

The guidelines given in this report are recommendations both to manufacturers and to USERS. They provide guidance to MANUFACTURERS on the needs of USERS in respect of the performance of ELECTRON ACCELERATORS and they provide guidance to USERS wishing to check the manufacturer's declared performance characteristics, to carry out acceptance tests and to check periodically the performance throughout the life of the equipment.

IEC 60601-1¹⁾ is a general standard for the safety of medical electrical equipment. It is supplemented by IEC 60601-2-1, a standard which lays down particular requirements for MEDICAL ELECTRON ACCELERATORS in the range of 1 MeV to 50 MeV. In addition, IEC 60976 second edition has been issued as a disclosure standard. It standardizes methods of declaring the MEDICAL ELECTRON ACCELERATOR functional performance characteristics. It standardizes the type test conditions and type test methods to which manufacturers' declared values of functional performance relate.

A format for the presentation of functional performance values is contained in IEC 60976. It is repeated herein as 3.1, with the addition of a set of suggested values which reflects the need for precision in RADIOTHERAPY and the knowledge of what is reliably achievable technically. A corresponding rationale for the suggested values is presented in 3.2.

In order to check whether each individual machine at the time of installation performs in a manner consistent with the set of functional performance values declared by the manufacturer based upon his type test data, it is customary to perform a series of acceptance tests at the USER's site before the machine is put into full medical use. Because of limitations of time and test equipment, this series of acceptance tests is usually less extensive than the type tests specified in the disclosure standard, IEC 60976.

Subclause 4.2 contains a summary of suggested test methods for machine acceptance. These are consistent with the test methods of IEC 60976 but have been presented in a form which may be more suitable for use in hospitals. For reasons of economy and time, the USER may prefer to have a more limited but still standardized test performed at the time of installation of the equipment.

Subclause 4.3 contains a set of suggested acceptance (commissioning) test conditions. It should be emphasized that these test conditions are presented only as examples and that a quite different set of test conditions may still be needed for the purpose of displaying the functional performance characteristics of the individual machine.

During the working life of the MEDICAL ELECTRON ACCELERATOR, periodic tests are usually conducted by the USER to check whether the functional performance of the machine is satisfactory. Because the available machine time is limited, a highly abbreviated set of test conditions is essential. Individual tests should not be repeated any more or less frequently than can be justified by experience with the particular machine or machine type. A set of suggested periodic test methods is presented in 5.2 and a list of suggested periodic tests during the working life of the MEDICAL ELECTRON ACCELERATOR and suggested intervals between such tests is presented in 5.3. The manufacturer may recommend different intervals or additional or different tests, depending on the special requirements of the MEDICAL ELECTRON ACCELERATOR in question.

Since the issue in 1989 of IEC 60977, a first amendment was published in 2000 to address the introduction and increasing use of multi-element BEAM LIMITING DEVICES (multi-element BLDs) for determining the shape of the RADIATION FIELD, with or without the use of back-up BLDs. This publication followed from the issue of the corresponding amendment to the disclosure standard itself, IEC 60976:1989, in 2000. The performance issues addressed in these first amendments were mainly associated with the applications of multi-element BLDs to

1) See Bibliography.

static RADIATION FIELDS. This second edition likewise follows on the issue of a second edition to the disclosure standard IEC 60976 in 2007. It includes the addition of performance guidelines relating to several relatively new technologies introduced within the last few years, including dynamic beam delivery techniques, such as moving beam radiotherapy, INTENSITY MODULATED RADIATION THERAPY (IMRT), IMAGE GUIDED RADIOTHERAPY (IGRT), and PROGRAMMABLE WEDGE FIELDS (PWF). Also included are STEREOTACTIC RADIOTHERAPY (SRT)/STEREOTACTIC RADIOSURGERY (SRS) and the use of certain ELECTRONIC IMAGING DEVICES (EIDs).

In recognition of the diversity of equipment produced by manufacturers in each of these technologies, this second edition, as with the first, has specified performance guidelines that are as basic and generic as possible.

MEDICAL ELECTRICAL EQUIPMENT – MEDICAL ELECTRON ACCELERATORS – GUIDELINES FOR FUNCTIONAL PERFORMANCE CHARACTERISTICS

1 Scope

This technical report applies to medical ELECTRON ACCELERATORS when used, for therapy purposes, in human medical practice.

This technical report applies to medical ELECTRON ACCELERATORS which deliver a RADIATION BEAM of either X-RADIATION or ELECTRON RADIATION with NOMINAL ENERGIES in the range 1 MeV to 50 MeV at maximum ABSORBED DOSE RATES between $0,001 \text{ Gy s}^{-1}$ and 1 Gy s^{-1} at 1 m from the RADIATION SOURCE and at NORMAL TREATMENT DISTANCES between 50 cm and 200 cm from the RADIATION SOURCE.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-2-1:1998, *Medical electrical equipment – Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV*
Amendment 1 (2002)

IEC 60976:2007, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*

3 General, type tests

3.1 Format of Annex A of the disclosure standard with suggested functional performance values

The purpose of this subclause is to provide a suggested format for the presentation of functional performance values corresponding to the standardized statements of functional performance in the disclosure standard, IEC 60976:2007. USERS of MEDICAL ELECTRON ACCELERATORS may find this format useful in getting information from the manufacturer on the expected performance, in recording acceptance test values measured at the time of installation and in periodic testing of performance during the working life of the machine. Manufacturers may find it useful in declaring the functional performance values for their particular types of MEDICAL ELECTRON ACCELERATORS in response to IEC 60976. Although the manufacturer may use his own set of type test methods in developing functional performance data, he should make sure that the functional performance values which he declares would be met if the test methods of IEC 60976 were used. It is not suggested that a manufacturer should provide information to USERS from his type test in any greater detail than a simple declaration of these functional performance values.

As a result of extensive deliberations by Working Group 1 of IEC subcommittee 62C, a set of suggested values of functional performance was agreed upon with respect to the standardized statements of IEC 60976:2007. These suggested values are shown in parentheses for each relevant clause. For Clauses 7 and 8, the suggested tolerance values are given only for NOMINAL ENERGIES in the range from 3 MeV to 50 MeV, since this range covers most of the practice with MEDICAL ELECTRON ACCELERATORS.

Tolerances are designated "+/-" where they represent permissible deviations in more than one direction from a desired point or value. The "+/-" designation is not used where the tolerance represents permissible deviation in any one direction between two points or values. The abbreviations "maxi" and "mini" are used for "maximum" and "minimum", respectively.

Where a functional performance value is required for a square RADIATION FIELD of specified dimensions, and the equipment is unable to provide these dimensions, then the required performance information may be provided for a square RADIATION FIELD nearest in size to that prescribed.

FORMAT FOR PRESENTATION OF FUNCTIONAL PERFORMANCES VALUES

Manufacturer _____

MEDICAL ELECTRON ACCELERATOR type designation _____

Date _____ Location _____

Clause Abbreviation of statement in disclosure standard

5.2 Available NOMINAL ENERGIES and ABSORBED DOSE RATES

X-radiation mode*:

NOMINAL ENERGY	_____ MV	_____	_____	Gy/min, 10 cm × 10 cm RADIATION FIELD
NOMINAL ENERGY	_____ MV	_____	_____	Gy/min, 10 cm × 10 cm RADIATION FIELD
NOMINAL ENERGY	_____ MV	_____	_____	Gy/min, 10 cm × 10 cm RADIATION FIELD
NOMINAL ENERGY	_____ MV	_____	_____	Gy/min, maximum RADIATION FIELD
NOMINAL ENERGY	_____ MV	_____	_____	Gy/min, maximum RADIATION FIELD
NOMINAL ENERGY	_____ MV	_____	_____	Gy/min, maximum RADIATION FIELD

* Where SRT/SRS modes are available, the following information shall also be provided for the applicable NOMINAL ENERGIES and X-RADIATION FIELDS

The same ABSORBED DOSE RATE applies for both 10 cm × 10 cm and maximum RADIATION FIELD in ELECTRON RADIATION mode.

5.5.3 Available RADIATION FIELDS (at NORMAL TREATMENT DISTANCE)

X-RADIATION mode:

Minimum square _____ cm $\times$ _____ cm

Maximum square _____ cm x _____ cm (Fully flattened RADIATION FIELD, square corners)

Maximum with clipped comers _____ cm $\times$ _____ cm Diagonals _____ cm $\times$ _____ cm

If SRT/SRS is provided, available RADIATION FIELD sizes shall be given

ELECTRON RADIATION mode:

Minimum square _____ cm × _____ cm

Maximum square _____ cm $\times$ _____ cm

Other rectangular

$\text{cm} \times \underline{\hspace{1cm}} = \underline{\hspace{1cm}}$, $\text{cm}, \dots$ $\text{cm} \times \underline{\hspace{1cm}} = \underline{\hspace{1cm}}$, cm , $\text{cm} \times \underline{\hspace{1cm}} = \underline{\hspace{1cm}}$

cm × _____

cm, _____

Adjustable RADIATION

FIELD range _____ cm × _____ cm to _____ cm × _____ cm

Clause

Abbreviation of statement in disclosure standard

Values declared (suggested)

Unless otherwise stated, all functional performance values, related to the selection of specific RADIATION FIELD sizes, are to be the result of selection of RADIATION FIELD size by the adjustable BLD system (jaws). Unless otherwise stated, all RADIATION FIELDS are symmetrically placed about the REFERENCE AXIS.

For a multi-element BLD, the following information shall be provided.

