
British Standard

Medical electrical equipment

Part 2. Particular requirements for safety

Section 2.1 Specification for medical electron accelerators in the range 1 MeV to 50 MeV

Appareils électromédicaux

Partie 2. Conditions particulières de sécurité

Section 2.1 Accélérateurs d'électrons à usage médical 1 MeV à 50 MeV—Spécifications

Elektromedizinische Geräte

Teil 2. Besondere Sicherheitsanforderungen

Abschnitt 2.1 Medizinische Elektronenbeschleuniger für den Bereich 1 MeV bis 50 MeV

CONTENTS*

	Page
Foreword	2
Committees responsible	Back cover
Clause	
0. Introduction.	3
SECTION ONE—GENERAL	
1. Scope and object	4
2. Terminology and definitions	5
4. General requirements for tests	5
5. Classification	6
6. Identification, marking and documents	6
7. Not applicable	9
SECTION TWO—SAFETY REQUIREMENTS	
9. Removable protective means	10
11. Special measures with respect to safety	10
SECTION THREE—PROTECTION AGAINST ELECTRIC SHOCK HAZARDS	
16. Enclosures and PROTECTIVE COVERS	10
18. Earthing and potential equalization.	10
19. Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	11
20. Dielectric strength.	11
SECTION FOUR—PROTECTION AGAINST MECHANICAL HAZARDS	
21. Mechanical strength.	11
22. Moving parts	12
27. Pneumatic and hydraulic power	13
28. Suspended masses.	13
SECTION FIVE—PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	
29. X-radiation	13
30. Not applicable	20
31. Not applicable	20
32. Not applicable	20
33. Not applicable	20
34. Not applicable	20
35. Not applicable	20
36. Not applicable	20
SECTION SIX—PROTECTION AGAINST HAZARDS OF EXPLOSIONS IN MEDICALLY USED ROOMS	
37. Not applicable	21
38. Not applicable	21
39. Not applicable	21
40. Not applicable	21
41. Not applicable	21
SECTION SEVEN—PROTECTION AGAINST EXCESSIVE TEMPERATURES, FIRE AND OTHER HAZARDS, SUCH AS HUMAN ERRORS	
49. Interruption of the power supply	21

* Only clauses with text differing from that given in BS 5724 : Part 1 are included in this list.

SECTION TEN—CONSTRUCTIONAL REQUIREMENTS

56. Components and general assembly	22
57. MAINS PARTS, components and layout.	22
APPENDIX AA—Terminology. Alphabetical index of definitions.	28
APPENDIX A—Not applicable.	32
APPENDIX M—Not applicable	32

FIGURES

101. Rotary GANTRY.	23
102. Wall- or floor-mounted GANTRY	24
103. Ceiling-mounted GANTRY	25
104. Limits of STRAY X-RADIATION during ELECTRON IRRADIATION	26
105. Limits of ABSORBED DOSE at the surface during X-IRRADIATION	26
106. Application of LEAKAGE RADIATION requirements	27
107. LEAKAGE RADIATION through BEAM-LIMITING DEVICES	27

Foreword

This British Standard has been prepared under the direction of the Health Care Standards Committee and it supersedes BS 5724 : Section 2.1 : 1984, which is withdrawn.

This British Standard is based on the following sections of IEC-601-2-1 'Safety of medical electrical equipment' Part 2 'Particular requirements for medical electron accelerators in the range 1 MeV to 50 MeV', published by the International Electrotechnical Commission (IEC):

Section one 'General'

Section two 'Radiation safety for equipment'

Section three 'Electrical and mechanical safety for equipment' (which was introduced by Amendment No. 1 in 1984).

The differences between this British Standard and the previous edition are limited to the requirements in Section three of IEC 601-2-1.

The format used in this British Standard follows that used in other standards in Section 2 of the BS 5724 series which themselves are identical with or based on Parts of IEC 601.

This Particular Standard is one of a series based on BS 5724 : Part 1 and it amends and supplements specific clauses of BS 5724 : Part 1, hereafter called the General Standard. As stated in 1.3 of the General Standard the requirements of this Particular Standard take precedence over those of the General Standard.

