

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.11: Specification for gamma beam therapy equipment

The European Standard EN 60601-2-11:1997, with the incorporation of amendment A1:2004, has the status of a British Standard

ICS 11.040.50; 11.040.60

National foreword

This British Standard is the official English language version of EN 60601-2-11:1997, including amendment A1:2004. It is identical with IEC 60601-2-11:1997, including amendment 1:2004. It supersedes BS 5724-2.11:1989, BS 5724-2.11:Supplement 1:1989 and BS 5724-2.11:Supplement 2:1993 which are withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags **A1** **A1**. Tags indicating changes to CENELEC text carry the number of the CENELEC amendment. For example, text altered by CENELEC amendment A1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee CH/81, Radiotherapy equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained to its secretary.

Cross-references

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Medical electrical equipment — Part 2-11: Particular requirements for the safety of gamma beam therapy equipment

(includes amendment A1:2004)

(IEC 60601-2-11:1997 + A1:2004)

Appareils électromédicaux —

Partie 2-11: Règles particulières de sécurité pour les appareils de gammathérapie

(inclut l'amendement A1:2004)

(CEI 60601-2-11:1997 + A1:2004)

Medizinische elektrische Geräte —

Teil 2-11: Besondere Festlegungen für die Strahlensicherheit von

Gamma-Bestrahlungseinrichtungen

(enthält Änderung A1:2004)

(IEC 60601-2-11:1997 + A1:2004)

This European Standard was approved by CENELEC on 1997-07-01; amendment A1 was approved by CENELEC on 2004-09-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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CENELEC

European Committee for Electrotechnical Standardization

Comité Européen de Normalisation Electrotechnique

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Foreword

The text of document 62C/173/FDIS, future edition 2 of IEC 60601-2-11, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-11 on 1997-07-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1998-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-05-01

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex ZA is normative and Annex AA is informative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-11:1997 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A1

The text of document 62C/372/FDIS, future amendment 1 to IEC 60601-2-11:1997, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-2-11:1997 on 2004-09-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2005-06-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2007-09-01

Endorsement notice

The text of amendment 1:2004 to the International Standard IEC 60601-2-11:1997 was approved by CENELEC as an amendment to the European Standard without any modification.

Contents

	Page
Foreword	2
Introduction	5
Section 1. General	
1 Scope and object	7
2 Terminology and definitions	8
4 General requirements for tests	11
5 Classification	12
6 Identification, marking and documents	13
Section 2. Environmental conditions	
10 Environmental conditions	17
Section 3. Protection against electric shock hazards	
16 ENCLOSURES and PROTECTIVE COVERS	19
18 Protective earthing, functional earthing and potential equalization	19
19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	19
20 Dielectric strength	20

	Page		Page
Section 4. Protection against mechanical hazards		29.4.5 Radioactive materials used in the construction of the EQUIPMENT	37
21 Mechanical strength	21	29.4.6 Environmental protection	37
22 Moving parts	21	Section 6. Protection against hazards of ignition of flammable anaesthetic mixtures	39
27 Pneumatic and hydraulic power	22	Section 7. Protection against excessive temperatures and other safety hazards	41
28 Suspended masses	22	Section 8. Accuracy of operating data and protection against hazardous output	43
Section 5. Protection against hazards from unwanted or excessive radiation		Section 9. Abnormal operation and fault conditions; environmental tests	45
29 RADIATION safety requirements	23	Section 10. Constructional requirements	
29.1 Protection of the PATIENT against incorrect ABSORBED DOSE in the TREATMENT VOLUME	23	57 MAINS PARTS, components and layout	47
29.1.1 SOURCE CARRIER or SHUTTER	23	Appendix L References — Publications mentioned in this standard	52
29.1.2 BEAM OFF and BEAM ON conditions	24	Annex AA (informative) Index of terms	53
29.1.3 Control of IRRADIATION	25	Annex ZA (normative) Normative references to international publications with their corresponding European publications	56
29.1.4 STATIONARY RADIOTHERAPY and MOVING BEAM RADIOTHERAPY	27	Figure 101 — LEAKAGE RADIATION	47
29.1.5 Beam distributing systems	28	Figure 102 — The 16 measurement points of the average LEAKAGE RADIATION	48
29.1.6 WEDGE FILTERS	29	Figure 103 — Test plane orthogonal to the RADIATION BEAM AXIS at the NORMAL TREATMENT DISTANCE	49
29.1.7 BEAM APPLICATORS	30	Figure 104 — Location of test points for SITE TEST of item a) 2) of 29.3.2	50
29.1.8 Facilities for starting IRRADIATION	30	Figure 105 — Matrix measurement points for BEAM OFF and BEAM ON conditions to be specified at the floor level, 0,5 m, 1,0 m, 1,5 m and 2 m above the floor	51
29.1.9 Facilities for INTERRUPTION OF IRRADIATION	30		
29.1.10 Facilities for TERMINATION OF IRRADIATION	30		
29.1.11 Unplanned TERMINATION OF IRRADIATION	31		
29.1.12 Facilities for checking INTERLOCK systems	31		
29.2 Protection of the PATIENT against STRAY RADIATION in the RADIATION BEAM	32		
29.2.1 RELATIVE SURFACE DOSE	32		
29.3 Protection of the PATIENT against RADIATION outside the RADIATION BEAM	32		
29.3.1 LEAKAGE RADIATION through BEAM LIMITING DEVICES during IRRADIATION	32		
29.3.2 LEAKAGE RADIATION outside the maximum RADIATION BEAM	33		
29.4 RADIATION safety for persons other than PATIENTS	35		
29.4.1 Indication of BEAM OFF and BEAM ON conditions	35		
29.4.2 STRAY RADIATION in the BEAM OFF condition	35		
29.4.3 Safety in setting operating states	36		
29.4.4 RADIATION SOURCE and RADIATION HEAD	36		