X-RADIATION mode:

Adjustable RADIATION FIELD range:

square corners from: _____ cm × _____ cm to: _____ cm × _____ cm
maximum with clipped corners _____ cm × _____ cm diagonals: _____ cm × _____ cm
Maximum offset of centre of RADIATION FIELD in relation to the REFERENCE AXIS: _____ mm

ELECTRON RADIATION mode (if applicable):

Adjustable RADIATION FIELD range:

square corners from: _____ cm × _____ cm to: _____ cm × _____ cm
maximum with clipped corners _____ cm × _____ cm diagonals: _____ cm × _____ cm
Maximum offset of centre of RADIATION FIELD in relation to the REFERENCE AXIS: _____ mm

5.4

NORMAL TREATMENT DISTANCE

X-RADIATION mode: _____ cm

ELECTRON RADIATION mode: _____ cm

5.5

Available wedge X-ray fields:

Designation	NOMINAL ENERGY	Maximum RADIATION FIELD	WEDGE ANGLE	Related isodose value	WEDGE FILTER FACTOR
_____	_____ MV	_____ cm × _____ cm	_____ °	_____ %	_____
_____	_____ MV	_____ cm × _____ cm	_____ °	_____ %	_____
_____	_____ MV	_____ cm × _____ cm	_____ °	_____ %	_____
_____	_____ MV	_____ cm × _____ cm	_____ °	_____ %	_____
_____	_____ MV	_____ cm × _____ cm	_____ °	_____ %	_____
_____	_____ MV	_____ cm × _____ cm	_____ °	_____ %	_____

Clause

5.6

Values declared (suggested)

Abbreviation of statement in disclosure standard

Available FLATTENING FILTERS

X-RAY FIELD FLATTENING FILTERS:

Designation	NOMINAL ENERGY	Maximum square RADIATION FIELD (square corners)
_____	_____ MV	_____ cm x _____ cm
_____	_____ MV	_____ cm x _____ cm
_____	_____ MV	_____ cm x _____ cm

ELECTRON FIELD-FLATTENING FILTERS:

Designation	NOMINAL ENERGY	Maximum square RADIATION FIELD (square corners)
_____	_____ MeV to _____ MeV	_____ cm x _____ cm
_____	_____ MeV to _____ MeV	_____ cm x _____ cm
_____	_____ MeV to _____ MeV	_____ cm x _____ cm
_____	_____ MeV to _____ MeV	_____ cm x _____ cm

5.7

Availability

Time necessary to reach the READY STATE from the STAND-BY STATE

_____ min

5.8

Influencing quantities

Environmental conditions:

Ambient temperature

Relative humidity

Atmospheric pressure

Maximum period of continuous operation:

(possibly influencing the functional performance characteristics)

Dimensions, clearances, within the RADIATION HEAD, and in the region RADIATION

HEAD to ISOCENTRE, of BEAM LIMITING DEVICES

Equipment layout drawing

_____ °C to _____ °C
_____ % to _____ %
_____ Pa to _____ Pa
_____ min

5.11

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
5.12	IMRT	
	Smallest number of DOSE MONITOR UNITS	_____
	Largest number of DOSE MONITOR UNITS	_____
7	DOSE MONITORING SYSTEM	
	Range of ABSORBED DOSE over which the standard is met...	_____ to _____ Gy
	Range of ABSORBED DOSE RATES over which the standard is met...	_____ to _____ Gy/min
7.2	Reproducibility	
	Maximum coefficients of variation of ratio <i>R</i> of	
	a) the number of DOSE MONITOR UNITS and ABSORBED DOSE for X-RADIATION	_____ % (0,5)
	b) the number of DOSE MONITOR UNITS and ABSORBED DOSE for ELECTRON RADIATION	_____ % (0,5)
7.3	Proportionality	
	Maximum deviation of the measured ABSORBED DOSE from the value given by multiplying the measured value <i>U</i> of DOSE MONITOR UNITS by the proportionality factor <i>S</i> over the following ranges of ABSORBED DOSE and ABSORBED DOSE RATES:	
	X-RADIATION NOMINAL ENERGY _____ MV	
	of _____ Gy to _____ Gy at _____ Gy/min to _____ Gy/min...	
	Declared deviation ± _____ ± _____ %	(2)
	ELECTRON RADIATION NOMINAL ENERGY _____ MeV	
	of _____ Gy to _____ Gy at _____ Gy/min to _____ Gy/min...	
	Declared deviation ± _____ ± _____ ± _____ ± _____ %	(2)
7.4	Dependence on angular positions	
	Maximum difference between the maximum and minimum values of $\bar{R}$ over the full angular ranges of the GANTRY and BEAM LIMITING SYSTEM...	

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
	X-RADIATION	
	Declared maximum difference...	_____ % (3)
	ELECTRON RADIATION	
	Declared maximum difference...	_____ % (3)
7.5	Dependence on GANTRY rotation	
	As the GANTRY moves, the maximum deviation of $\bar{R}$ from the arithmetic mean of the maximum and minimum values of $\bar{R}$ determined in 6.2	
	X-RADIATION	
	Declared maximum deviation...	_____ % (3)
	ELECTRON RADIATION	
	Declared maximum deviation...	_____ % (2)
7.6	Dependence on the shape of the RADIATION FIELD	
	Maximum difference of $\bar{R}$ between 5 cm × 20 cm and 20 cm × 5 cm fields (or maximum if less than 20 cm)...	
	X-RADIATION	
	Declared maximum difference...	_____ %
	ELECTRON RADIATION	
	Declared maximum difference...	_____ %
7.7	Stability of calibration	
7.7.1	Stability after high ABSORBED DOSE delivered	
	X-RADIATION	
	Maximum difference of $\bar{R}$ between beginning and end of...	
	a) IRRADIATION of 100 Gy at NORMAL TREATMENT DISTANCE...	_____ % (2)
	b) or a period of 30 min at maximum nominal ABSORBED DOSE RATE, whichever results in the shorter period...	_____ % (2)
	ELECTRON RADIATION	

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
	Maximum difference of $\bar{R}$ between beginning and end of...	
	a) IRRADIATION of 100 Gy at NORMAL TREATMENT DISTANCE...	____ % (2)
	b) or a period of 30 min at maximum nominal ABSORBED DOSE RATE, whichever results in the shorter period...	____ % (2)
7.7.2	Stability throughout the day Maximum difference of $\bar{R}$ between beginning and end of 8 h of successive 4 Gy IRRADIATIONS followed by 10 min without IRRADIATION...	
	X-RADIATION	____ % (2)
	ELECTRON RADIATION	____ % (2)
7.7.3	Stability throughout the week Maximum difference between the highest and lowest values of R measured immediately following switch-on on 5 consecutive days...	
	X-RADIATION	____ % (2)
	ELECTRON RADIATION	____ % (2)
7.8	Stability in MOVING BEAM RADIOTHERAPY X-RADIATION Where GANTRY angular range TERMINATES IRRADIATION the maximum difference between the reading of DOSE MONITOR UNITS and the value calculated by multiplying preset DOSE MONITOR UNITS per unit angle by preset angular range of GANTRY rotation... Where the DOSE MONITOR SYSTEM TERMINATES IRRADIATION the maximum difference in degrees between the GANTRY rotation angular range traversed and the angular range calculated by dividing preset DOSE MONITOR UNITS by the value of preset DOSE MONITOR UNITS per unit angle...	____ % (5)
	ELECTRON RADIATION	____ ° (3)

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
	Where GANTRY angular range TERMINATES IRRADIATION, the maximum difference between the reading of DOSE MONITOR UNITS and the value calculated by multiplying preset DOSE MONITOR UNITS per unit angle by preset angular range of GANTRY rotation...	_____ % (5)
	Where the DOSE MONITOR SYSTEM TERMINATES IRRADIATION, the maximum difference in degrees between the GANTRY rotation angular range traversed and the angular range calculated by dividing preset DOSE MONITOR UNITS by the value of preset DOSE MONITOR UNITS per unit angle...	_____ ° (3)
8	Depth ABSORBED DOSE characteristics	
8.1	X-RADIATION	
	NOMINAL X-RAY ENERGY (of electrons striking the X-RAY TARGET)	_____ MV
	DEPTH OF DOSE MAXIMUM for 10 cm x 10 cm RADIATION FIELD...	_____ cm
	DEPTH OF DOSE MAXIMUM for maximum RADIATION FIELD...	_____ cm
	PENETRATIVE QUALITY (10 cm x 10 cm RADIATION FIELD)...	_____ cm
	Maximum deviation of actual value from declared value of PENETRATIVE QUALITY...	_____ % (3)
		_____ mm (3)
	QUALITY INDEX	_____
8.1.1	Depth dose charts	
8.1.2	SURFACE DOSE	
	RELATIVE SURFACE DOSE for 10 cm x 10 cm RADIATION FIELD...	_____ %
	RELATIVE SURFACE DOSE for maximum RADIATION FIELD...	_____ %
8.1.4	STEREOTACTIC RADIOTHERAPY (SRT) or STEREOTACTIC RADIOSURGERY (SRS)	
	For SRT/SRS modes, repeat the information required in 8.1 and 8.1.2 above for the maximum SRT/SRS FIELD size available	
	And for either a 1 cm diameter X-RAY RADIATION FIELD or as close as can be achieved to a 1 cm x 1cm square RADIATION FIELD.	