As in the General Standard the requirements are followed by compliance tests. This Particular Standard refers to the General Standard and indicates the changes to be made to relevant clauses of that standard. The changes from the text of the General Standard are specified by the use of the following words:

'Replacement' means that the clause or sub-clause of the General Standard is replaced completely by the text of this standard.

'Amendment' means that the clause or sub-clause of the General Standard is amended as indicated by the text of this standard.

'Supplement' means that the text of this standard is additional to the requirements of the General Standard.

The following print types are used in this standard.

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

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

Test procedures: in italic type.

Terms defined in clause 2 of the General Standard and this Particular Standard: small capitals.

Cross references

International standard	Corresponding British Standard
IEC 788 : 1984	BS 6641 : 1984 Glossary of medical radiology terms (Identical)

There is no corresponding British Standard to ICRU Report 21, but copies are available from the International Commission on Radiation Units and Measurements Publications, Washington DC.

NOTE. Attention is drawn to the existence in some countries of legislation covering radiation safety that may not align with the provisions of this British Standard.

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

0. Introduction

The use of MEDICAL ELECTRON ACCELERATORS for therapy purposes may expose PATIENTS to danger because of failure of the EQUIPMENT to deliver the required dose to the PATIENT, or because of EQUIPMENT design which does not satisfy agreed standards of electrical and mechanical safety. The EQUIPMENT may also cause danger to persons in the vicinity because of failure of the EQUIPMENT itself adequately to contain the RADIATION; or from inadequacies in the design of the room in which the EQUIPMENT is housed.

In addition to these safety aspects there is a need for internationally accepted descriptions of the performance of such EQUIPMENT and of the accessories which may be used with them. It is the intention to issue a standard covering all these aspects of the design of MEDICAL ELECTRON ACCELERATORS, the rooms in which they are used, and the accessory equipment. However, in view of the urgent need to apply rules for EQUIPMENT safety at the earliest possible moment, it has been decided to issue as a separate publication at this time the sections of this comprehensive standard which deal with general aspects of MEDICAL ELECTRON ACCELERATORS and with the electrical, mechanical and radiation safety of the EQUIPMENT.

Section one 'General' and Section two 'Radiation safety for equipment' of IEC 601-2-1 describe requirements to be met by manufacturers in the design and construction of MEDICAL ELECTRON ACCELERATORS. Section two contains tolerance limits beyond which INTERLOCKS have to prevent or INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition. Section three of IEC 601-2-1 contains particular requirements for electrical and mechanical safety and a subsequent publication will address the subject of performance to achieve and maintain efficacy of the MEDICAL ELECTRON ACCELERATOR in its production of useful RADIATION.

It has to be emphasized that Section two of IEC 601-2-1 does not attempt to define the optimum performance requirements for a MEDICAL ELECTRON ACCELERATOR for use in RADIOTHERAPY. Rather, it describes those features of design which are regarded at the present time as essential for the safe operation of such EQUIPMENT and places limits on the degradation of accelerator performance at which it may be presumed that a fault condition applies (for example a component failure) and INTERLOCKS should operate to prevent continued operation of the EQUIPMENT. It is hoped that the publication of these sections at this time will enable all manufacturers of MEDICAL ELECTRON ACCELERATORS to find out as soon as possible about the standardization work in progress and to take it into account in an appropriate manner. Work is already in hand within the IEC on other Sections and in due course this Particular Standard will be incorporated in a comprehensive standard dealing with all aspects of MEDICAL ELECTRON ACCELERATORS.

Many preselection procedures listed in this Particular Standard (29.1.5 to 29.1.9) which were formerly carried out in the TREATMENT ROOM by the OPERATOR may now and in the future be carried out automatically following selection at the TREATMENT CONTROL PANEL. If these automatic operations remove the possibility of confirmation of the preselection by the operator, it is urged that attention be given to the provision of a system which prevents IRRADIATION if any preselection does not agree with the RADIATION treatment prescription for the PATIENT.