Introduction

The use of GAMMA BEAM THERAPY EQUIPMENT for RADIOTHERAPY purposes may expose PATIENTS to danger if the EQUIPMENT fails to deliver the required dose to the PATIENT, or if the EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The EQUIPMENT may also cause danger to persons in the vicinity if the EQUIPMENT itself fails to contain the RADIATION adequately and/or if there are inadequacies in the design of the TREATMENT ROOM.

This Particular Standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of GAMMA BEAM THERAPY EQUIPMENT. Clause **29** states tolerance limits beyond which INTERLOCKS must prevent, INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition. TYPE TESTS which are performed by the MANUFACTURER, and/or SITE TESTS, which are not necessarily performed by the MANUFACTURER, are specified for each requirement.

Clause **29** does not attempt to define the optimum performance requirements for a GAMMA BEAM THERAPY EQUIPMENT for use in RADIOTHERAPY. Its purpose is to identify those features of design which are regarded at the present time as essential for the safe operation of such EQUIPMENT. It places limits on the degradation of EQUIPMENT performance at which it can be presumed that a fault condition applies, e.g. a component failure, and where an INTERLOCK then operates to prevent continued operation of the EQUIPMENT.

It should be understood that, before installation, a MANUFACTURER can provide a compliance certificate relating only to TYPE TESTS. Data available from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTS, in the form of a SITE TEST report, by those who test the EQUIPMENT after installation.

The relationship of this Particular Standard with IEC 60601-1 (including the amendments) and the Collateral Standards is explained in **1.3**.

Section 1. General

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

aa)

This Particular Standard specifies requirements for the safety of GAMMA BEAM THERAPY EQUIPMENT intended for RADIOTHERAPY in human medical practice and includes EQUIPMENT in which the selection and DISPLAY of operating parameters can be controlled by a PROGRAMMABLE ELECTRONIC SYSTEM (PES).

bb)

This Particular 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.

[A1] This standard applied also to multi-source STEREOTATIC RADIOTHERAPY equipment used to IRRADIATE a single ISOCENTRE simultaneously with more than one SEALED RADIOACTIVE SOURCE. The sources may be stationary or moving. **[A1]**

cc)

This Particular Standard applies to EQUIPMENT intended to be:

- used under the authority of appropriately licensed or QUALIFIED PERSONS, by OPERATORS having the skills required for a particular medical application and acting in accordance with the INSTRUCTIONS FOR USE;
- maintained at predetermined intervals;
- subject to regular checks by the USER;
- used for particular specified clinical purposes, e.g. STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY.

dd)

This Particular Standard is applicable to the manufacture and some installation aspects of GAMMA BEAM THERAPY EQUIPMENT by the inclusion of TYPE TESTS and SITE TESTS respectively.

ee)

This Particular Standard specifies the requirements for EQUIPMENT. It does not specify the requirements for the RADIATION SOURCES.

