



DPC: 19/30402598 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 04 September 2019

Origin: International

Latest date for receipt of comments: 25 September 2019

Project No. 2019/00247

Responsible committee: CH/62/3 Equipment for radiotherapy, nuclear medicine and radiation dosimetry

Interested committees:

Title: Draft BS EN IEC 62083 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 25 September 2019

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <https://standardsdevelopment.bsigroup.com/>.

Responsible Committee Secretary: Ms Jacinta Hampton (BSI)

Direct tel:

E-mail: jacinta.hampton@bsigroup.com

Full document details: 19/30402598 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62C/745/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

IEC 62083 ED3

DATE OF CIRCULATION:

2019-08-30

CLOSING DATE FOR COMMENTS:

2019-10-25

SUPERSEDES DOCUMENTS:

62C/735/CD, 62C/739B/CC

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY

SECRETARIAT:

Germany

SECRETARY:

Mr Norbert Bischof

OF INTEREST TO THE FOLLOWING COMMITTEES:

SC 62B

PROPOSED HORIZONTAL STANDARD:

☐

Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☒ SAFETY

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems

NOTE FROM TC/SC OFFICERS:

The Members of SC 62C/WG1 are requested to bring their National Committee comments to the forthcoming meeting October, 2019 in Shanghai, or send them by email to the secretariat iectc62@cocir.org before the meeting. However, comments also must be provided through the IEC commenting system.

Copyright © 2019 International Electrotechnical Commission, IEC. All rights reserved. It is permitted to download this electronic file, to make a copy and to print out the content for the sole purpose of preparing National Committee positions. You may not copy or "mirror" the file or printed version of the document or any part of it, for any other purpose without permission in writing from IEC.

Documents
Document Sharing Hub

CONTENTS

1	Scope	5
2	Normative references	5
3	Terms and definitions	6
4	General	9
4.1	Test grades	9
4.2	Development	9
4.3	Testing the RTPS installation	10
5	ACCOMPANYING DOCUMENTATION	10
5.1	General	10
5.2	INSTRUCTIONS FOR USE	11
6	General requirements for operational safety	12
6.1	Distances and linear and angular dimensions	12
6.2	*Coordinate systems, movements, and scales	12
6.3	RADIATION quantities	13
6.4	Date and time format	13
6.5	Security	13
6.5.1	Protection against unauthorized use	13
6.5.2	Backup and recovery of data	14
6.5.3	Protection against unauthorized modification	14
6.5.4	Change in software versions	15
6.5.5	Changes in installation environment	16
6.6	Data limits	16
6.7	PATIENT identification	16
6.8	Interfaces	17
6.8.1	Correctness of data transfer	17
6.8.2	Data input to the RTPS	17
6.8.3	Data output from the RTPS	18
7	Approval	18
7.1	Approving an item	18
7.2	Modifying an approved item	19
7.3	Deletion of an approved item	19
8	Algorithms	19
8.1	General	19
8.2	ABSORBED DOSE Calculation	20
8.2.1	Accuracy	20
8.2.2	Calculation data Input	20
8.2.3	PATIENT SPECIFIC beam modifying devices calculation	21
8.2.4	Elapsed time calculations in brachytherapy	21
8.2.5	In-room image dose calculation	21
8.2.6	Radiobiological effect	22
9	Modelling	22
9.1	EQUIPMENT MODELLING	22
9.1.1	General EQUIPMENT MODELLING	22
9.1.2	EQUIPMENT MODEL approval	23
9.1.3	RADIATION description	23
9.1.3.1	MEDICAL ELECTRON ACCELERATOR	23