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
8.2	ELECTRON RADIATION	
8.2.1 and 8.2.3	DEPTH DOSE charts	
	SURFACE DOSE	
	NOMINAL ENERGY of electrons	_____ MeV
	DEPTH OF DOSE MAXIMUM (10 cm × 10 cm RADIATION FIELD), minimum	_____ cm (0,1)
	DEPTH OF DOSE MAXIMUM (maximum RADIATION FIELD), minimum	_____ cm (0,1)
	Ratio of PRACTICAL RANGE to depth of 80 % ABSORBED DOSE (for 10 cm × 10 cm RADIATION FIELD), maximum	_____ (1,6)
	Ratio of PRACTICAL RANGE to depth of 80 % ABSORBED DOSE (for maximum RADIATION FIELD), maximum	_____ (1,6)
	PRACTICAL RANGE... (10 cm × 10 cm RADIATION FIELD)	_____ cm
	PENETRATIVE QUALITY... (10 cm × 10 cm RADIATION FIELD)	_____ cm
	Maximum deviation of actual value from declared value of PENETRATIVE QUALITY	_____ % (3)
	RELATIVE SURFACE DOSE (10 cm × 10 cm RADIATION FIELD), maximum	_____ mm (2)
	RELATIVE SURFACE DOSE (maximum RADIATION FIELD), maximum	_____ % (100)
8.2.2	Stability of PENETRATIVE QUALITY	
	Maximum variation of PENETRATIVE QUALITY of ELECTRON RADIATION with angular position of the GANTRY and usable range of nominal ABSORBED DOSE RATES...	_____ mm (2) _____ % (1)

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
9	Uniformity of RADIATION FIELDS (see Figure 5 of IEC 60976 for flattened area)	
9.1	X-RADIATION	
9.1.1	Flatness of square X-RAY FIELDS	
	NOMINAL ENERGY	_____ MV
	Maximum ratio of maximum ABSORBED DOSE anywhere in the RADIATION FIELD to minimum ABSORBED DOSE in flattened area of RADIATION FIELD both at STANDARD MEASUREMENT DEPTH...	
	5 cm × 5 cm to 30 cm × 30 cm ENERGY ...	_____ % (106)
	greater than 30 cm × 30 cm to maximum square ENERGY ...	_____ % (110)
9.1.2	Deviation of dose distribution of square X-RAY FIELDS with angular positions	
	Maximum variation in the ratio of ABSORBED DOSE at a point in the flattened area to ABSORBED DOSE on the RADIATION BEAM AXIS both at STANDARD MEASUREMENT DEPTH for all angular positions of the GANTRY and BEAM LIMITING SYSTEM.	
	NOMINAL ENERGY less than 30 MV ...	_____ % (3)
	NOMINAL ENERGY 30 MV and above...	_____ % (4)
9.1.3	Symmetry of square X-RAY FIELDS	
	Maximum ratio of ABSORBED DOSES at points symmetrically displaced from the AXIS OF THE BEAM and within the MEASUREMENT DEPTH flattened area at STANDARD MEASUREMENT DEPTH	_____ % (103)
9.1.4	Maximum ratio of ABSORBED DOSE	
	NOMINAL ENERGY	_____ MV
	Maximum ratio of ABSORBED DOSE in the RADIATION FIELD to ABSORBED DOSE on the RADIATION BEAM AXIS in the plane at the DEPTH OF DOSE MAXIMUM...	
	up to and including 30 cm × 30 cm...	_____ % (107)
	greater than 30 cm × 30 cm to maximum square...	_____ % (109)

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
9.1.5	Wedge X-RAY FIELDS	
	NOMINAL ENERGY	_____ MV
	Maximum deviation of WEDGE FACTOR...	_____ % (2)
	Maximum deviation of WEDGE ANGLE...	_____ deg (2)
9.1.6	X-RAY FIELDS with IMRT	
	Where applicable the tests in subclauses 7.2 to 7.5, 7.8, 8.1.1 (Quality index only) and 9.1.1 to 9.1.4, shall be undertaken for the smallest number of DOSE MONITOR UNITS specified in subclause 5.12. Where applicable the tests in subclauses 7.2 to 7.5, 7.8, 8.1 (QUALITY INDEX only) and 9.1.1 to 9.1.4, shall be undertaken for the final 2 % of the largest number of the DOSE MONITOR UNITS specified in Clause 5.12.	
	These values shall be declared where applicable. The suggested tolerances in those subclauses apply.	
9.2	Electron radiation	
9.2.1	Flatness of ELECTRON FIELDS	
	Maximum distance between 80 % isodose contours and edge of GEOMETRICAL FIELD projection at BASE DEPTH... along major axes...	_____ mm (15)
	Maximum distance between 90 % isodose contours and edge of GEOMETRICAL FIELD projection at STANDARD MEASUREMENT DEPTH... along major axes...	_____ mm (10)
	along bisectors of corners...	_____ mm (20)
	Ratio of the highest ABSORBED DOSE anywhere in the RADIATION FIELD at STANDARD MEASUREMENT DEPTH to the ABSORBED DOSE on the RADIATION BEAM AXIS at the DEPTH OF DOSE MAXIMUM...	_____ %

Clause

9.2.2

Abbreviation of statement in disclosure standard

Deviation of dose distribution of ELECTRON FIELDS with angular positions

Values declared (suggested)

Maximum variation in the ratio of ABSORBED DOSE at any point in the flattened area confined by the line 1 cm inside the 90 % isodose contour at STANDARD MEASUREMENT DEPTH to the ABSORBED DOSE on the RADIATION BEAM AXIS at the same depth for all angular positions of the GANTRY and BEAM LIMITING SYSTEM

_____ % (3)

9.2.3

Symmetry of ELECTRON FIELDS

Maximum ratio of ABSORBED DOSES at points symmetrically displaced from the RADIATION BEAM AXIS and more than 1 cm inside the 90 % isodose contour at STANDARD MEASUREMENT DEPTH

_____ % (105)

9.2.4

Maximum ratio of ABSORBED DOSE

Maximum ratio of ABSORBED DOSE in the RADIATION FIELD at 0,5 mm depth to ABSORBED DOSE on the RADIATION BEAM AXIS at DEPTH OF DOSE MAXIMUM

_____ % (109)

9.3

Penumbra of RADIATION FIELDS

Maximum distance along major axes between points of 80 % and 20 % of the ABSORBED DOSE on the RADIATION BEAM AXIS, all measurements being in the plane at STANDARD MEASUREMENT DEPTH

RADIATION FIELD

5 cm x 5 cm square field 10 cm x 10 cm Maximum

X-RADIATION...

_____ mm

ELECTRON RADIATION

_____ mm

For RADIATION FIELDS shaped by a multi-element BLD, the required information shall be provided as follows:

10 cm x 10 cm Maximum (square or rectangular)

X-RADIATION:

_____ mm

ELECTRON RADIATION (if applicable):

_____ mm

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
10	Indication of RADIATION FIELDS	
10.1	X-RADIATION	
10.1.1	Numerical field-indication	
	Maximum difference between the numerical RADIATION FIELD-indication and the dimensions of the RADIATION FIELD at NORMAL TREATMENT DISTANCE...	
	5 cm × 5 cm to 20 cm × 20 cm...	_____ mm (3) _____ % (1,5)
	Greater than 20 cm × 20 cm to maximum square...	_____ mm (5) _____ % (1,5)
	For a multi-element BLD, the information required shall be provided as follows.	
	Maximum differences are measured between the numerical indication of the RADIATION FIELD sizes defined by each pair of opposed element edges, and the dimensions of the RADIATION FIELDS at NORMAL TREATMENT DISTANCE, specified in 5.4:	
	10 cm × 10 cm:	_____ mm (3)
	maximum (square or rectangular):	_____ mm (5) _____ % (1,5)
10.1.2	LIGHT FIELD-INDICATOR	
	Maximum distance along the major axes between the LIGHT FIELD edge and the RADIATION FIELD edge at NORMAL TREATMENT DISTANCE in mm or percent of dimensions of the RADIATION FIELD	
	5 cm × 5 cm to 20 cm × 20 cm...	_____ mm (2) _____ % (1)
	Greater than 20 cm × 20 cm to maximum square...	_____ mm (3) _____ % (1)
	Maximum distance along the major axes between the LIGHT FIELD edge and the RADIATION FIELD edge at 1,5 times NORMAL TREATMENT DISTANCE...	
	5 cm × 5 cm to 20 cm × 20 cm...	_____ mm (4) _____ % (2)

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
	Greater than 20 cm × 20 cm to maximum...	____ mm (6) ____ % (2)
	Maximum distance between the centres of the RADIATION FIELD and the LIGHT FIELD...	
	At NORMAL TREATMENT DISTANCE...	____ mm (2)
	At 1,5 times NORMAL TREATMENT DISTANCE...	____ mm (4)
	For a multi-element BLD the information required shall be provided as follows.	
	Maximum distance along the major axes between the LIGHT FIELD edges and the RADIATION FIELD edges at NORMAL TREATMENT DISTANCE:	
	10 cm × 10 cm:	____ mm (2)
	maximum (square or rectangular):	____ mm (3)
		____ % (1)
	and at 1,5 times NORMAL TREATMENT DISTANCE:	
	maximum (square or rectangular):	____ mm (6)
		____ % (2)
	For multi-element BLD RADIATION FIELDS, the maximum distance between the centres of the RADIATION FIELD and the LIGHT FIELD:	
	at NORMAL TREATMENT DISTANCE:	____ mm (2)
	at 1,5 times the NORMAL TREATMENT DISTANCE:	____ mm (4)
	For SRT/SRS X-RAY FIELDS, where a LIGHT FIELD is provided, the maximum distance along the major axes between the LIGHT FIELD edge and the RADIATION FIELD edge at NORMAL TREATMENT DISTANCE in mm	
	Smallest X-RAY FIELD, at NTD	____ mm (0,5)
	at 1,5 times NTD	____ mm (1)
	Maximum X-RAY FIELD, at NTD	____ mm (0,5)
	at 1,5 times NTD	____ mm (1)