1.2 Object

Addition:

aa)

This Particular Standard establishes requirements to ensure the RADIATION safety and enhance the electrical and mechanical safety of GAMMA BEAM THERAPY EQUIPMENT used in human medical practice and specifies tests for demonstrating compliance with those requirements.

bb)

In EQUIPMENT of the type covered by this Standard, ABSORBED DOSE¹⁾ is controlled by the time of IRRADIATION. Tolerances for other methods of controlling the ABSORBED DOSE are not included in this Standard.

¹⁾ In this Particular Standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water at the depth of maximum BUILD UP.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety* and amendments 1 (1991) and 2 (1995).

IEC 60601-1 is referred to as the General Standard. As in the General Standard, the requirements are followed by compliance tests. The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard applies without modification.

This Standard is to be read in conjunction with the collateral Standard IEC 60601-1-2 (1993): Electromagnetic compatibility. No other collateral Standards apply.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard takes precedence over these requirements.

2 Terminology and definitions

Addition:

NOTE Annex AA lists defined terms alphabetically with their source references.

Additional definitions:

2.101

BEAM OFF

condition in which the RADIATION SOURCES are fully shielded, and are also in a position in which they can be secured

2.102

BEAM ON

condition in which the RADIATION SOURCES are fully exposed for RADIOTHERAPY 

2.103

CONTROLLING TIMER (abbreviation: TIMER)

device to measure the time during which IRRADIATION occurs and, when a predetermined time is reached, to TERMINATE IRRADIATION

2.104

FIELD SIZE

abbreviation for IRRADIATION FIELD SIZE

2.105

GANTRY

that part of the EQUIPMENT supporting and allowing possible movements of the RADIATION HEAD

2.106**GEOMETRICAL FIELD SIZE**

geometrical projection of the distal end of the BEAM LIMITING DEVICE on a plane orthogonal to the RADIATION BEAM AXIS, as seen from the centre of the front surface of the RADIATION SOURCE. The RADIATION FIELD is thus of the same shape as the aperture of the BEAM LIMITING DEVICE. The GEOMETRICAL FIELD SIZE may be defined at any distance from the RADIATION SOURCE

2.107**INTERRUPTION (OF IRRADIATION)/TO INTERRUPT (IRRADIATION)**

stopping of/to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions (i.e. a return to the READY STATE)

2.108**NORMAL TREATMENT DISTANCE**

a specified distance measured along the RADIATION BEAM AXIS from the RADIATION SOURCE to the ISOCENTRE or, for EQUIPMENT without an ISOCENTRE, to a specified plane

2.109**PRIMARY/SECONDARY (TIMER) COMBINATION**

combination of two TIMERS in which one is arranged to be the PRIMARY TIMER and the other is to be the SECONDARY TIMER

2.110**PRIMARY TIMER**

the CONTROLLING TIMER which is intended to TERMINATE IRRADIATION at the preselected time

2.111**PROGRAMMABLE ELECTRONIC SYSTEM (abbreviation: PES)**

term used to cover systems incorporating a wide range of programmable devices including microprocessors, programmable controllers, programmable logic controllers and other computer based devices. These devices may contain one or more central processing units connected to sensors and/or actuators, for the purpose of control, protection or monitoring

2.112**QUALIFIED PERSON**

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

2.113**REDUNDANT (TIMER) COMBINATION**

combination of two CONTROLLING TIMERS in which both are arranged to TERMINATE IRRADIATION at the preselected time

2.114**RELATIVE SURFACE DOSE**

ratio of the ABSORBED DOSE on the RADIATION BEAM AXIS at the depth of 0,5 mm to the maximum ABSORBED DOSE on the RADIATION BEAM AXIS, both measured in a PHANTOM with its surface at a specified distance

2.115**SECONDARY TIMER**

the CONTROLLING TIMER which is intended to TERMINATE IRRADIATION in the event of failure of the PRIMARY TIMER

2.116**SITE TEST**

after installation, test of the individual device or EQUIPMENT to establish compliance with specified criteria

2.117

TERMINATION (OF IRRADIATION)/TO TERMINATE (IRRADIATION)

stopping of/to stop IRRADIATION with no possibility of re-starting without the re-selection of all operating conditions, (i.e. returning/to return to the PREPARATORY STATE)

— when the preselected value of elapsed time is reached;

or:

— by deliberate manual act;