9.1.3.2	GAMMA BEAM THERAPY EQUIPMENT	24
9.1.3.3	LIGHT ION EQUIPMENT	24
9.1.3.4	BRACHYTHERAPY	24
9.1.3.4.1	RADIONUCLIDE sources	24
9.1.3.4.2	Electronic BRACHYTHERAPY	24
9.1.4	Preconfigured model.....	25
9.1.5	EXTERNAL BEAM EQUIPMENT	25
9.1.5.1	GANTRY, RADIATION HEAD, PATIENT POSITIONERS and beam modifiers	25
9.1.5.2	ABSORBED DOSE to DOSE MONITOR UNIT ratio for REFERENCE CONDITIONS.....	25
9.1.6	BRACHYTHERAPY EQUIPMENT	26
9.1.6.1	AFTERLOADING EQUIPMENT	26
9.1.6.2	Temporary low dose rate manual application.....	27
9.1.6.3	Permanent implants	27
9.1.7	Radiobiological dose-effect modelling.....	27
9.1.7.1	General radiobiological dose-effect model.....	27
9.1.7.2	Radiobiological dose-effect model approval	28
9.1.8	Imaging EQUIPMENT MODELLING.....	28
9.2	Immobilization and supporting devices modelling	29
9.3	PATIENT SPECIFIC BEAM MODIFYING DEVICES modelling.....	29
9.4	PATIENT MODELLING	29
9.4.1	General PATIENT MODELLING	29
9.4.2	Regions of interest	30
9.4.3	IMAGE REGISTRATION.....	30
9.4.4	PATIENT MODEL approval	31
10	RADIATION TREATMENT PRESCRIPTION	31
10.1	Display of RADIATION TREATMENT PRESCRIPTION.....	31
10.2	Change of RADIATION TREATMENT PRESCRIPTION	31
10.3	RADIATION TREATMENT PRESCRIPTION approval.....	32
11	TREATMENT PLAN	32
11.1	Display of RADIATION TREATMENT PRESCRIPTION	32
11.2	TREATMENT PLAN limitations	32
11.3	PATIENT orientation.....	32
11.4	Combination of TREATMENT PLAN	32
11.5	TREATMENT PLAN identification	33
11.6	TREATMENT PLAN approval.....	33
12	TREATMENT PLAN RECORD	34
12.1	Common TREATMENT PLAN RECORD parameters	34
12.2	Plan parameters for EBE	35
12.3	Plan parameters for BRACHYTHERAPY	35
13	TREATMENT PLAN report	35
13.1	Common TREATMENT PLAN report information	35
13.2	TREATMENT PLAN report for EQUIPMENT using RADIONUCLIDE sources.....	36
13.3	TREATMENT PLAN report for a TREATMENT PLAN with unapproved models.....	36
14	Exporting of a TREATMENT PLAN	36
14.1	Common TREATMENT PLAN export parameters	36
14.2	Plan parameters for EBE	37
14.3	Plan parameters for BRACHYTHERAPY EQUIPMENT	37

15	PATIENT-specific QA	37
16	ADAPTIVE RADIOTHERAPY	38
16.1	OFFLINE ADAPTIVE RADIOTHERAPY	38
16.2	ONLINE ADAPTIVE RADIOTHERAPY	38
16.3	REAL-TIME ADAPTIVE RADIOTHERAPY	39
Annex A (informative)	Imported and exported data	40
A.1.1	Subclause 6.2 Coordinate systems, movements, and scales	41
Table 1 –	Clauses and subclauses in this standard that require the provision of information in the ACCOMPANYING DOCUMENTATION and the technical description	10

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –
REQUIREMENTS FOR THE SAFETY OF RADIOTHERAPY
TREATMENT PLANNING SYSTEMS**

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.

International Standard IEC 62083 has been prepared by IEC subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition replaces the second edition of IEC 62083, published in 2009.

The edition of this standard considers many aspects of technology used by healthcare organizations. Clause 16 has been designed to facilitate current practice between RADIOTHERAPY TREATMENT MEDICAL ELECTRICAL EQUIPMENT (MEE), IMAGE GUIDED RADIOTHERAPY (IGRT) MEE, RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS), and Radiotherapy Treatment Management Systems. To pursue compatibility, the equipment standards for this equipment are being developed in parallel as much as possible to facilitate workflow communication.

The text of this standard is based on the following documents:

FDIS

Report on voting

--	--

54
55 Full information on the voting for the approval of this standard can be found in the report on
56 voting indicated in the above table.

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

58 In this standard, the following print types are used:

- 59 – requirements, compliance with which can be tested, and definitions: in roman type;
60 – explanations, advice, general statements, exceptions and notes: in small roman type;
61 – *test specifications: in italic type*;
62 – TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED
63 TERMS AND DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: SMALL CAPITALS.

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

- 67 • reconfirmed;
68 • withdrawn;
69 • replaced by a revised edition, or
70 • amended.