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
10.1.3	Reproducibility Difference between the maximum and the minimum X-RAY FIELD for repeated settings of the same numerical field indication... Maximum distance between any LIGHT FIELD edge and the X-RAY FIELD edge for repeated settings of the same numerical field-indication... For RADIATION FIELDS shaped by a multi-element BLD: difference between the maximum and minimum X-RAY FIELD for repeated measurements of the same numerical field-indication: maximum distance between any LIGHT FIELD edge and the X-RAY FIELD edge for repeated settings of the same numerical field-indication:	 ____ mm (2) ____ mm (2) ____ mm (2) ____ mm (2)
10.1.4	Alignment of an SRS STEREOTACTIC FRAME OF REFERENCE with ANATOMICAL REGISTRATION POINTS	
10.1.4.2	Tests Standard deviation of the 4 measurements of the positions of the ANATOMICAL REGISTRATION POINTS relative to the STEREOTACTIC FRAME OF REFERENCE: Along the longitudinal axis of the PATIENT SUPPORT ASSEMBLY Along the lateral axis of the PATIENT SUPPORT ASSEMBLY Along the vertical axis of the PATIENT SUPPORT ASSEMBLY	 ____ mm (0,5) ____ mm (0,5) ____ mm (0,5)
10.1.5	SRS X-RAY BEAM guidance Maximum distance between central axis of the SRS X-RAY BEAM from the ISOCENTRE Smallest SRS X-RAY FIELD Maximum SRS X-RAY FIELD	 ____ mm (0,5) ____ mm (0,5)
10.2	Electron radiation	
10.2.1	Numerical field-indication Maximum difference (over all available RADIATION FIELDS and all NOMINAL ENERGIES) between the numerical field indication and the distance between the points on the major axes where the ABSORBED DOSE is 50 % of the ABSORBED DOSE on the RADIATION BEAM AXIS, all measurements being made at STANDARD MEASUREMENT DEPTH...	 ____ mm

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
	For a multi-element BLD, the information required shall be provided over the following range of RADIATION FIELD sizes: from 5 cm × 5 cm to maximum (square or rectangular):	_____ mm
10.2.2 LIGHT FIELD-INDICATOR	Maximum difference between the numerical field-indication and the dimensions of the LIGHT FIELD at NORMAL TREATMENT DISTANCE...	_____ mm (2)

10.3 Geometry and motion speeds of adjustable BLDs for X-RADIATION and ELECTRON RADIATION

X-RADIATION:		
maximum range of motion	Xb	Yb
coordinates maximum	_____ cm	_____ cm
coordinates minimum	_____ cm	_____ cm
	_____ cm	_____ cm
ELECTRON RADIATION:	Xb	Yb
maximum range of motion	_____ cm	_____ cm
coordinates maximum	_____ cm	_____ cm
coordinates minimum	_____ cm	_____ cm
Maximum and minimum speeds by which any RADIATION FIELD-defining BLD can move:		
X-RADIATION:		
maximum speed		_____ cm/s
minimum speed		_____ cm/s
ELECTRON RADIATION:		
maximum speed		_____ cm/s
minimum speed		_____ cm/s

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
	For rectangular RADIATION FIELDS: maximum angular deviation, in degrees, from parallelity of the opposing edges maximum angular deviation, in degrees, from orthogonality of the adjacent edges	 ____ deg (0,5) ____ deg (0,5)
	For a multi-element BLD: maximum distance, to which the edges of adjacent and opposed elements can be extended beyond one another minimum distance between opposed elements maximum displacement of the RADIATION FIELD from symmetry when rotating the BEAM LIMITING SYSTEM through 180°	 ____ cm ____ mm ____ mm (2)
10.4	Illuminance and PENUMBRA of the LIGHT FIELD Average illuminance at NORMAL TREATMENT DISTANCE ≥... Edge contrast ratio at points 3 mm apart ≥...	 ____ lx (25) ____ % (400)
11	Indication of the RADIATION BEAM AXIS	
11.1 and 11.2 and 11.3	General Indication on entry to the PATIENT Indication on exit from the PATIENT Maximum deviation of the indication of the RADIATION BEAM AXIS from the RADIATION BEAM AXIS... over NTD ± 25 cm or working range at NTD	 ____ mm (2) ____ mm (4)

Clause	over NTD to NTD + 50 cm or working range	Abbreviation of statement in disclosure standard	Values declared (suggested)
	Exit X-RAY BEAM...		mm (3)
	For SRS X-RAY FIELDS		
	over NTD ± 25 cm or working range	Entry X-RAY BEAM...	mm (0.5)
	over NTD to NTD + 50 cm or working range	Exit X-RAY BEAM...	mm (0.5)
12	ISOCENTRE		
12.1	Displacement of the RADIATION BEAM AXIS from the ISOCENTRE		
	Maximum displacement of the RADIATION BEAM AXIS from the ISOCENTRE...		mm (2)
12.2	Indication of the ISOCENTRE		
	Maximum displacement from the ISOCENTRE of any device for indicating the position of the ISOCENTRE...		
	device a)		mm (2)
	device b)		mm (2)
	device c)		mm (2)
13	Indication of distance along the RADIATION BEAM AXIS		
13.1	Indicating device		
	Maximum difference between the indicated distance and the actual distance from a reference point:		
	For ISOCENTRIC EQUIPMENT the reference point shall be the ISOCENTRE		mm (2)
	For NON-ISOCENTRIC EQUIPMENT the reference point shall be on the RADIATION BEAM AXIS at NORMAL TREATMENT DISTANCE		mm (2)
13.2	Additional indicating device for equipment with variable distance between RADIATION SOURCE and ISOCENTRE and for NON-ISOCENTRIC EQUIPMENT		
	Maximum difference between the indicated distance and the actual distance from the RADIATION SOURCE...		mm (5)

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
14	Zero position of rotational scales	
14.2	Information to the USER	
	Maximum difference between the zero position indicated by the rotational scale and the zero position defined by Clause 14...	
	Rotation of GANTRY	_____ ° (0,5)
	Roll of the RADIATION HEAD	_____ ° (0,1)
	Pitch of the RADIATION HEAD	_____ ° (0,1)
	Rotation of the BEAM LIMITING SYSTEM	_____ ° (0,5)
	ISOCENTRIC rotation of the table	_____ ° (0,5)
	Rotation of the table top	_____ ° (0,5)
	Pitch of the table	_____ ° (0,5)
	Roll of the table	_____ ° (0,5)
15	Congruence of the opposed RADIATION FIELDS	
	Maximum displacement at ISOCENTRE between axes of opposed RADIATION FIELDS	_____ mm (1)
16	Movements of the PATIENT table	
16.2	Vertical movement of the table	
	Maximum horizontal displacement of the table for a change in height of 20 cm when loaded with 30 kg distributed over 1 m and when loaded with 135 kg distributed over 2 m, both weights acting through the ISOCENTRE...	_____ mm (2)
16.3	ISOCENTRIC rotation of the table	
	Maximum displacement of the axis of ISOCENTRIC rotation of the table from the ISOCENTRE...	_____ mm (2)
16.4	Parallelism of table rotational axis	
	Maximum angle between the axis of ISOCENTRIC rotation of the table and the axis of rotation of the table top...	_____ ° (0,5)

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
16.5.1 Longitudinal rigidity of the table		
	Maximum difference in table height near ISOCENTRE between 30 kg load at retracted condition and 135 kg load at extended condition...	_____ mm (5)
16.5.2 Lateral rigidity of the table		
	Maximum angle of lateral tilt from horizontal of the plane of the table top as the table is laterally displaced...	_____ ° (0,5)
	Maximum deviation of the height of the table top as the table is laterally displaced...	_____ mm (5)
17 Electronic imaging device (e.g. EPID)		
17.1.3.2 Detector area and pixel pitch:		
	In the imaging plane of the detector:	
	Active detector dimensions	_____ cm X _____ cm
	Pixel pitch in each dimension	_____ mm X _____ mm
17.1.3.3 Detector characteristics:		
	Field of view at NTD (ISOCENTER)	_____ cm X _____ cm
17.1.3.4 Viewable pixels		
	Size of largest image that can be displayed (in pixels)	_____ pixels x _____ pixels
17.1.3.5.2 Detector frame time		
	Minimum detector frame time	_____ sec (0,5)
	Corresponding maximum frame rate	_____ frames/sec (2)

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
17.1.3.5.3 Imager SIGNAL-TO-NOISE RATIO and DYNAMIC RANGE		
SIGNAL-TO-NOISE RATIO for a dose of 1 cGy		_____ % (5 000)
DYNAMIC RANGE		_____ dB
17.1.3.5.4 Imager lag		
Following the end of an exposure, percent ratio of measured signals:		
of the second to the first frame		_____ % (5)
or, of the fifth to the first frame		_____ % (0,3)
17.1.3.7 Imager SPATIAL RESOLUTION		
Imager spatial resolution (MTF) at the highest frequency that can be resolved, for a given X-RAY ENERGY, DOSE, and DOSE RATE:		
ENERGY,		_____ MV
DOSE or DOSE RATE		_____ Gy or Gy/min
with contrast bars positioned on the EID surface, at NTD		_____ lp/mm (0,6)

3.2 Rationale for functional performance values suggested by the Working Group

3.2.1 Introduction

In the development of IEC 60976 on functional performance tolerances the Working Group met about twice a year over a number of years and also invited comments at intervals from National Committees. The nature of the document changed materially over this time. Guidelines, recommendations and standards of recognized national and international organizations and unpublished calculations and measurements of equipment performance were used as input for deliberations. The purpose of this rationale statement is not to record the history of this work but to present a concise review of the final essential reasoning by the Working Group for many of the suggested values of functional performance listed in 3.1 of this report. A more thorough discussion is presented where the clause may represent a change from traditional practice.

3.2.2 IEC 60976, Clause 6

“6 Standardized test conditions”

Extensive measurements are made in the plane at STANDARD MEASUREMENT DEPTH within the PHANTOM to simulate conditions at approximately average tumour depth. The distance from X-RAY SOURCE to ISOCENTRE is defined as the NORMAL TREATMENT DISTANCE for ISOCENTRIC EQUIPMENT. ISOCENTRIC X-RADIATION treatment techniques are commonly used with ISOCENTRIC EQUIPMENT, and to simulate these techniques the PHANTOM surface is positioned nearer to the RADIATION SOURCE from the ISOCENTRE by a distance equal to the STANDARD MEASUREMENT DEPTH. This constitutes a more severe test condition than SSD treatment technique (PATIENT surface at NORMAL TREATMENT DISTANCE) because the surface is closer to secondary RADIATION SOURCES such as the BEAM LIMITING SYSTEM, and because a greater solid angle from the RADIATION SOURCE is included by a given RADIATION FIELD. For NON-ISOCENTRIC EQUIPMENT and for ELECTRON RADIATION, SSD treatment techniques are normally used and are simulated by positioning the PHANTOM surface at the NORMAL TREATMENT DISTANCE specified by the manufacturer.