SECTION ONE – GENERAL

1. Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Supplement:

1.1.1 This Particular Standard covers MEDICAL ELECTRON ACCELERATORS used for therapy purposes in human medical practice, including EQUIPMENT in which the selection and DISPLAY of operating parameters are automatically controlled by programmable electronic systems.

1.1.2 This Particular Standard applies to accelerators which deliver a USEFUL BEAM of either X-RADIATION or ELECTRON RADIATION, with energies in the range 1 MeV to 50 MeV, and at maximum ABSORBED DOSE* rates between 0.001 Gy.s^{-1} and 1 Gy.s^{-1} at 1 m from the RADIATION SOURCE and at NORMAL TREATMENT DISTANCES between 0.5 m and 2 m from the RADIATION SOURCE.

1.1.3 This Particular Standard applies to EQUIPMENT intended for use under the jurisdiction of a QUALIFIED PERSON.

1.1.4 This Particular Standard covers both manufacture and installation of MEDICAL ELECTRON ACCELERATORS.

1.2 Object

Replacement:

The object of this Particular Standard is to establish requirements for a satisfactory level of RADIATION safety and of electrical and mechanical safety for MEDICAL ELECTRON ACCELERATORS used in human medical practice.

In particular, it is intended to ensure that the EQUIPMENT:

- a) delivers the preselected RADIATION TYPE;
- b) delivers the preselected energy of RADIATION;
- c) delivers the preselected ABSORBED DOSE;
- d) delivers the RADIATION in accordance with the preselected relationship of the USEFUL BEAM to the PATIENT (STATIONARY BEAM RADIOTHERAPY or MOVING BEAM RADIOTHERAPY, beam modifying devices, etc.);
- e) delivers the RADIATION without causing unnecessary risk to the PATIENT, the operator, other persons or the immediate surroundings.

1.3 Particular Standards

Supplement:

This Particular Standard should be read in conjunction with the General Standard. This Particular Standard contains RADIATION safety requirements which replace section five of the General Standard for this EQUIPMENT, together with particular requirements for the electrical and mechanical safety of MEDICAL ELECTRON ACCELERATORS, covered by other sections of the General Standard.

*1.4 Environmental conditions**Item a) Transport and Storage*

Replacement:

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

*Item b) Operation**1) Environment*

Replacement:

Except where other allowable environmental conditions are stated in the 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 $7 \times 10^4 \text{ Pa}$ to $11 \times 10^4 \text{ Pa}$ (700 mbar to 1100 mbar).

*2) Power supply**Item a)*

Amendment:

Amend line 35 (2nd dash) to read as follows:

‘— a sufficiently low internal impedance to prevent voltage fluctuations between the on-load and off-load steady states exceeding $\pm 5\%$.’

* In this standard all references to ABSORBED DOSE refer to the ABSORBED DOSE in water.

2. Terminology and definitions

This clause of the General Standard applies except as follows:

Supplement:

Additional terms printed in capitals in this Particular Standard are indicated in appendix AA. Improvements on many of these definitions are to be found in IEC Publication 788.

3. General requirements

This clause of the General Standard applies.

4. General requirements for tests

This clause of the General Standard applies except as follows:

4.1 Type tests and routine tests

Replacement:

All tests described in this section are type tests except for those listed below which shall be carried out on each item of EQUIPMENT after installation:

Clause 9—Removable protective means

Clause 11—Special measures with respect to safety (conditional)

Clause 16—Enclosures and PROTECTIVE COVERS

Clause 18—Earthing and potential equalization

4.5 Ambient temperature, humidity, atmospheric pressure

Replacement:

a) After the EQUIPMENT to be tested has been set up for NORMAL USE (according to Sub-clause 4.8), tests are carried out under normal operating conditions at:

- an ambient temperature within the range 15 °C to 35 °C;*
- a relative humidity within the range 30 % to 75 %;*
- an atmospheric pressure within the range 7×10^4 Pa to 11×10^4 Pa (700 mbar to 1100 mbar).*

b) The EQUIPMENT shall be shielded from other conditions which might affect the validity of the tests (for example, draughts).

c) In cases where ambient temperatures cannot be maintained, the test conditions are to be consequently modified and the results adjusted accordingly.

