

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.11 Specification for gamma beam therapy equipment —

(Implementation of CENELEC HD 395.2.11 S2)

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Committees responsible for this British Standard

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- Association of X-ray Equipment Manufacturers (BEAMA Ltd.)
- British Institute of Radiology
- College of Radiographers
- Department of Health
- Department of Trade and Industry (National Physical Laboratory)
- Institute of Physical Sciences in Medicine
- Institution of Electrical Engineers
- National Radiological Protection Board
- Royal College of Radiologists

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 29 September 1989

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Contents

	Page
Committees responsible	Inside front cover
National foreword	iii
Section 1. General	
1 Scope and object	1
1.1 Scope	1
1.2 Object	1
2 Terminology and definitions	1
2.1 Degree of requirements	1
2.2 Definitions	1
3 Engineering specifications	1
3.1 General requirements	1
3.2 Environmental conditions	2
3.3 Power supply	2
4 Identification, marking and documentation	2
4.1 Identification and marking of scales and movements	2
4.2 ACCOMPANYING DOCUMENTS	3
4.3 Information to be provided by the equipment manufacturer for the purposes of radiation protection calculations	3
4.4 Instructions for use	4
Section 2. Radiation safety requirements for equipment (manufacturer)	
5 Protection of the PATIENT against incorrect ABSORBED DOSE in the TARGET VOLUME	4
5.1 SOURCE CARRIER or SHUTTER	5
5.2 BEAM OFF and BEAM ON condition	5
5.3 Control of IRRADIATION	5
5.4 STATIONARY RADIOTHERAPY and MOVING BEAM RADIOTHERAPY	6
5.5 Beam distributing systems	7
5.6 WEDGE FILTERS	7
5.7 BEAM APPLICATORS	8
5.8 Starting facilities	8
5.9 INTERRUPTION facilities	8
5.10 TERMINATION facilities	8
5.11 Unplanned TERMINATION	8
5.12 System checking facilities	9
6 Protection of the PATIENT against STRAY RADIATION in the RADIATION BEAM	9
6.1 Relative ABSORBED DOSE at the surface	9
7 Protection of the PATIENT against RADIATION outside the RADIATION BEAM	9
7.1 LEAKAGE RADIATION through BEAM LIMITING DEVICES during gamma IRRADIATION	9
7.2 LEAKAGE RADIATION outside the maximum RADIATION BEAM	10
8 RADIATION safety for persons other than PATIENTS	11
8.1 Indication of BEAM OFF or BEAM ON conditions	11
8.2 STRAY RADIATION in the BEAM OFF condition	11
8.3 Safety in setting operating states	11
8.4 RADIATION SOURCE and RADIATION HEAD	12
8.5 Radioactive materials used in the construction of the equipment	12
8.6 Environmental protection	12

	Page
Appendix A Terminology	19
Figure 1 — Rotary GANTRY	13
Figure 2 — Wall- or floor-mounted GANTRY	14
Figure 3 — Ceiling-mounted GANTRY	15
Figure 4 — RADIATION FIELD dimensions	16
Figure 5 — LEAKAGE RADIATION	17
Figure 6 — The 16 measurements points of the average LEAKAGE RADIATION	18
Publications referred to	Inside back cover

National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee and is identical with IEC 601-2-11:1987 “*Medical electrical equipment*” Part 2 “*Particular requirements for the safety of gamma beam therapy equipment*”, prepared by Technical Committee 62, Electrical equipment in medical practice, of the International Electrotechnical Commission (IEC). This Particular Standard amends and supplements certain clauses of BS 5724-1, hereinafter called the General Standard. Section 1 of this Particular Standard amends and supplements clauses **1.4**, **2**, **4.5** and **6** of the General Standard, and section 2 of this Particular Standard provides requirements not given under clause **30** of the General Standard. (See also Additional information, below.)

NOTE Amendments to section 1 of this Particular Standard together with the new section 3 of this Particular Standard will be published as a Supplement to this Particular Standard.

This Particular Standard, together with Supplement 1, also implements Harmonization Document HD 395.2.11 S2 which was published by the European Committee for Electrotechnical Standardization (CENELEC) and approved by the CENELEC Technical Board on 1 February 1990. There are no CENELEC modifications in HD 395.2.11 S2.

Cross-references

International Standard	Corresponding British Standard
IEC 788:1984	BS 6641:1985 <i>Glossary of medical radiology terms</i> (Identical)
IEC 601-1:1977	BS 5724 <i>Medical electrical equipment</i> Part 1:1979 <i>Specification for general safety requirements</i> (Technically equivalent)

ICRP Publication 26, referred to in **8.4.1**, for information only, has been prepared by the International Commission for Radiological Protection and is obtainable from Pergamon Press, Headington Hill Hall, Oxford OX3 0BW.