“6.3 Properties and positioning of the PHANTOM”

For tests with very large RADIATION FIELDS a water PHANTOM covering somewhat more than a quadrant of the RADIATION FIELD may suffice by performing a test in each successive quadrant. However, when flatness and other parameters which depend on SCATTERED RADIATION are tested, solid blocks of water equivalent material should be added to provide the appropriate contribution of SCATTERED RADIATION. For dose measurements involving GANTRY rotation, a solid PHANTOM or an enclosed water PHANTOM attached to the RADIATION HEAD may be used.

“6.6 STANDARD MEASUREMENT DEPTHS”

For electrons the STANDARD MEASUREMENT DEPTH is specified as half the PENETRATIVE QUALITY because this depth corresponds approximately to the depth of the centre of the tumour for the majority of PATIENTS. This is in lieu of the discrete steps in reference depth which have been used traditionally for stepwise ranges of energy.

3.2.3 Suggested functional performance values

“7 DOSE MONITORING SYSTEM”

The suggested tolerances for the DOSE MONITORING SYSTEM are selected wide enough to accommodate well-designed equipment, yet narrow enough that the randomized total of all uncertainties in the ABSORBED DOSE delivered to any selected point in the planned TREATMENT VOLUME and directly attributable to the MEDICAL ELECTRON ACCELERATOR functional performance does not exceed a standard deviation of +3,3 % (see <Table 1). If the full standard deviation is used up, it means that there is about 32 % probability that the suggested

SCALE READING will be in error by more than this deviation and about a 5 % probability that any single SCALE READING will be in error by more than the double standard deviation.

“7.2 Reproducibility”

The reproducibility tolerance for the DOSE MONITORING SYSTEM is suggested as 0,5 %. Hence, to test other aspects of the DOSE MONITORING SYSTEM performance, it will be necessary to obtain an average value of R of the ratio of DOSE MONITOR UNITS to ABSORBED DOSE by making a number of repeated IRRADIATIONS for each data point, the required number being dependent on the actual reproducibility of the DOSE MONITORING SYSTEM and how much of the specified tolerance is used up by the DOSE MONITORING SYSTEM for each of the other aspects of performance. Hence, to be able to test the system in a reasonable amount of time, the specification encourages manufacturers to achieve much better than 0,5 % reproducibility so that perhaps only two or three IRRADIATIONS will be required to obtain an average value R for each data point in clauses and subclauses after 7.2.

“7.3 Proportionality”

The goal is to have sufficient precision in the ELECTRON ACCELERATOR DOSE MONITORING SYSTEM so that its calibration with respect to a standard IONIZATION CHAMBER for the full nominal range of delivered ABSORBED DOSE remains constant within a specified standard deviation over the full nominal range of ABSORBED DOSE RATES. Subclause 7.3 and Figure 3 of this report describe a test and calculation procedure. The recommended tolerances for both X-RADIATION and ELECTRON RADIATION of 2 % were chosen as representative of practical dosimeter systems in modern accelerators and as not excessive in relation to other uncertainties in delivered ABSORBED DOSE, recognizing that most treatment fractions are given within a rather limited range of ABSORBED DOSE and ABSORBED DOSE RATE.

“7.6 Dependence on the shape of the RADIATION FIELD”

It has been observed in some equipment that the ratio of DOSE MONITOR UNITS to ABSORBED DOSE depends upon whether the upper or the lower jaws of the BEAM LIMITING SYSTEM are used to define the long edges of a rectangular RADIATION FIELD. The causes for this can involve such factors as proximity of the upper jaws to the IONIZATION CHAMBER, an oblong distribution of ABSORBED DOSE in the RADIATION BEAM at the X-RADIATION TARGET and asymmetric distribution of ABSORBED DOSE in the ELECTRON BEAM extracted from the ELECTRON ACCELERATOR magnet system. Since USERS have not traditionally taken account of this possible variation in calibration, manufacturers are asked to bring it to the attention of USERS by stating its magnitude.

“8 Depth ABSORBED DOSE characteristics”

“8.1 X-RADIATION”

The depth dose distribution of the X-RAY BEAM is dependent upon several factors other than the energy of the ELECTRON BEAM striking the X-RADIATION TARGET of MEDICAL ELECTRON ACCELERATORS. Similarly, the depth dose distribution of the ELECTRON BEAM is dependent upon several factors other than the energy of the ELECTRON BEAM striking the electron window. Therefore, instead of NOMINAL ENERGY, the term "PENETRATIVE QUALITY" is used as a more precise descriptor of the RADIATION BEAM produced by such equipment.

The tolerance is chosen in terms of treatment planning. For example a +3 % change from one machine to another in the 6,3 cm (BJR Suppl. 17) average depth to 80 % ABSORBED DOSE for a 6 MV X-RAY BEAM corresponds to a change in the value of the depth dose curve at STANDARD MEASUREMENT DEPTH from 67,7 % to 68,9 % or 66,5 % of maximum ABSORBED DOSE. This in itself does not cause an error in ABSORBED DOSE but merely characterizes the RADIATION BEAM energy of the machine.

The deviation of PENETRATIVE QUALITY of X-RADIATION with the angular position of the GANTRY is not specified because it is expected to be quite small and because such energy changes are readily detected by a monitor of variations in dose distribution (axial vs. symmetrical peripheral dose); see 29.1.1.5 of IEC 60601-2-1.

“8.2 ELECTRON RADIATION”

The PENETRATIVE QUALITY for ELECTRON RADIATION is specified at 80 % ABSORBED DOSE because therapists typically specify the TARGET VOLUME to be within an isodose contour of at least 80 %. The tolerance is chosen in recognition of the typical accuracy of anatomical measurements and to be similar to other positional tolerances for the equipment. To protect sensitive regions below the TARGET VOLUME, a steep fall-off of ABSORBED DOSE beyond the depth of 80 % is desired. Hence, manufacturers are encouraged to minimize lower energy IONIZING RADIATION content in the RADIATION BEAM. This becomes a more difficult design problem at NOMINAL ENERGIES above 20 MeV, so the suggested ratio of 1,6 for the ratio of PRACTICAL RANGE to a depth of 80 % of maximum ABSORBED DOSE is applied only up to 20 MeV.

“8.2.2 Stability of PENETRATIVE QUALITY”

Over the range of 3 MeV to 50 MeV, PENETRATIVE QUALITY ranges from about 1 cm to 15 cm for ELECTRON RADIATION. The suggested tolerance of ± 2 mm for stability of PENETRATIVE QUALITY of ELECTRON RADIATION with GANTRY rotation is consistent with other positional tolerances for the equipment.

“9 Uniformity of RADIATION FIELDS”

“9.1 X-RADIATION”

“9.1.1 Flatness of square X-RAY FIELDS”

Because of X-RADIATION scatter in the PHANTOM and variation in RADIATION SPECTRUM over the RADIATION FIELD, the shoulders of the dose profile at STANDARD MEASUREMENT DEPTH tend to be lower for small RADIATION FIELDS and higher for large RADIATION FIELDS than the axis value of the dose profile with a single FIELD-FLATTENING FILTER. A major requirement for RADIOTHERAPY is that the range of dose variation over the TARGET VOLUME be limited so that all points in the volume receive the prescribed ABSORBED DOSE within a tolerance range. However, whether the ABSORBED DOSE to the point on RADIATION BEAM AXES at STANDARD REFERENCE DEPTH is high or low in this range is not a major factor as long as its value is accurately known so that it can be considered in the treatment planning process.

By specifying the flatness of X-RAY FIELDS in terms of the ratio of maximum to minimum ABSORBED DOSE instead of specifying the ratios of maximum and minimum ABSORBED DOSE to ABSORBED DOSE on the RADIATION BEAM AXIS dose, the range of RADIATION FIELDS that can be flattened by a single FIELD-FLATTENING FILTER is extended, thereby simplifying equipment and improving its safety in operation.

The ratio of maximum to minimum ABSORBED DOSE is allowed to have a larger value for square RADIATION FIELDS larger than 30 cm $\times$ 30 cm in order to permit flattening such RADIATION FIELDS with the same FIELD-FLATTENING FILTER as for smaller RADIATION FIELDS, thereby maintaining simplicity of equipment and corresponding safety.

IEC 60976 requires that the equipment provide a flattened RADIATION FIELD. Variations from this basic condition of flatness to achieve other desired ABSORBED DOSE distributions (such as higher ABSORBED DOSE to the core of the TARGET VOLUME) can then be achieved in therapy by coning down RADIATION FIELDS during the course of treatment or by using compensation, for example.

“9.1.2 Deviation of dose distribution of square X-RAY FIELDS with angular positions”

The range of dose variation over the RADIATION FIELD can be incorporated into the treatment plan. RADIATION FIELD and given ABSORBED DOSE at DEPTH OF DOSE MAXIMUM for each portal and other factors can be adjusted to limit the range of ABSORBED DOSE over the TARGET VOLUME. However, the isodose curves used to compute the treatment plan are taken for only one angular position of the GANTRY and BEAM LIMITING SYSTEM and variations of these isodose curves with angular position of the GANTRY and BEAM LIMITING SYSTEM will produce errors in the dose distribution delivered to the PATIENT. Therefore a relatively tight tolerance is placed on stability of flatness with angular position of GANTRY and BEAM LIMITING SYSTEM.