— by the operation of an INTERLOCK;

— by preselected value of GANTRY angular position in MOVING BEAM RADIOTHERAPY

2.118

TREATMENT

the application of a prescribed procedure, or a part thereof, for therapeutic purposes

2.119

TREATMENT FIELD

in RADIOTHERAPY, area at the PATIENT'S surface which is to be IRRADIATED

2.120

TYPE TEST

for a particular design of device or EQUIPMENT, a test by the MANUFACTURER to establish compliance with specified criteria

2.121

ZERO APPLICATOR

in a system which includes an INTERLOCK against IRRADIATION without a BEAM APPLICATOR, means to bypass the INTERLOCK

** 2.122**

HELMET

three-dimensional multi-source ISOCENTRIC BEAM LIMITING SYSTEM (MIBLS) used in MSSR for treatment of a human head

2.123

REPOSITIONING

movement and adjustment of the STEREOTACTIC frame with respect to the MIBLS to alter the intended treatment volume

2.124

REPOSITIONING POINT

retracted position of the MIBLS where REPOSITIONING of the frame is possible

2.125

REPOSITIONING TIME

added time the equipment needs to move from the BEAM ON condition to the REPOSITIONING POINT, to achieve REPOSITIONING and to return from the REPOSITIONING POINT to the BEAM ON condition

2.126

STEREOTAXIS

STEREOTACTIC

method for locating points within the human body using an external, three-dimensional frame of reference

2.127

TRANSITION TIME

time between when the SHUTTER is opened and the MIBLS or SOURCE CARRIER is in the TREATMENT position

2.128

TRANSITION RADIATION

dose received during the TRANSITION TIME 

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.1 Tests

Addition:

aa)

Test procedures described in this standard are generally classified into three grades. Their requirements are as follows:

Grade A:

In case of TYPE TEST: analysis of EQUIPMENT design, as related to the specified RADIATION safety provisions, which shall result in a statement included in the ACCOMPANYING DOCUMENTS, regarding the working principles or constructional means by which the requirement is fulfilled.

In case of SITE TEST: inspection of the ACCOMPANYING DOCUMENTS for the required information.

Grade B:

Visual inspection or functional test or measurement of the EQUIPMENT. The test shall be in accordance with the procedure specified in this standard and shall be based on operating states, including fault condition states, which are achievable without interference with the circuitry or construction of the EQUIPMENT.

Grade C:

Functional test or measurement of the EQUIPMENT. The test shall be in accordance with the principle specified in this standard. The SITE TEST procedure shall be included in the technical description. When the procedure involves operating states that require interference with the circuitry or the construction of the EQUIPMENT, the test should be performed by, or under the direct supervision of, the MANUFACTURER.

This Particular Standard does not specify procedures or intervals for periodic tests during the working life of the GAMMA BEAM THERAPY EQUIPMENT.

NOTE Requirements for tests of RADIATION safety of GAMMA BEAM THERAPY EQUIPMENT are subject to legal regulations in certain countries.

4.6 Other conditions

Addition:

aa)

SITE TEST information shall be provided in the technical description and shall include:

- statements resulting from grade A TYPE TESTS;
- details of, and results from, grade B and grade C TYPE TESTS;
- specific procedures and test conditions for grade C SITE TESTS;
- instructions on how to generate a described fault condition or, if not practicable, how to generate a test signal as close as practicable to the source of the signal which would have generated it, with a statement confirming that the test signal simulates the one which would be produced in a particular fault condition;

NOTE In some cases, one test signal may simulate more than one fault condition.

- instructions on how to reset the EQUIPMENT into the NORMAL USE condition after the completion of the SITE TESTS and how to verify this condition.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

The person responsible for the SITE TESTS shall record the results in a report which will then form part of the ACCOMPANYING DOCUMENTS. In addition, the SITE TEST report should contain at least the following:

- a) name and address of USER site;
- b) MODEL OR TYPE REFERENCE and SERIAL NUMBER of the EQUIPMENT;
- c) name, office and address of all personnel taking part in the tests and dates of their participation;

- d) environmental and power supply conditions;
- e) the actual conditions, when test conditions, procedures or devices differ from those given by the MANUFACTURER, or where the information cannot be derived from this Particular Standard.

NOTE SITE TESTS need not be performed by the MANUFACTURER.

4.8 Preconditioning

Addition:

aa)

This test condition applies only to EQUIPMENT parts which have been subjected to the humidity preconditioning treatment specified in 4.10.