71

72

INTRODUCTION

73 A RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS) is a device that is used to simulate the
74 application of RADIATION to a PATIENT for a proposed RADIOTHERAPY TREATMENT. It usually, but
75 not necessarily, provides estimates of ABSORBED DOSE distributions in human tissue using a
76 particular algorithm or series of algorithms. These estimations, referred to in this International
77 Standard as ABSORBED DOSE distributions, are used by a QUALIFIED PERSON in planning a
78 course of RADIOTHERAPY.

79 The output of an RTPS is used by appropriately QUALIFIED PERSONS for clinical decisions and
80 for treatment delivery. Inaccuracies in the input data, the limitations of the algorithms, errors
81 in the TREATMENT PLANNING process, or improper use of output data, may represent a safety
82 HAZARD to PATIENTS should the resulting output data be used for TREATMENT purposes. This
83 standard defines requirements to be complied with by MANUFACTURERS in the design and
84 construction of an RTPS in order to provide protection against the occurrence of such HAZARDS.
85 It establishes the minimum requirements for the contents of the ACCOMPANYING DOCUMENTS
86 that will permit the OPERATOR to make informed choices during the TREATMENT PLANNING
87 process.

88 Generally, an RTPS does not have direct interface to the PATIENTS, so it is not MEDICAL
89 ELECTRICAL EQUIPMENT as defined by IEC 60601-1. Consequently, this standard is written in an
90 independent format rather than as a particular standard to IEC 60601-1. For the purpose of
91 this standard, RTPS is a software application for medical purposes, therefore, IEC 62304
92 Medical device software - Software life cycle and IEC 62366 Application of usability
93 engineering to medical devices processes applies.

94 With this new edition of RTPS standard the concept of interchanging the conditions of machine
95 calibration regarding the MU/Dose conversion between the RTPS and the delivery systems is
96 introduced. Prior any treatment delivery at the MEE, a check of the calibration data is
97 mandated is to match plan and MEE setting on reference conditions

98 IEC 61217 defines coordinate systems and movements, the marking of scales, their zero
99 position, and the direction of movement with increasing value. While IEC 61217 scales must
100 be provided, it was deemed more of a safety risk to force this coordinate system for use with
101 equipment that was not IEC compliant. Hence the requirement that all coordinates will be in
102 IEC 61217 or the delivery machine's coordinate system.

103 IEC 63183 defines guidelines on error and warning messages for software used in
104 radiotherapy. While this document requires messages to be displayed, these messages
105 should be implemented according the guidance of IEC 63183.

106 In case of online and real-time adaptive radiotherapy, Clause 17 is meant to be used in
107 conjunction with other particular standards of the IEC 60601-2 series.

108 TYPE TESTS that are performed by the MANUFACTURER, or SITE TESTS, which are not necessarily
109 performed by the MANUFACTURER, are SPECIFIED for each requirement. It is understood that
110 SITE TESTS may or may not be required of the MANUFACTURER, per the agreement between the
111 MANUFACTURER and RESPONSIBLE ORGANIZATION.

112 Given that before installation a MANUFACTURER cannot provide SITE TEST data, data obtained
113 from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTATION, in the form of a
114 SITE TEST report, by those who test the MEE at installation.

115

MEDICAL ELECTRICAL EQUIPMENT – REQUIREMENTS FOR THE SAFETY OF RADIOTHERAPY TREATMENT PLANNING SYSTEMS

1 Scope

This International Standard, with the inclusion of TYPE TESTS and SITE TESTS, applies to the design, manufacture, installation, and maintenance of the software in a RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS) as well as communication of the RTPS to other devices

- in human medical practice;
- that imports data either through input by the OPERATOR or from other devices;
- that outputs data to other devices; and
- which is intended to be
 - for NORMAL USE, under the authority of appropriately QUALIFIED PERSONS, by OPERATORS having the required skills and training;
 - used and maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE, and
 - used within the environmental conditions SPECIFIED in the technical description.

This standard applies to any software application that is used for the development, evaluation, or approval of a TREATMENT PLAN, whether standalone or part of another system.

NOTE Such software applications include prescribing systems, contouring systems, quality assurance systems, plan analysis systems, or plan review systems.