It should be noted that there was considerable controversy within the Working Group regarding whether or not the stability variations with rotation of GANTRY and BEAM LIMITING SYSTEM should be added to the unflatness measured at a single angular position of GANTRY and BEAM LIMITING SYSTEM in determining compliance with the tolerance on ratio of maximum to minimum ABSORBED DOSE over the flattened area. For example, if the full +1,5 % tolerance for stability of the ratio of maximum to minimum ABSORBED DOSE with rotation of GANTRY and BEAM LIMITING SYSTEM is used up by the equipment, then the allowed tolerance on ratio of maximum to minimum ABSORBED DOSE at a single angular position of GANTRY and BEAM LIMITING SYSTEM would have been limited to only 103 % for RADIATION FIELDS up to 30 cm × 30 cm. Yet with modern equipment there is considerable difficulty in achieving even 106 % over the full flattened area at a single angular position of GANTRY and BEAM LIMITING SYSTEM over the full range of RADIATION FIELDS to 30 cm × 30 cm within the constriction of 107 % maximum ABSORBED DOSE anywhere in the plane at the depth of 100 % ABSORBED DOSE on the RADIATION BEAM AXIS.

Because of scatter in the PHANTOM and variation in RADIATION SPECTRUM over the RADIATION FIELD, PENETRATIVE QUALITY of the RADIATION BEAM decreases with displacement from RADIATION BEAM AXIS toward the edges and corners of the RADIATION FIELD and decreases differently for different RADIATION FIELDS. The magnitude of this decrease is largely beyond the control of the manufacturer, especially at NOMINAL ENERGIES of X-RADIATION where the spectral quality distribution over the RADIATION FIELD is not easily trimmed by filtration.

Since treatment plans are typically prepared from isodose contours measured or calculated for a single angular position of GANTRY and BEAM LIMITING SYSTEM, unflatness of these RADIATION FIELDS can be accommodated to achieve the desired uniformity of ABSORBED DOSE over the TARGET VOLUME. The really insidious contribution to error in the treatment plan is then the instability of flatness with GANTRY and BEAM LIMITING SYSTEM rotation; hence a tight tolerance is placed on this instability.

The Working Group concluded that the standard should be written so that stability variations with equipment rotation in 9.1.2 should not be added to the flatness variations at the single angular position of the equipment in determining compliance with the flatness tolerance ratio of maximum to minimum ABSORBED DOSE in 9.1.1. This results in a simpler and more easily implemented standard and it corresponds to good current practice in the design of MEDICAL ELECTRON ACCELERATORS.

“9.1.4 Maximum ratio of ABSORBED DOSES”

For simplicity of specification and measurement, the maximum value of ABSORBED DOSE was specified in the plane normal to the RADIATION BEAM AXIS at the depth of maximum ABSORBED DOSE on the RADIATION BEAM AXIS. It was recognized that the actual maximum ABSORBED DOSE in the RADIATION FIELD may be above or below this plane, especially in the corners of the RADIATION FIELD, but it is not anticipated that this will represent a severe excess in ABSORBED DOSE over the maximum ABSORBED DOSE in the measurement plane.

“9.1.5 WEDGE X-RAY FIELDS”

For better accuracy in measuring WEDGE FILTER ANGLE, the slope of the isodose contour at STANDARD MEASUREMENT DEPTH on the RADIATION BEAM AXIS is measured by a line congruent with this isodose contour at points displaced $\pm\frac{1}{4}$ of the GEOMETRICAL FIELD dimension from the RADIATION BEAM AXIS rather than finding the tangent at a single point on the RADIATION BEAM AXIS. The STANDARD MEASUREMENT DEPTH of 10 cm is chosen as relevant to RADIOTHERAPY and deep enough so that the wedged isodose contour at this depth extends across most of the RADIATION FIELD.

“9.2 ELECTRON RADIATION”

“9.2.1 Flatness of ELECTRON FIELDS”

Radiotherapy physicians typically specify the TARGET VOLUME to be within an electron isodose contour of at least 80 %. For abutment of contiguous RADIATION FIELDS as well as for the majority of single portal treatments it is desirable that the 80 % isodose surface near the plane at BASE DEPTH be relatively flat over most of the GEOMETRICAL FIELD area with short radius curvature, as this 80 % isodose surface turns upward in the region of the GEOMETRICAL FIELD edge and corner. The specification is written to encourage manufacturers to design the devices which spread and collimate the ELECTRON BEAM so as to achieve these goals for the flatness of the 80 % isodose surface without producing excessive ABSORBED DOSE at the STANDARD MEASUREMENT DEPTH.

The GEOMETRICAL FIELD SIZE is defined as constant with depth into the PHANTOM (RADIATION FIELD edges projected normal to PHANTOM surface) because the border between the GEOMETRICAL FIELD edge and the 80 % isodose contour at BASE DEPTH tends to be relatively independent of NOMINAL ENERGY of the RADIATION BEAM and RADIATION FIELD, hence simplifying specification of this border for dose measurements as well as for PATIENT treatment planning.

Even though the physician may choose to have the TARGET VOLUME extend as far as the 80 % isodose contour, it is desirable for RADIOTHERAPY that as much as practicable of the TARGET VOLUME be encompassed by the 90 % isodose contour; hence 90 % dose is used to define compliance with the flattened area in the plane at STANDARD MEASUREMENT DEPTH. The 90 % dose on the RADIATION BEAM AXIS is used to define the position of the plane at BASE DEPTH as a convenient way to specify and to measure flatness of the 80 % isodose surface, such as by measurement of dose profiles in the BASE DEPTH or measurement of isodose contours in planes containing the RADIATION BEAM AXIS and each major axis and in planes containing the bisectors of the corners of rectangular RADIATION FIELDS.

“9.2.3 Symmetry of ELECTRON FIELDS”

A symmetry specification for ELECTRON RADIATION is included in much the same way as for X-RADIATION. It should be noted that a minority opinion was expressed in the Working Group as to the need for symmetry specification for electrons. The question arises as to the biological significance of a cell displaced one way from the RADIATION BEAM AXIS receiving slightly more or less ABSORBED DOSE than its mirror image cell displaced equally the other way from the RADIATION BEAM AXIS, as long as both these cells receive an ABSORBED DOSE within the specified range from maximum to minimum ABSORBED DOSE, which is specified as between 103 % maximum and 90 % minimum over the flattened area at the STANDARD MEASUREMENT DEPTH. The Working Group chose to include the symmetry specification simply to encourage manufacturers to optimize the appearance of isodose contours for ease of treatment planning.

“9.3 PENUMBRA of RADIATION FIELDS”

PENUMBRA is minimized by employing a small effective diameter RADIATION SOURCE, maximizing the ratio of RADIATION SOURCE-BEAM LIMITING SYSTEM distance to NORMAL TREATMENT DISTANCE, and properly aligning the field defining edges of the BLD's with the edges of the finite size RADIATION SOURCE. Scatter in the PHANTOM causes PENUMBRA to be larger at larger RADIATION FIELDS and to be a function of RADIATION BEAM PENETRATIVE QUALITY.

Because of these many variables, a single simple tolerance on PENUMBRA would have limited meaning. Therefore, manufacturers are asked to state the PENUMBRA for various conditions and these statements can be confirmed by inspection of dose profiles run in the tests of 9.1.1 and 9.2.1.

“10 Indication of RADIATION FIELDS”

“10.1 X-RADIATION”

“10.1.2 LIGHT FIELD INDICATOR”

The positions of the LIGHT FIELD edges are commonly used to adjust X-RAY FIELD dimension and position relative to PATIENT skin marks. To avoid excessive ABSORBED DOSE to nearby sensitive organs and to obtain uniform ABSORBED DOSE at selected depth (such as the depth of a sensitive organ) over the contiguous region of adjacent RADIATION FIELDS without excessive under- or over-ABSORBED DOSE, it is important that the congruence of the RADIATION FIELD and the projection of the LIGHT FIELD at the selected depth is relatively precise. Since the projection of the LIGHT FIELD follows the RADIATION FIELD 50 % decrement line rather accurately down to the STANDARD MEASUREMENT DEPTH, congruence is specified at this depth.

The suggested tolerances are chosen in recognition of the PENUMBRA of practical LIGHT FIELD edges and recognizing that the LIGHT FIELD is defined by an infinitesimal thickness of the upper or lower edge of the jaw, whereas the X-RAY FIELD is defined by a finite thickness of the jaw of the BEAM LIMITING SYSTEM. Also, in practice in compact RADIATION HEADS the jaw faces are not always precisely parallel to the RADIATION FIELD edge over the full range of RADIATION FIELDS.

Compensation for the displacement of the LIGHT FIELD edge from the X-RAY FIELD edge can be achieved with a calibration chart, provided this displacement is constant for a given RADIATION FIELD, hence the tolerance on reproducibility of this displacement in 10.1.2.

The tolerance at 1,5 times NORMAL TREATMENT DISTANCE (NTD) is double the tolerance at NTD since errors are multiplied by about 2 for typical equipment with BEAM LIMITING SYSTEM at about half NTD from the RADIATION SOURCE.

“10.2 ELECTRON RADIATION”

“10.2.1 Numerical field-indication”

For consistency, the same definition of tolerance on numerical indication of RADIATION FIELD is used for ELECTRON RADIATION as for X-RADIATION, relating it to the points on the major axes in the plane at STANDARD MEASUREMENT DEPTH where the ABSORBED DOSE is 50 % of the ABSORBED DOSE on the RADIATION BEAM AXIS at the same depth. The 50 % ABSORBED DOSE point is important when abutting adjacent RADIATION FIELDS.

“10.2.2 LIGHT FIELD-INDICATOR”

Numerical identification of RADIATION FIELD is often used as the primary indication of RADIATION FIELD in electron therapy. Hence, the specification is written to require congruence of numerical indication and LIGHT FIELD, on the assumption that calibration tables based on isodose curves will be used to achieve congruence with RADIATION FIELDS.