4.10 Humidity preconditioning treatment

Addition:

aa)

The ACCOMPANYING DOCUMENTS shall identify those parts of the EQUIPMENT which:

- are likely to be influenced by the climatic conditions simulated by this treatment;
- have been tested under the conditions set down in this subclause.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

5 Classification

Replacement:

EQUIPMENT shall be marked and/or identified according to its classification as described in Clause 6. This includes:

5.1 According to the type of protection against electric shock:

EQUIPMENT within the scope of this standard shall be CLASS 1 EQUIPMENT.

5.2 According to the degree of protection against electric shock:

A1 EQUIPMENT within the scope of this standard shall be TYPE B EQUIPMENT except for MSSR, which shall be TYPE B EQUIPMENT or TYPE BF EQUIPMENT. **A1**

5.3 According to the degree of protection against harmful ingress of water:

Unless otherwise specified, EQUIPMENT within the scope of this standard shall be ordinary EQUIPMENT (enclosed EQUIPMENT without protection against ingress of water).

5.4 According to the method(s) of sterilisation or disinfection recommended by the MANUFACTURER:

Unless otherwise specified, EQUIPMENT (or parts thereof) within the scope of this standard shall be disinfectable EQUIPMENT (or parts).

5.5 According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:

EQUIPMENT within the scope of this standard shall be classified as EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

5.6 According to the mode of operation:

Unless otherwise specified, EQUIPMENT within the scope of this Standard shall be classified as suitable for CONTINUOUS OPERATION WITH INTERMITTENT LOADING.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

z) Removable protective means

Addition:

aa)

Where the requirements of this subclause are wholly or partly met by the nature of the installation, compliance is checked by inspection. The results should be included in the SITE TEST report.

6.2 Marking on the inside of the EQUIPMENT or EQUIPMENT parts

Addition:

aa)

Removal of the covers of the RADIATION HEAD shall expose symbol number 14 of Table DI of the General Standard, indicating “Attention, consult ACCOMPANYING DOCUMENTS”.

6.3 Marking of controls and instruments

Addition:

aa)

Provision of scales and indications for moving parts:

- 1) Each available movement shall be provided with a mechanical scale or a numerical indication. A1 This applies in case of MSSR, with the exception of PATIENT SUPPORT and when needed for patient treatment. A1
- 2) The scaling of all movements shall comply with the requirements of IEC 61217: Radio-therapy equipment — Coordinates, movements and scales. A1 For MSSR: IEC 61217 shall be used where applicable. A1
- 3) A LIGHT FIELD and an indication of the RADIATION BEAM AXIS shall be provided. A1 This requirement is not applicable for MSSR. A1
- 4) A scale, or numerical indication, of the RADIATION SOURCE-SKIN DISTANCE shall be provided. A1 This requirement is not applicable for MSSR. A1

6.7 Indicator lights and push-buttons

a) Colours of indicator lights:

Addition:

aa)

Where indicator lights are used on the TREATMENT CONTROL PANEL or other control panels, the colours of the lights shall accord with the following:

— immediate action required to terminate an unintended state of operation	red
— RADIATION BEAM ON	yellow ²⁾
— READY STATE	green ²⁾
— PREPARATORY STATE	other colour

Light emitting diodes (LEDs) in the red spectrum are not considered to be red indicator lights when:

- on any one TREATMENT CONTROL PANEL, all indications for which no particular colours are required are given by LEDs of the same colour; and
- the indications for which particular colours are required are clearly distinguishable.

²⁾ In the TREATMENT ROOM, or at other locations, these states may require urgent action or caution; different colours, in accordance with Table III of the General Standard, may therefore be used in such locations.

6.8 ACCOMPANYING DOCUMENTS

6.8.1 General

Amendment:

Amend the third paragraph to read as follows:

All markings specified in **6.1** and in the MANUFACTURER'S specifications for Clause **10** shall be included in full in the ACCOMPANYING DOCUMENTS.