4.6 Other conditions

Supplement:

This test condition applies only in the case of type tests.

4.7 Supply and test voltages, type of current, nature of supply, frequency

Supplement:

j) The power supply used for the tests of this section shall have a sufficiently low internal impedance to prevent voltage fluctuations between the on-load and off-load steady states exceeding ± 5 %.

4.8 Preconditioning

Supplement:

This test condition applies only in the case of parts, which have been subjected to the moisture preconditioning treatment specified in Sub-clause 4.10.

4.10 Moisture preconditioning treatment

Supplement:

This test condition applies only in the case of type tests. The ACCOMPANYING DOCUMENTS shall contain an indication of those parts of the EQUIPMENT that are likely to be influenced by the climatic conditions that are simulated by this treatment and of those parts that have been tested under this test condition, as well as an address or other reference where the results of the tests may be obtained.

5. Classification

This clause of the General Standard applies except as follows:

Replacement:

5.1 According to the type of protection against electric shock:

MEDICAL ELECTRON ACCELERATORS are classified as CLASS I EQUIPMENT.

5.2 According to the degree of protection against electric shock:

MEDICAL ELECTRON ACCELERATORS are classified as TYPE B EQUIPMENT.

5.3 According to the degree of protection against ingress of liquids:

MEDICAL ELECTRON ACCELERATORS are classified as ordinary equipment (enclosed equipment without protection against ingress of liquids).

5.4 According to the method(s) of sterilization or disinfection allowed by the manufacturer:

MEDICAL ELECTRON ACCELERATORS (or parts thereof) are classified as DISINFECTABLE EQUIPMENT (or parts).

5.5 According to the degree of safety of application in the presence of flammable anaesthetics and/or flammable cleaning agents:

MEDICAL ELECTRON ACCELERATORS are classified as equipment for use in environments where no flammable anaesthetics and/or flammable cleaning agents are present.

5.6 According to the mode of operation:

MEDICAL ELECTRON ACCELERATORS are classified as suitable for CONTINUOUS OPERATION WITH INTERMITTENT LOADING.

5.7 According to the degree of electrical connection between equipment and PATIENT:

MEDICAL ELECTRON ACCELERATORS are classified as EQUIPMENT with an APPLIED PART but not specifically designed for application where a functional CONDUCTIVE CONNECTION to the PATIENT is made.

6. Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 *Marking on the outside . . .*

Replacement:

6.1.1 *Marking of MEDICAL ELECTRON ACCELERATORS.* MEDICAL ELECTRON ACCELERATORS and their constituent sub-assemblies shall be provided with 'permanently affixed' and 'clearly legible' markings on the outside of the EQUIPMENT so that their correlation to each other can be assessed wherever safety is involved. The markings shall include at least the following information.

a) Indication of origin. The name and/or trade mark of the manufacturer or supplier responsible for ensuring that the EQUIPMENT complies with this Particular Standard.

b) MODEL OR TYPE REFERENCE and SERIAL NUMBER. This is to identify the relationship between possible separated parts of EQUIPMENT and their, or its, ACCOMPANYING DOCUMENTS.

By means of the MODEL OR TYPE REFERENCE, and SERIAL NUMBER, the manufacturer, assembler or importer shall be able to indicate, if required, exactly and verifiably, the date of manufacture, assembly or importation within five years after these events.

NOTE. Although a MODEL OR TYPE REFERENCE usually denotes a certain performance specification, it may possibly not denote the exact construction, including the applied components and materials. If this is required, the MODEL OR TYPE REFERENCE may have to be supplemented by a SERIAL NUMBER. The SERIAL NUMBER may also be used for other purposes.

Indication of a manufacturing series only may not be sufficient if local requirements require individual identification.

c) Mains power output. AUXILIARY MAINS SOCKET OUTLET(S) of EQUIPMENT shall be marked with the maximum allowed output.

d) Fuses. The type and rating of fuses accessible from the outside of the EQUIPMENT shall be marked adjacent to the fuse-holder.