Additional information. The following print types are used.

Requirements, compliance with which can be tested, and definitions: in roman type.

Explanations, advice, general statements and exceptions: in small roman type.

Terms defined in clause **2** of the General Standard, in BS 6641 and in Appendix A of this Particular Standard: SMALL CAPITALS.

Attention is drawn to the difference between the recommendations of ICRP Publication 33 (1982) “Protection against ionizing radiation from external sources used in medicine” and **8.2** of this Particular Standard.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, pages 1 to 22, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Section 1. General

1 Scope and object

1.1 Scope

1.1.1 This standard specifies requirements for the safety, design and construction of gamma beam equipment when used for RADIOTHERAPY in human medical practice. It lies within the scope of IEC Publication 601-1: Safety of Medical Electrical Equipment, Part 1: General Requirements, which applies to all medical electrical equipment.

1.1.2 This standard applies to equipment which is intended to deliver a GAMMA RADIATION BEAM(S) at NORMAL TREATMENT DISTANCES greater than 5 cm using a SEALED RADIOACTIVE SOURCE(S). For equipment operating at shorter distances, special precautions may be necessary.

1.1.3 This standard specifies the requirements for equipment. It does not specify the requirements for the RADIATION SOURCES.

1.2 Object

It is the purpose of the requirements contained in this standard to ensure that the proposed IRRADIATION conditions are met and the actual settings retained during IRRADIATION and that unintentional exposure to IRRADIATION of the PATIENT, operating personnel and the environment is kept as low as reasonably achievable. It is thus a prerequisite that:

- this standard applies to equipment intended for use under the jurisdiction of a QUALIFIED PERSON;
- maintenance of the equipment is performed at prescribed intervals;
- and regular function checks be performed by the user.

1.2.1 In equipment of the type covered by this standard, ABSORBED DOSE is controlled by the time of IRRADIATION. Tolerances for the other methods of controlling the ABSORBED DOSE are under consideration. Such other methods are not included in this standard.

2 Terminology and definitions

2.1 Degree of requirements

in this standard the auxiliary verb:

- “shall” implies that compliance with a requirement or test is mandatory for compliance with the standard;
- “should” implies that compliance with a requirement or test is strongly recommended but is not mandatory for compliance with the standard.
- “may” implies that compliance with a requirement or test is permitted to be accomplished in a particular manner for compliance with the standard.

2.2 Definitions

Terms printed in capitals in this standard are used in compliance with the definitions given in IEC Publication 788: Medical Radiology — Terminology. The definitions introduced for this standard are therefore given in Appendix A.

3 Engineering specifications

3.1 General requirements

This standard assumes that a RADIOTHERAPY TREATMENT prescription is available which adequately defines the TREATMENT parameters.

The requirements are intended to ensure that the equipment:

- a) delivers the intended ABSORBED DOSE at a specified position;¹⁾
- b) delivers the RADIATION in accordance with the selected relationship of the RADIATION BEAM to the PATIENT (STATIONARY or MOVING BEAM THERAPY, beam modifying devices, etc.);

¹⁾ In this standard all references to ABSORBED DOSE refer to the ABSORBED DOSE at a given point in a standard water phantom.

- c) delivers the RADIATION without causing unnecessary risk to the PATIENT, the operator, other persons, or the immediate environment.

3.2 Environmental conditions

3.2.1 General

Except where other allowable environmental conditions are stated in ACCOMPANYING DOCUMENTS, this Particular Standard applies to equipment, installed, used or kept in locations where the following environmental conditions prevail:

- a) the ambient temperature falls within the range 15 °C to 35 °C;
- b) the relative humidity falls within the range 30 % to 75 %;
- c) the atmospheric pressure falls within the range 7×10^4 Pa to 11×10^4 Pa (700 mbar to 1 100 mbar).

3.2.2 Transport and storage

The allowable environmental conditions for transport and storage shall be stated in the ACCOMPANYING DOCUMENTS.

3.3 Power supply

The power supply shall be as specified in Item b) 2) of Sub-clause 1.4 of IEC Publication 601-1 with a sufficiently low internal impedance to prevent voltage fluctuations between the on-load and off-load steady states exceeding 5 %.

4 Identification, marking and documentation

The requirements of Clause 4 are additional to those contained in Clause 6 of IEC Publication 601-1.

4.1 Identification and marking of scales and movements

Three types of GANTRY are identified:

- the rotary GANTRY (Figure 1, page 13);
- the wall- or floor-mounted GANTRY (Figure 2, page 14);
- the ceiling-mounted GANTRY (Figure 3, page 15).

The possible axes of rotation and directions of linear movements are identified in Figure 1, Figure 2, Figure 3 and Figure 4.