“10.3 Geometry and motion speeds of adjustable BLDs for X-RADIATION AND ELECTRON RADIATION”

A $\pm 0,5^\circ$ error in parallelism of opposing edges of a 20 cm $\times$ 20 cm RADIATION FIELD corresponds to a difference in length of the other two edges of 1,7 mm. BEAM LIMITING SYSTEM jaws may have the greatest tendency to tilt away from RADIATION BEAM AXIS at 90° (or 270°) GANTRY angle, hence the corresponding test condition.

“10.4 Illuminance and PENUMBRA of the LIGHT FIELD”

The suggested minimum value of illuminance of the LIGHT FIELD for RADIOTHERAPY equipment is smaller than the typical specification for diagnostic X-RADIATION equipment so that a smaller LIGHT FIELD source can be used to achieve finer resolution of LIGHT FIELD edges, major axes and RADIATION BEAM AXIS for more accurate PATIENT set-up. The 40 lux average value over the full LIGHT FIELD is adequate under typical treatment room subdued ambient light. A relatively uniform intensity over the full LIGHT FIELD is anticipated for delineation of shadow blocks.

“12 ISOCENTRE”

“12.1 Displacement of the RADIATION BEAM AXIS from the ISOCENTRE”

The ISOCENTRE is specified in terms of the X-RAY BEAM because this is the point to which the tumour position is referred in ISOCENTRIC RADIOTHERAPY treatment planning and hence is desired for PATIENT positioning. The X-RAY BEAM ISOCENTRE tolerance is not directly comparable to ISOCENTRE tolerance statements of the past, which related traditionally only to an approximation to the ISOCENTRE established by mechanical means or to a thin fixed-size X-RAY FIELD at a fixed angular position of BEAM LIMITING SYSTEM and often only in the vertical plane normal to the GANTRY rotation axis (for example the star test with one vertical film). The resulting tests for the present definition of ISOCENTRE are consequently more complex than for the traditional specification of a "mechanical" ISOCENTRE in terms of axes of equipment rotation. The suggested tolerance of ± 2 mm is slightly larger than the typical equipment specification for mechanical ISOCENTRE to accommodate contributions to X-RAY BEAM position error that are in addition to mechanical contributions, as well as to accommodate large heavy equipment and equipment with retractable beam stopper. A minority opinion was expressed in the Working Group that the tolerance should be +3 mm in order to allow for wear over the working life of the machine. An insensitive RADIOGRAPHIC FILM requiring about 1 Gy exposure is recommended for the test because it corresponds to a typical treatment ABSORBED DOSE and will include variations due to transient effects during the start of IRRADIATION.

“12.2 Indication of the ISOCENTRE”

The ISOCENTRE is a point in space; its location is determined by the test of 12.2. This suggested tolerance requires that the RADIATION BEAM AXIS always pass within ± 2 mm of this point. The indicator of ISOCENTRE may be used to position a selected point in the PATIENT TARGET VOLUME at the ISOCENTRE, within the suggested tolerance for this indicator of ± 2 mm. Thus, for parallel opposed RADIATION FIELDS, one of which is displaced 0 mm to +2 mm and the other –2 mm from the ISOCENTRE with the tolerance given in 12.1.2, it is possible that one RADIATION FIELD will be displaced –2 mm to 0 mm and the other RADIATION FIELD displaced –4 mm from the selected point in the TARGET VOLUME (see Figure 1).

The indicator of RADIATION BEAM AXIS in 11.2 and 11.3 (such as the projection of cross-hairs and the LIGHT FIELD system) may be used to locate the PATIENT relative to the RADIATION BEAM by the PATIENT skin marks for the centre of each portal. If these skin marks are precisely placed relative to the selected point in the TREATMENT VOLUME (such as by using a "perfect" simulator), then the axes of the parallel opposed RADIATION FIELDS positioned by this indicator would be within ± 2 mm of this selected point.

The tolerance of ± 2 mm for both the indicator of ISOCENTRE and the RADIATION BEAM AXIS was selected as achievable by practical equipment and as consistent with the overall spatial tolerance of precision RADIOTHERAPY (see Table 1).

The tolerance on indication of the RADIATION BEAM AXIS (Clause 10) is made larger for ELECTRON RADIATION than for X-RADIATION because ELECTRON RADIATION scatter in air and bend in magnetic fields, introducing variables beyond the NORMAL TREATMENT DISTANCE and with the RADIATION FIELD defining aperture 5 cm to 50 cm from the NORMAL TREATMENT DISTANCE.

“13 Indication of the distance along the RADIATION BEAM AXIS”

The indicator of distance from ISOCENTRE (such as graduated mechanical FRONT POINTER) may be used for example to displace the PATIENT surface from the ISOCENTRE vertically or horizontally in order to position a selected point in the PATIENT TREATMENT VOLUME at the ISOCENTRE, within the suggested tolerance of ± 2 mm. The tolerance was chosen as comparable to the indicators of the ISOCENTRE.

The indicator of distance from the RADIATION SOURCE is specified with a tolerance adequate for square law correction of ABSORBED DOSE. For example, at 100 cm distance from the RADIATION SOURCE, a ± 5 mm tolerance corresponds to ± 1 % tolerance on the calculated ABSORBED DOSE.

“14 Zero position of rotational scales”

Tolerances on the zero positions of pitch and roll of the RADIATION HEAD are suggested as $+0,1^\circ$ to limit displacement of the RADIATION BEAM AXIS from the ISOCENTRE to less than ± 2 mm. Tolerance on reproducibility of the 0° GANTRY angle is suggested as $\pm 0,5^\circ$, which will limit displacement of the RADIATION BEAM at the PATIENT surface to $\pm 1,8$ mm for 20 cm vertical movement of the PATIENT.

“16 Movement of the PATIENT table”**“16.2 Vertical movement of the table”**

The tolerance on horizontal displacement due to vertical movement of the PATIENT table by 20 cm was selected so that the TARGET VOLUME will not translate horizontally more than 2 mm when the PATIENT is raised from one position to the second position in a typical parallel opposed SSD treatment with vertical RADIATION BEAM and ISOCENTRIC EQUIPMENT.

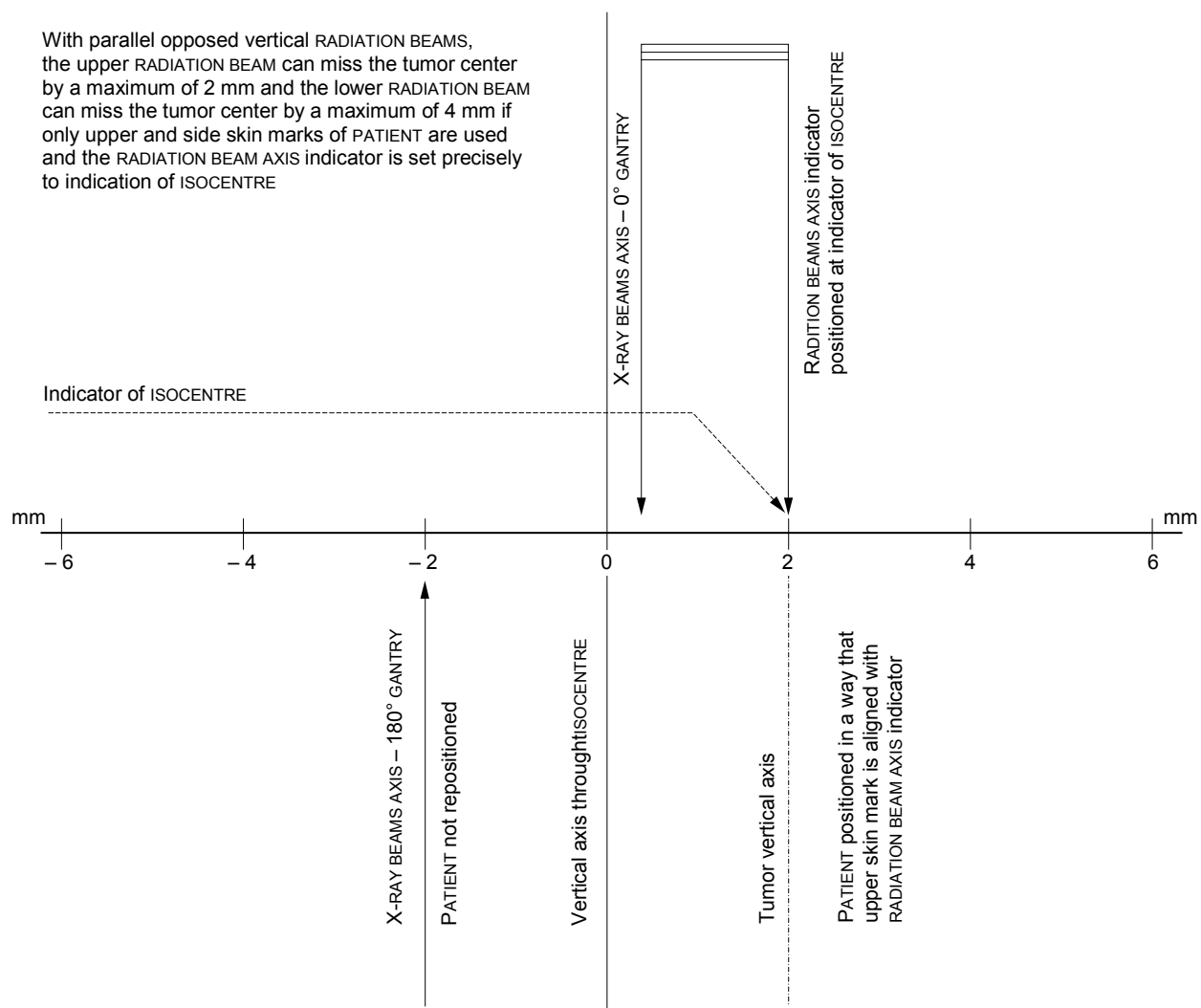
“16.3 ISOCENTRIC rotation of the table”

For rotation of the RADIATION BEAM relative to the PATIENT by table rotation rather than by GANTRY rotation (e.g. fixed horizontal RADIATION BEAM and coronal arc), the same tolerance is used for table isocentricity as for the X-RAY BEAM isocentricity in 12.1.