Compliance with the requirements of Sub-clause 6.1 shall be checked as follows:

- *Inspect the presence of required markings on the outside of EQUIPMENT.*
- *Test the durability of markings.*

For determination of durability, the markings are rubbed by hand, without undue pressure first for 15 s with a cloth rag soaked with SURGICAL SPIRIT and then for 15 s with a cloth rag soaked with PETROLEUM SPIRIT.

Markings shall be "clearly legible" after all the tests of this Particular Standard have been performed.

Adhesive labels should not have worked loose or become curled at the edges.

When evaluating durability, the effect of NORMAL USE on the markings shall also be taken into account.

6.1.2 *Identification and marking of scales and movements*

6.1.2.1 *General.* Three types of GANTRY are identified:

- the rotary GANTRY (see figure 101);
- the wall- or floor-mounted GANTRY (see figure 102);
- the ceiling-mounted GANTRY (see figure 103) (under consideration).

The possible axes of rotation and directions of linear movement are identified in figures 101, 102, 103.

NOTE. All scales should be easily visible from a convenient working position.

6.1.2.2 *EQUIPMENT movements.* The movements shall be designated as follows (see figures 101, 102 and 103):

— Axis 1	Rotation of the GANTRY
— Axis 2	Roll of the RADIATION HEAD
— Axis 3	Pitch of the RADIATION HEAD
— Axis 4	Rotation of the DIAPHRAGM system
— Axis 5	Isocentric rotation of the table
— Axis 6	Rotation of the table top
— Axis 7	Pitch of the table
— Axis 8	Roll of the table
— Direction 9	Height of the table
— Direction 10	Lateral displacement of the table
— Direction 11	Longitudinal displacement of the table
— Direction 12	Axis 1 to source
— Direction 13	Height of the source
— Dimension 14	Dimension X of the RADIATION FIELD at a specified distance*
— Dimension 15	Dimension Y of the RADIATION FIELD at a specified distance*

Axes 1 to 8, directions 9, 12 and 13 and dimensions 14 and 15 shall be provided with scales if the appropriate movement is available on the EQUIPMENT. Scales shall be graduated in accordance with the following sub-clauses.

6.1.2.3 *Rotation scales*

- a) Rotation scales shall be graduated in units of degrees, using positive numbers, for example ... 358°, 359°, 0°, 1°, 2° ... irrespective of movement available.
- b) In the case of rotary-mounted GANTRIES (and other types of GANTRIES so far as is practicable) the rotation scales 1, 2, 5 and 6 shall read zero when all axes (except 3 and 7) are coplanar, the AXIS OF THE BEAM being directed vertically downwards, the longitudinal axis of the table parallel to the axis 1 or 2 and the isocentric support (see figure 101) distant from the GANTRY.

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

Scale 4 shall read zero when the edges of the DIAPHRAGM system are parallel and normal to the rotation axis of the GANTRY with the thin end of the WEDGE FILTER pointing towards the GANTRY for one direction of insertion.

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

- c) Except in the case of ceiling-mounted GANTRIES, rotation scales 1, 4 and 5 shall increase in reading for clockwise rotation when viewed from a point on the AXIS OF THE BEAM between the DIAPHRAGM system and the table surface. Rotations 2 and 6 shall be scaled contrary to 1 and 5 respectively so that the same settings of scales 1 and 2 describe a vertical beam and on scales 5 and 6 indicate that the treatment table is parallel to axis 1 or 2. In the case of the pitch of the RADIATION HEAD 3, the reading shall increase with rotation of the USEFUL BEAM away from the GANTRY. If axes 5 and 6 coincide, the one axis shall be regarded as axis 5. With the EQUIPMENT as described in b) above rotations 7 and 8 shall be scaled contrary to 3 and 2 respectively.