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 60601-1:2005 + A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-1:2014, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

IEC 60601-2-8:2010+A1:2015, *Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*

IEC 60601-2-11:2013, *Medical electrical equipment – Part 2: Particular requirements for the safety of gamma beam therapy equipment*

IEC 60601-2-17:2013, *Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment*

IEC 60601-2-64:2014, *Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment*

157 IEC 60601-2-68:2014, *Medical electrical equipment – Part 2: Particular requirements for the*
158 *basic safety and essential performance of X-ray-based image-guided radiotherapy equipment*
159 *for use with electron accelerators, light ion beam therapy equipment and RADIONUCLIDE beam*
160 *therapy equipment*

161 IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

162 IEC 61217:2011, *Radiotherapy equipment – Coordinates, movements and scales*

163 IEC 62274:2005, *Medical electrical equipment – Safety of radiotherapy record and verify*
164 *systems*

165 IEC 62304:2006, *Medical device software – Software life cycle processes*

166 IEC TR 63183:2019, *Guidance on error and warning messages for software used in*
167 *radiotherapy*

168 IEC TR 80001-2-8:2016 Application of risk management for IT-networks incorporating medical
169 devices – Part 2-8: Application guidance – Guidance on standards for establishing the
170 security capabilities identified in IEC TR 80001-2-2

171 **3 Terms and definitions**

172 For the purposes of this document, the terms and definitions given in IEC 60601-
173 1:2005/AMD1:2012, IEC TR 60788:2004, and the following apply.

174 ISO and IEC maintain terminological databases for use in standardization at the following
175 addresses:

- 176 • IEC Electropedia: available at <http://www.electropedia.org/>
- 177 • ISO Online browsing platform: available at <http://www.iso.org/obp>

178 **3.1**

179 **ADAPTIVE RADIOTHERAPY**

180 RADIOTHERAPY that monitors PATIENT anatomy or physiology and, based upon the monitored
181 information, allows changes to TREATMENT PARAMETERS throughout the course of TREATMENT

182 Note 1 to entry: IMAGE GUIDED RADIATION THERAPY (IGRT) is one form of ADAPTIVE RADIOTHERAPY

183 [SOURCE: 60601-2-1:20xx, 201.3.202; standard in FDIS stage]

184 **3.2**

185 **BRACHYTHERAPY**

186 radiotherapy using one or more radiation sources with the radiation source/sources inside or
187 close to the target volume

188 Note 1 to entry: BRACHYTHERAPY techniques include interstitial, intracavitary, superficial or intraluminal radiotherapy.

189 [SOURCE: IEC 60601-2-17:2013, 201.3.204]

190 **3.3**

191 **COMMISSIONING**

192 <radiotherapy treatment planning system> process of preparing an RTPS for clinical use by
193 determining the operating characteristics and limitations of the RTPS, collecting and installing
194 facility specific data

195 **3.4**196 **CT SCANNER**

197 X-RAY EQUIPMENT intended to generate cross-sectional images of the body by computer
198 reconstruction of X-ray transmission data obtained at different angles, which may include
199 signal analysis and display equipment, PATIENT SUPPORT, support parts and ACCESSORIES

200 [SOURCE: IEC 60601-2-44:2009+A1:2012, 201.3.201, modified – notes removed]

201 **3.5**202 **EQUIPMENT MODEL**

203 representation of physical, geometric, and RADIATION parameters for any particular equipment
204 required to plan a course of RADIOTHERAPY

205 **3.6**206 **EQUIPMENT MODELLING**

207 process of establishing the EQUIPMENT MODEL

208 **3.7**209 **EXTERNAL BEAM EQUIPMENT**210 **EBE**

211 external RADIATION equipment utilizing MEDICAL ELECTRON ACCELERATORS, LIGHT ION BEAM
212 equipment or RADIONUCLIDE BEAM THERAPY EQUIPMENT

213 Note 1 to entry: This note applies to the French text only.

214 [SOURCE: IEC 60601-2-68:2014, 201.3.207, modified – Note rephrased.]

215 **3.8**216 **EXTERNAL MONITORING DEVICE**

217 device that can be connected to MEE and monitors patient anatomy or physiology

218 [SOURCE: IEC 60601-2-1:20xx, 201.3.223, standard in FDIS stage]

219 **3.9**220 **GANTRY**

221 part of the MEE supporting the RADIATION HEAD

222 Note 1 to entry: The GANTRY is any mechanical device that supports the RADIATION HEAD regardless of movement limitations.