Table 1 – Summary of major tolerances in routine X-RAY THERAPY

A. Affecting the precision of ISOCENTRIC positioning of a selected point in the TARGET VOLUME			
Clause/Subclause		x and y	z
10	LIGHT FIELD indication of centre and edges of the RADIATION FIELD	±2 mm	
11	Indication of RADIATION BEAM AXIS (combine with Clause 8)	±2 mm	
12	RADIATION BEAM AXIS relative to ISOCENTRE	±2 mm	±2 mm
12.2	Indication of position of ISOCENTRE	±2 mm	±2 mm
14	Indication of distance from ISOCENTRE along the RADIATION BEAM AXIS	_____	±2 mm
	Root square sum	±4 mm	±3,5 mm
B. Affecting the precision of ABSORBED DOSE delivered to a selected point in the PATIENT TARGET VOLUME			
7	DOSE MONITORING SYSTEM		
7.2	Reproducibility	±0,5 %	
7.3	Proportionality	±2,0 %	
7.4	Dependence on equipment position	±1,5 %	
7.7.2	Stability throughout the day	±1,0 %	
7.7.3	Stability throughout the week	±1,0 %	
	Root square sum	±2,9 %	±2,9 %
8.1	Stability of ABSORBED DOSE due to assumed ±1 % stability of PENETRATIVE QUALITY (e.g. 6 MV X-RADIATION at STANDARD MEASUREMENT DEPTH)		±0,4 %
8.1.2	Stability of flatness with angular position		±1,5 %
	Root square sum		±3,3 %

With parallel opposed vertical RADIATION BEAMS, the upper RADIATION BEAM can miss the tumor center by a maximum of 2 mm and the lower RADIATION BEAM can miss the tumor center by a maximum of 4 mm if only upper and side skin marks of PATIENT are used and the RADIATION BEAM AXIS indicator is set precisely to indication of ISOCENTRE



IEC 1137/08

Subclause		Value suggested
10.1.1	Deviation of the indicated RADIATION BEAM axis from the X-RAY BEAM AXIS for all angular positions of the GANTRY and BEAM LIMITING SYSTEM and for all RADIATION FIELDS and all NOMINAL ENERGIES	± 2 mm
12.1	Displacement of the X-RAY BEAM AXIS from ISOCENTRE for all angular positions of the GANTRY AND BEAM LIMITING SYSTEM AND FOR ALL RADIATION FIELDS AND ALL NOMINAL ENERGIES	± 2 mm
12.2	Deviation from the ISOCENTRE for all devices which indicate the position of the ISOCENTRE	± 2 mm

Figure 1 – Cumulative errors in beam displacement

4 Acceptance tests

4.1 General

Prior to the adoption of IEC 60976, the set of tests used for acceptance was typically significantly shorter than the set of acceptance tests described in Clause 4 of this report. These prior acceptance tests were usually performed by the manufacturer's personnel, although in some cases they were performed by the USER. The work in performing these tests is often interspersed with the work of installing the machine.

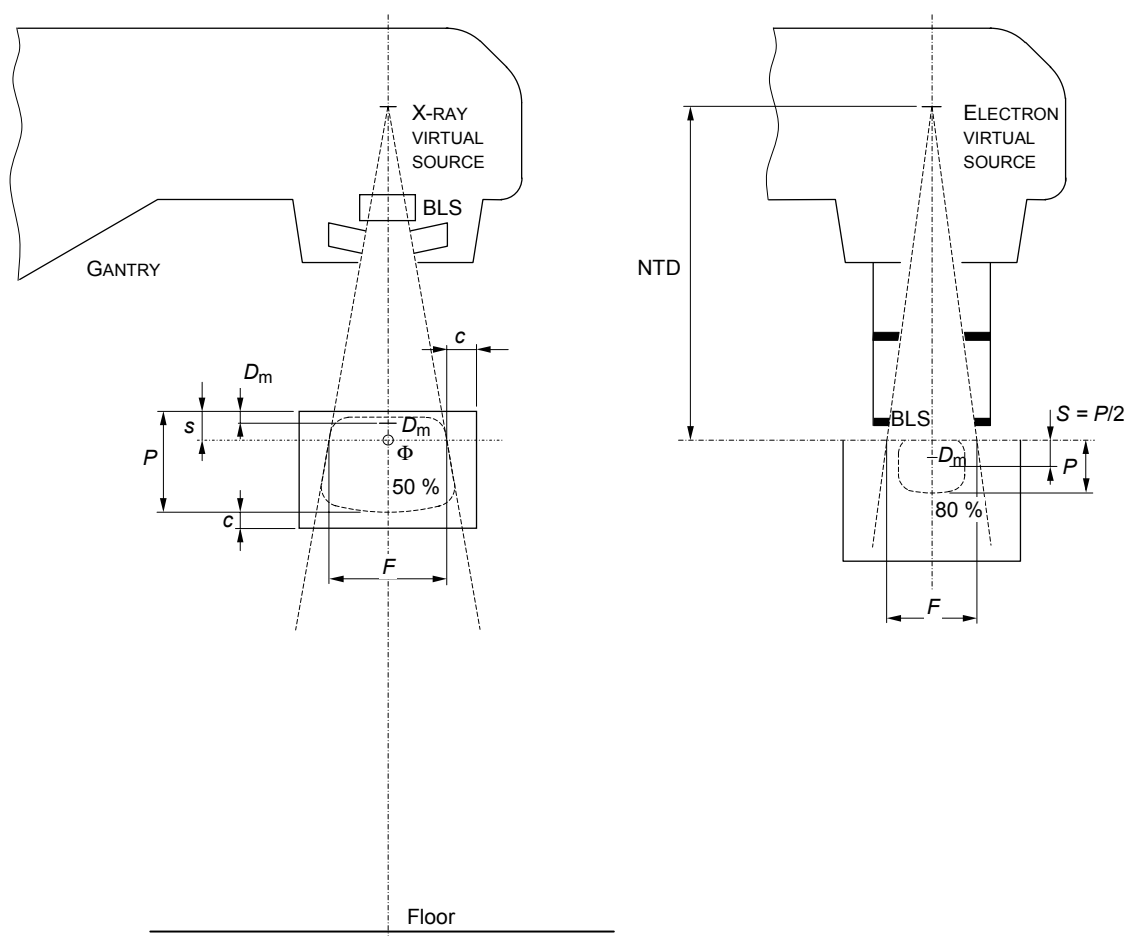
It has been estimated that the total time to complete the acceptance tests described in Section 4 may be roughly twice this prior practice. The additional effort represented by the difference between this prior practice and the tests described in Section 4 may be performed by the USER or by the manufacturer's personnel, upon agreement. There will also be other measurements, not included in this Section 4, such as isodose plots, that the USER will normally want to perform subsequent to the acceptance tests.

The suggested test methods listed in 4.2 are consistent with the test methods of IEC 60976 but are presented in a form which may be more suitable for use in hospitals. The suggested values listed in 3.1 of this report and the values declared by manufacturers for their machine types relate to the type test conditions of IEC 60976. For machine acceptance, the test methods and test conditions necessary to measure these values on an individual machine can be different from those in the type test. The format of 3.1 can also be used to record these measured values for the individual machine.

Suggested test methods and test conditions are presented in 4.2 and 4.3 for all relevant clauses of IEC 60976. Particular machine types may not provide features corresponding to all these clauses. These test methods and conditions apply only to those clauses for which the manufacturer has declared a performance value in accordance with IEC 60976.

Inaccuracies resulting from the test equipment and test method should be minimized, since such errors need to be taken into account when assessing compliance with the manufacturer's declared tolerance values.

Unless otherwise stated, measurements are made under the standardized test conditions of Clause 6 of IEC 60976. In 9.1 (uniformity of RADIATION FIELDS – X-RADIATION) for ISOCENTRIC machines the surface of the PHANTOM remains at a position 10 cm toward the RADIATION SOURCE from the ISOCENTRE for measurements of ABSORBED DOSE distribution in the plane at STANDARD MEASUREMENT DEPTH of 10 cm (9.1.1, 9.1.2, 9.1.3 and 9.1.5) and in the plane at DEPTH OF DOSE MAXIMUM (8.1.4). In 8.1 for NON-ISOCENTRIC machines and in 9.2 for ELECTRON RADIATION, the surface of the PHANTOM remains at the NORMAL TREATMENT DISTANCE for the measurements in planes at the various specified depths (see Figure 2).



IEC 1138/08

Φ	=	X-RAY ISOCENTRE
F	=	RADIATION FIELD
P	=	PENETRATIVE QUALITY
S	=	STANDARD MEASUREMENT DEPTH
C	=	PHANTOM clearance
D_m	=	DEPTH OF DOSE MAXIMUM on the RADIATION BEAM AXIS
NTD	=	NORMAL TREATMENT DISTANCE
BLS	=	BEAM LIMITING SYSTEM

Figure 2 – Phantom position

4.2 Summary of suggested test methods for MEDICAL ELECTRON ACCELERATOR acceptance

The following clause numbering refers to IEC 60976:

“7 DOSE MONITORING SYSTEM”

Position a RADIATION DETECTOR at the ISOCENTRE at STANDARD MEASUREMENT DEPTH in a PHANTOM rigidly attached to the RADIATION HEAD.

“7.2 Reproducibility”

The reproducibility is defined as the coefficient of variation. Measure the ratio $\bar{R}$ of DOSE MONITOR UNITS to dosimeter SCALE READING for $n = 10$ consecutive IRRADIATIONS of approximately 1 Gy. Calculate the average ratio $\bar{R} = (\sum R_i)/n$ and the coefficient of variation s .