6.1.2.4 *Linear scales*

- a) Linear scales shall be graduated in units of centimetres with subdivisions at intervals of 5 mm or less. Positive numbers shall be used with sufficient digits to ensure that there is no ambiguity of indications, for example ... 997, 998, 999, 0, 1, 2, 3 ... cm.
- b) The linear table movements shall read zero when the surface is at the normal height of the ISOCENTRE, the mid-line is co-linear with the rotation axis of the GANTRY and 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 of the table to the right when facing the GANTRY (angles 5 and 6 zero), and
 - longitudinal movement 11 of the table 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. Additional scales indicating distances from the RADIATION SOURCE along the AXIS OF THE BEAM such as the source-axis distance or source-skin distance may be provided.
- e) With scale 4 at zero, X14 is the dimension parallel to axis 1 or 2 and Y15 is the perpendicular dimension.

Compliance shall be checked by inspection.

6.2 *Marking on the inside of EQUIPMENT or EQUIPMENT parts*

Supplement:

- h) Removal of the covers of the RADIATION HEAD shall expose symbol number 14 of table D1 of the General Standard indicating 'Attention, consult ACCOMPANYING DOCUMENTS'.

* A number of specified distances may be allowed.

6.7 Indicator lights and push-buttons

a) Colours of indicator lights

Supplement:

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 on	Yellow*
READY STATE	Green*
PREPARATORY STATE	White*

6.8 ACCOMPANYING DOCUMENTS

6.8.1 General

Supplement:

Information necessary for the safe operation of the EQUIPMENT shall be provided in English.

6.8.2 Instructions for use

Supplement:

h) Functional checks

The instructions for use shall additionally contain the following:

- Detailed operating instructions including recommendations to the USER on the regular functional checks to be performed.
- A list with the functional description of all INTERLOCKS and other radiation safety devices, instructions for checking their correct operation and a recommendation of the frequency with which such checks should be carried out.
- Advice on precautions which should be taken during servicing (see Sub-clause 29.4.3).

6.8.3 Technical description

Supplement:

e) SUPPLY MAINS

For MEDICAL ELECTRON ACCELERATORS the technical description shall specify, together with the no-load MAINS VOLTAGE and the number of phases and the frequency thereof, the highest allowable internal impedance of the SUPPLY MAINS and the over-current protection required with which it is possible to demonstrate compliance of the EQUIPMENT with this Particular Standard.

f) Power input

For MEDICAL ELECTRON ACCELERATORS the technical description shall include a statement of the RATED input in amperes or, where the power factor exceeds 0.9, in volt-amperes or watts.

In the case of EQUIPMENT for one or several RATED voltage ranges, the RATED input shall always be given for the upper and lower limits of the range or ranges if the range(s) is/are greater than $\pm 10\%$ of the mean value of the given range.

In the case of range limits which do not differ by more than 10 % from the mean value, a statement of the input at the mean value of the range is sufficient.

If the rating of EQUIPMENT includes both long-time and momentary current or volt-ampere ratings, the statement shall include both long-time and the most relevant momentary volt-ampere rating, each plainly identified.

g) Cooling

If in order to function safely and correctly, a MEDICAL ELECTRON ACCELERATOR or a sub-assembly thereof needs to dissipate heat at a certain rate, the cooling requirements shall be indicated in the technical description, including as appropriate:

- the maximum rate of heat to be dissipated into the surrounding air, given separately for each sub-assembly that dissipates more than 100 W and might be separately located on installation;
- the maximum rate of heat to be dissipated into forced air cooling devices and the corresponding flow rate and temperature rise of the forced air stream;
- maximum rate of heat to be dissipated into a cooling medium service and the highest permissible input temperature, minimum flow rate and pressure requirements for the cooling service.

Where essential, a maximum allowable temperature at a specified place shall be indicated.

h) Other technical information

The technical description shall additionally contain the following:

- a statement of the environmental conditions if different from those specified in Sub-clause 1.4, and the allowable environmental conditions for transport and storage;

*In the TREATMENT ROOM, or at other locations, these states may require urgent action or caution and different colours in accordance with table 3 of BS 5724 : Part 1 may therefore be used in such locations.