223 [SOURCE: IEC 60601-2-1:20xx, 201.3.224, standard in FDIS stage]

224 **3.10**225 **IMAGE-GUIDED RADIOTHERAPY**226 **IGRT**

227 RADIOTHERAPY process by which the location of a RADIOTHERAPY beam relative to the intended
228 TARGET VOLUME within a PATIENT'S anatomy is determined by imaging of the TARGET VOLUME
229 and surrounding anatomical structures at the time of TREATMENT, so as to enable any
230 necessary positional corrections to the intended relative location of the beam to the TARGET
231 VOLUME

232 Note 1 to entry: The time period of "at the time of TREATMENT" is specified in the definitions of REAL-TIME IGRT, ONLINE IGRT and
233 OFFLINE IGRT.

234 Note 2 to entry: This note applies to the French language only.

235 [SOURCE: IEC 60601-2-68:2014, 201.3.209 modified – Notes added.]

236 **3.11**237 **RADIATION TREATMENT PRESCRIPTION**

238 Quantitative description of the clinical aims that guide TREATMENT PLANNING.

239 NOTE For radiotherapy treatment, this may include various levels of detail, such as the treatment site, delivery
240 method, dose per fraction, number of fractions and total dose.

241 **3.12**242 **NOMINAL ENERGY**

243 numerical value stated by the MANUFACTURER to identify the RADIATION BEAM

244 [SOURCE: IEC 60601-2-1:20xx, 201.3.233, standard in FDIS stage]

245 **3.13**246 **PATIENT MODEL**

247 representation of physical and anatomical parameters for a particular patient required to plan
248 a course of RADIOTHERAPY

249 **3.14**250 **PATIENT MODELLING**

251 process of establishing the PATIENT MODEL

252 **3.15**253 **PATIENT POSITIONER**

254 <radiotherapy> assembly of equipment upon which the PATIENT is placed and positioned for
255 RADIOTHERAPY

256 NOTE 1 The PATIENT POSITIONER includes the TABLE TOP and TABLE TOP SUPPORT.

257 [SOURCE: IEC 60601-2-1:20xx, 201.3.237, standard in FDIS stage]

258 **3.16**259 **QUALIFIED PERSON**

260 person recognised by a competent authority as having the requisite knowledge and training to
261 perform particular duties

262 [SOURCE: IEC 60601-2-1:20xx, 201.3.237, standard in FDIS stage, modified – Word "specified"
263 replaced by "particular" in the definition.]

264 **3.17**265 **RADIOTHERAPY TREATMENT PLANNING SYSTEM**266 **RTPS**

267 a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM, that is used to simulate the application of
268 RADIATION to a patient for RADIOTHERAPY TREATMENT

269 NOTE 1 to entry: An RTPS usually, but not necessarily, provides estimations of ABSORBED DOSE distributions in
270 human tissue using a particular algorithm or algorithms. These algorithms provide simulations of RADIATION that
271 typically emanates from, but not necessarily limited to, MEDICAL ELECTRON ACCELERATORS, LIGHT ION BEAM MEDICAL
272 EQUIPMENT, GAMMA BEAM THERAPY EQUIPMENT, or BRACHYTHERAPY from RADIOACTIVE SOURCES.

273 Note 2 to entry: An RTPS software is any software application that participates in the development, evaluation, or
274 approval of a TREATMENT PLAN, whether standalone or part of another system

275 **3.18**276 **TABLE TOP**

277 device attached to the TABLE TOP SUPPORT to which registration or immobilization devices are
278 attached and upon which the PATIENT is placed

279 Note 1 to entry: The TABLE TOP can be exchangeable.

280 [SOURCE: IEC 60601-2-64:2014, 201.3.238, modified – Words "an interchangeable device
281 attached to the PATIENT POSITIONER" have been replaced by "device attached to the TABLE TOP
282 SUPPORT", and note added.]

283 **3.19**

284 **TABLE TOP SUPPORT**

285 device used in conjunction with the TABLE TOP to support and position the PATIENT during
286 RADIOTHERAPY

287 [SOURCE: IEC 60601-2-1:20xx, 201.3.259, standard in FDIS stage]

288 **3.20**

289 **TREATMENT PARAMETER**

290 factor that describes one aspect of the IRRADIATION of a PATIENT during RADIOTHERAPY

291 Note 1 to entry: Examples of a TREATMENT PARAMETER include such values as RADIATION ENERGY, SOURCE STRENGTH and TREATMENT TIME.

292 [SOURCE: IEC 60601-2-17:2013, 201.3.214, modified – Information in the new note moved from
293 the definition.]