4.1.1 Equipment movements

The movements shall be designated as follows (see Figure 1, Figure 2, Figure 3 and Figure 4):

Axis ①	GANTRY rotation
Axis ②	RADIATION HEAD rotation
Axis ③	RADIATION HEAD pitch
Axis ④	BEAM LIMITING DEVICE rotation
Axis ⑤	Isocentric table rotation
Axis ⑥	Table top rotation
Axis ⑦	Table pitch
Axis ⑧	Table roll
Direction ⑨	Table height
Direction ⑩	Table lateral
Direction ⑪	Table longitudinal
Direction ⑫	Axis 1 to source distance
Direction ⑬	Source-height distance
Direction ⑭	Dimension X of the RADIATION FIELD at a specified distance ^a
Direction ⑮	Dimension Y of the RADIATION FIELD at a specified distance ^a

^a A number of specified distances may be allowed.

Axes ① to ⑧ and directions ⑨ to ⑮ shall be provided with scales if the appropriate movements are available on the equipment. Scales shall be graduated in accordance with the following sub-clauses.

4.1.2 Rotation scales

a) Rotation scales shall be graduated in units of degrees, using positive numbers, e.g. 358°, 359°, 0°, 1°, 2° irrespective of movement available.

b) ²⁾The rotation scales ①, ②, ⑤ and ⑥ shall read zero when all axes (except ③ and ⑦) are coplanar, the RADIATION BEAM AXIS being directed vertically downwards, the longitudinal axis of the table parallel to the axis ① or ② and the eccentric support (Figure 1) in the position farthest from the GANTRY.

Scale ③ shall read zero when the RADIATION BEAM AXIS is directed vertically downwards and scales ① and ② are at zero.

Scale ④ shall read zero when the edges of the BEAM LIMITING DEVICE are parallel and normal to the GANTRY rotation axis with the thin edge of the WEDGE FILTER pointing towards the GANTRY considering the direction of insertion.

Scales ⑦ and ⑧ shall read zero when the table top is horizontal.

c) ²⁾Viewed from a point on the radiation beam axis, between the diaphragm system and the table surface, rotation scales ①, ④ and ⑤ shall increase in reading for a clockwise rotation. Rotation scales ② and ⑥ shall be graduated contrary to ① and ⑤ respectively so that the same settings on scales ① and ② describe a vertical beam and on scales ⑤ and ⑥ indicate that the table is parallel to axis ① or ②. In the case of radiation head pitch ③, the reading shall increase with rotation of the radiation beam away from the gantry.

If axes ⑤ and ⑥ coincide, axis ⑤ shall be the one considered as the axis.

With the equipment as described in Item b) of Sub-clause 4.1.2 rotation scales ⑦ and ⑧ shall be graduated contrary to ③ and ② respectively.

4.1.3 Linear scales

a) Linear scales shall be graduated in units of centimetres with sub-divisions at intervals of 5 mm or less. Positive numbers shall be used with sufficient digits to ensure that there is no ambiguity of indication, for example: 97, 98, 99, 0, 1, 2, 3 ... cm or 997, 998, 999, 0, 1, 2, 3 ... cm.

b) The linear table scales shall read zero when the surface is at the normal height of the ISOCENTRE, the mid-line is co-linear with the GANTRY rotation axis and the table is at its maximum longitudinal distance from the GANTRY with rotations ⑤ and ⑥ at zero.

c) Increasing reading shall be associated with decrease in table height ⑨, lateral movement ⑩ to the right when facing the GANTRY (angles ⑤ and ⑥ zero) and longitudinal movement ⑪ into the GANTRY (angles ⑤ and ⑥ zero).

d) For ISOCENTRIC equipment, the zero of the axis-source distance ⑫ shall be the ISOCENTRE.

For non-ISOCENTRIC equipment, an indication of the NORMAL TREATMENT DISTANCE shall be provided.

The zero of the source-height distance ⑬ shall be at the finished floor level.

A scale indicating distances from the RADIATION SOURCE along the RADIATION BEAM AXIS shall be provided.

e) With scale ④ at zero, X ⑭ is the dimension parallel to axis ① or ② and Y ⑮ is the perpendicular dimension.

4.2 ACCOMPANYING DOCUMENTS

In addition to the requirements stated in Sub-clause 6.8 of IEC Publication 601-1, the ACCOMPANYING DOCUMENTS shall include the information specified in Sub-clauses 4.3 and 4.4.

4.3 Information to be provided by the equipment manufacturer for the purposes of radiation protection calculations

The following information shall be provided:

a) The RADIONUCLIDE(S) for which that particular equipment is designed.

b) The maximum RADIATION SOURCE ACTIVITY for each RADIONUCLIDE for which the equipment is capable of meeting the requirements of this standard. The maximum RADIATION SOURCE ACTIVITY may depend on the source geometry and construction.

²⁾ Not applicable to ceiling mounted GANTRIES.