6.8.2 INSTRUCTIONS FOR USE

a) General information

Addition:

aa)

INSTRUCTIONS FOR USE shall contain:

- 1) a list together with an explanation of the function of all INTERLOCKS and other RADIATION safety devices;
- 2) instructions for checking their operation;
- 3) a recommendation of the frequency with which such checks should be made;
- 4) dimensional drawings necessary for the use of the EQUIPMENT;
- 5) instructions for the procedure to put the EQUIPMENT into the BEAM OFF condition in an emergency (see **29.1.1.3**);
- 6) a description of the transition times from the BEAM OFF to BEAM ON condition and the BEAM ON to BEAM OFF condition and the proportion of the transition time for which the RADIATION SOURCE is EXPOSED (see **29.1.3.3**);
- 7) a description of the functioning of the PRIMARY TIMER. In the case of a REDUNDANT TIMER COMBINATION the functioning of both TIMERS SHALL be given (see **29.1.3.3**);
- 8) a description of the functioning of the SECONDARY TIMER if it may be caused to TERMINATE IRRADIATION in special therapy techniques (see **29.1.3.5**);
- 9) a description of the levels of the relative ABSORBED SURFACE DOSE on the RADIATION BEAM AXIS for any ACCESSORY provided by the MANUFACTURER if those levels exceed the values specified in **29.2**;
- 10) a description of the circumstances and the levels to be expected if, for non-square fields, the levels specified in **29.3** are exceeded. $\overline{A_1}$ This requirement is not applicable for MSSR; $\overline{A_1}$
- 11) a description of the parts of the EQUIPMENT ENCLOSURE where the ABSORBED DOSE due to LEAKAGE RADIATION exceeds the levels specified in **29.3.2** and a statement of the level to be expected;
- 12) instructions for emergency procedures to be adopted after failure of the SHUTTER or SOURCE CARRIER actuating means (see **29.4.4.1**);
- 13) a statement of the dimensions of the RADIATION SOURCE cavity and the outer dimensions of the RADIATION SOURCE for which the EQUIPMENT can be used;
- 14) a statement of the positions on the RADIATION HEAD where wipe tests may be performed and the results of such tests undertaken by the MANUFACTURER (see **29.4.4.5**); and
- 15) information on radioactive material used in the construction of the EQUIPMENT as required in **29.4.5**.

bb)

INSTRUCTIONS FOR USE shall state the recommended inspection or replacement intervals for any parts having a safety function which are subject to impairment caused, during the NORMAL USE of the EQUIPMENT, by the effects of IONISING RADIATION on the dielectric and/or mechanical strength of those parts.

cc)

If, in order to function safely and correctly, the GAMMA BEAM THERAPY EQUIPMENT or a sub-assembly thereof needs to dissipate heat at a certain rate, the cooling requirements shall be given in the INSTRUCTIONS FOR USE, including, as appropriate:

- the maximum rate of heat to be dissipated into the surrounding air for each sub-assembly which dissipates more than 100 W and which might be located separately on installation;
- flow rates and temperature rises in forced-air cooling systems at the stated maximum rates of heat dissipation;
- the maximum allowable input temperatures, the minimum allowable flow rates and input pressures, for the maximum rates of heat dissipation into any cooling medium other than air;
- other essential requirements, e.g. maximum permissible temperatures at specified places.

6.8.3 Technical description

a) General

Addition:

aa)

To assist the USER'S RADIOLOGICAL PROTECTION adviser, the following data 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.

c) The maximum ABSORBED DOSE RATE for the maximum cross-section of the RADIATION BEAM at a distance of 1 m from the RADIATION SOURCE for each RADIONUCLIDE for which the requirements of this standard are met. A1 In case of MSSR the maximum ABSORBED DOSE RATE for the maximum cross-section of the RADIATION BEAM at the ISOCENTRE or at the centre of the common volume defined by all the RADIATION BEAMS for each RADIONUCLIDE for which the requirements of this standard are met. A1

d) The location, with reference to an accessible point on the RADIATION HEAD, of the centre of the front surface of the RADIATION SOURCE in both the BEAM ON and BEAM OFF conditions. A1 This item is not applicable for MSSR. A1

e) The NORMAL TREATMENT DISTANCE and maximum GEOMETRICAL FIELD SIZE available at the NORMAL TREATMENT DISTANCE.

f) The available directions of the RADIATION BEAM.

g) The transition times from the BEAM OFF to BEAM ON condition and from the BEAM ON to BEAM OFF condition and the proportion of the transition times for which the RADIATION SOURCE is EXPOSED.

A1 h) Matrix measurement points for RADIATION levels for BEAM ON and BEAM OFF conditions at the floor level and at 0,5, 1,0, 1,5 and 2,0 m above the floor level in MSSR (see Figure 105). A1