294 **3.21**

295 **TREATMENT PLAN**

296 all information that is intended for use by appropriately QUALIFIED PERSONS for the purpose of
297 prescribing or administering RADIOTHERAPY treatment, including any information to be
298 transmitted to other equipment

299 NOTE to entry Typical other equipment include treatment management systems and treatment delivery systems.

300 **3.22**

301 **TREATMENT PLANNING**

302 process of generating a TREATMENT PLAN

303 **4 General**

304 **4.1 Test grades**

305 Three grades of TYPE TEST and three of SITE TEST procedures are SPECIFIED. Their
306 requirements are as follows:

- 307 – TYPE TEST/SITE TEST grade A: An analysis of design, as related to the SPECIFIED safety
308 provisions, which shall result in a statement included in the technical description,
309 regarding the working principles or constructional means by which the requirement is
310 fulfilled.
- 311 – TYPE TEST/SITE TEST grade B: Visual inspection or functional test or measurement of the
312 RTPS. The test shall be in accordance with the procedure SPECIFIED in this document and
313 shall be based on operating states, including fault condition states, which are achievable
314 only without interference with the circuitry or construction of the RTPS.
- 315 – TYPE TEST/SITE TEST grade C: Functional test or measurement of the TRPS. The test shall
316 be in accordance with the principle SPECIFIED in this document. The SITE TEST procedure
317 shall be included in the technical description.

318 **4.2 Development**

319 Compliance with IEC 62304 requires identification of HAZARDS, assessment of their RISKS, and
320 appropriate verification and validation of RISK CONTROLS:

- 321 – Demonstration of compliance with the requirements of IEC 62083:20xx shall be
- 322 included as part of the above processes, with explicit reference to each requirement of
- 323 IEC 62083:20xx.
- 324 – Compliance data shall be retained by the MANUFACTURER as a permanent RECORD.
- 325 – Each test shall include a protocol containing all the necessary input data, sufficient
- 326 detail to provide for exact reproducibility, and the expected result.
- 327 – A statement of compliance to IEC 62083:20xx shall be included in the technical
- 328 description.

329 *Compliance is checked as follows:*

- 330 • *TYPE TEST grade A – Statement regarding RISK CONTROLS in the RECORDS of the*
- 331 *MANUFACTURER*
- 332 • *SITE TEST grade A – Compliance is checked by inspection of the ACCOMPANYING*
- 333 *DOCUMENTATION.*

334 4.3 Testing the RTPS installation

335 As part of the ACCOMPANYING DOCUMENTATION the MANUFACTURER shall provide an installation
 336 test procedure for the RESPONSIBLE ORGANIZATION that includes, as a minimum, tests for
 337 verifying the performance of the ABSORBED DOSE distribution calculation and other algorithms
 338 to which Clause 8 applies to demonstrate that predetermined results are achieved for the
 339 algorithms in the installation environment.

340 NOTE The installation environment may include the hardware components and peripherals; IT infrastructure, e.g.
 341 firewalls, routers, network stability; physical conditions, e.g. cooling, dust conditions.

342 The ACCOMPANYING DOCUMENTATION shall include all descriptions necessary for the
 343 RESPONSIBLE ORGANIZATION to reproduce the pre-defined conditions, or suitable references if
 344 these conditions are publicly available. It shall also include test procedures that permit testing
 345 by the RESPONSIBLE ORGANIZATION to show that the expected results are achievable.

346 *Compliance is checked as follows:*

- 347 • *TYPE TEST grade A – Statement regarding installation test procedures and descriptions for*
- 348 *the RESPONSIBLE ORGANIZATION.*
- 349 • *SITE TEST grade A – Compliance is checked by inspection of the ACCOMPANYING*
- 350 *DOCUMENTATION.*

351 5 ACCOMPANYING DOCUMENTATION

352 5.1 General

353 The ACCOMPANYING DOCUMENTATION shall include a technical description and INSTRUCTIONS
 354 FOR USE, which shall contain the information as required by this standard (see Table 1 for
 355 references).

356 **Table 1 – Clauses and subclauses in this standard that require the provision of**
 357 **information in the ACCOMPANYING DOCUMENTATION and the technical description**

Check reference	INSTRUCTIONS FOR USE	Technical description
1		4.1
2		4.2
3		6.4 a)
4	6.4 c)	
5	6.4 d)	