- a list with the functional description of all INTERLOCKS and other radiation safety devices, instructions for checking their correct operation and a recommendation of the frequency with which such checks should be carried out;
- a statement of the arrangement employed for the two DOSE MONITORING SYSTEMS, and the performance of such systems as required in Sub-clause 29.1.2.1;
- information on the operating value of the device provided to TERMINATE IRRADIATION when the ABSORBED DOSE RATE exceeds the specified maximum and the design and test results obtained when proving the design of that device (see Sub-clause 29.1.4);
- information on the design of the device incorporated to prevent the electron beam current from exceeding twice the value corresponding to the specified maximum ABSORBED DOSE RATE as required in Sub-clause 29.1.4 and the results of the tests to prove the design;
- information on any disabling or by-passing of INTERLOCKS or DOSE MONITORING SYSTEMS required to meet testing or servicing procedures and the means employed to meet the requirement of Sub-clause 29.1.15;
- information relating to the amount of STRAY X-RADIATION during ELECTRON IRRADIATION as required in Sub-clause 29.2.1;
- a statement of the maximum ABSORBED DOSE as a percentage of the total ABSORBED DOSE at the NORMAL TREATMENT DISTANCE due to NEUTRON STRAY RADIATION or the maximum neutron flux to be expected, together with information on the methods and conditions of determination and the estimate as required in Sub-clause 29.2.3;
- a statement of the areas where the ABSORBED DOSE rises above 2 % and the levels to be expected (see Sub-clause 29.3.2.2);
- a statement if, for non-square fields, specified levels are exceeded, the circumstances in which this occurs and the levels to be expected (see Sub-clause 29.3.2.3);
- a statement of the parts of the EQUIPMENT casing where the ABSORBED DOSE due to LEAKAGE RADIATION at a distance 5 cm from the EQUIPMENT casing might exceed 0.5 % of the ABSORBED DOSE on the AXIS OF THE BEAM as required in Sub-clause 29.3.3 and the ABSORBED DOSE levels to be expected in those places;
- a statement of the areas and under what conditions the level of 0.02 % is exceeded (see Sub-clause 29.3.4);
- advice on precautions which should be taken during servicing (see Sub-clause 29.4.3);
- advice that information can be made available for compliance purposes as indicated in the compliance paragraphs of Sub-clauses 29.1.2.1, 29.1.2.7, 29.1.4, 29.1.6.1, 29.1.7.1 and 29.3.5.

6.8.5 *Reference to ACCOMPANYING DOCUMENTS*

Supplement:

Other clauses and sub-clauses of this Particular Standard in which requirements concerning the contents of ACCOMPANYING DOCUMENTS are given:

Moisture preconditioning treatment: Sub-clause 4.10.

Removable protective means: Clause 9.

Enclosures and PROTECTIVE COVERS: Clause 16.

Dielectric strength: Clause 20.

Mechanical strength: Clause 21.

Moving parts: Clause 22.

Separation from the SUPPLY MAINS: Sub-clause 57.1.

Supplement:

6.8.6 *Information to be provided for the purpose of RADIATION protection calculations*

The following information shall be provided:

- A statement of the NORMAL ENERGIES of the USEFUL BEAM and the maximum associated ABSORBED DOSE RATES at the NORMAL TREATMENT DISTANCE under conditions of maximum BUILD-UP, which the EQUIPMENT can deliver under normal operating conditions for both X-RADIATION and ELECTRON RADIATION. The methods and conditions of measurement shall be described.
- If the EQUIPMENT is delivered with an ADDED FILTER other than a WEDGE FILTER and if normal operation with and without the ADDED FILTER is possible, the maximum ABSORBED DOSE RATES at the NORMAL TREATMENT DISTANCE shall be given for both situations.
- A statement of the maximum GEOMETRICAL FIELD SIZES available at the NORMAL TREATMENT DISTANCE for the X-RADIATION and ELECTRON RADIATION.
- A statement of the location(s) with reference to accessible points on the RADIATION HEAD, of:
 - a) the TARGET or the VIRTUAL SOURCE OF X-RADIATION;
 - b) the electron window or the VIRTUAL SOURCE of electrons.
- A statement of the available directions of the USEFUL BEAM.

7. Power input

This clause of the General Standard does not apply.