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

Interested committees:

Title: BS EN 60601-2-93 Medical electrical equipment

Part 2-93: Particular requirements for the basic safety and essential performance of neutron capture therapy equipment

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

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THIS DRAFT IS NOT CURRENT BEYOND 10 July 2024**

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.**

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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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.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
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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/916/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER: IEC 60601-2-93 ED1	
DATE OF CIRCULATION: 2024-06-14	CLOSING DATE FOR COMMENTS: 2024-08-09
SUPERSEDES DOCUMENTS: 62C/879/CD, 62C/892A/CC	

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY	
SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES:	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.

Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE: Medical electrical equipment - Part 2-93: Particular requirements for the basic safety and essential performance of neutron capture therapy equipment
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NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Medical electrical equipment - Part 2-93: Particular requirements for the basic safety and essential performance of accelerator-based neutron capture therapy me equipment

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.
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IEC 60601-2-93 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

The text of this International Standard is based on the following documents:

Draft	Report on voting
XX/XX/FDIS	XX/XX/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- "clause" means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

159

INTRODUCTION

160 NEUTRON CAPTURE THERAPY (NCT) is a type of RADIOTHERAPY that uses a two-step process. First,
161 the PATIENT is injected with a tissue localizing drug containing a stable compound that has a
162 high propensity for capturing NEUTRONS. In the second step, the PATIENT is irradiated with
163 NEUTRONS. The radionuclides produced after capture then decay and emit short-penetrating
164 ions that interact with the cells of the tissue causing a therapeutic effect.

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

170 This particular standard establishes requirements to be complied with by MANUFACTURERS in the
171 design and construction of NCT ME EQUIPMENT for use in RADIOTHERAPY; it does not attempt to
172 define their optimum performance requirements. Its purpose is to identify those features of
173 design that are regarded, at the present time, as essential for the safe operation of such ME
174 EQUIPMENT; it places limits on the degradation of ME EQUIPMENT performance beyond which it
175 can be presumed that a fault condition exists and where an INTERLOCK then operates to prevent
176 continued operation of the ME EQUIPMENT.

177 Clause 201.10 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE
178 IRRADIATION in order to insure that ESSENTIAL PERFORMANCE is maintained and to avoid an unsafe
179 condition. TYPE TESTS that are performed by the MANUFACTURER, or SITE TESTS, which are not
180 necessarily performed by the MANUFACTURER, are SPECIFIED for each requirement. It should be
181 understood that, before installation, a MANUFACTURER can provide a compliance certificate
182 relating only to TYPE TESTS. Data available from SITE TESTS should be incorporated in the
183 ACCOMPANYING DOCUMENTATION, in the form of a SITE TEST report, by those who test the ME
184 EQUIPMENT at installation.

185

186

MEDICAL ELECTRICAL EQUIPMENT –

Medical electrical equipment - Part 2-93: Particular requirements for the basic safety and essential performance of accelerator-based neutron capture therapy me equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of accelerator-based NEUTRON CAPTURE THERAPY (NCT) ME EQUIPMENT, hereafter referred to as ME EQUIPMENT, used for treatment of PATIENTS.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation aspects of NCT ME EQUIPMENT

- intended for RADIOTHERAPY in human medical practice, including those in which the selection and DISPLAY of operating parameters can be controlled automatically by PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS),
- that, in NORMAL USE, deliver NEUTRONS obtained by charged particles acceleration using a specified particle accelerator,

and

- intended to be
 - for NORMAL USE, operated under the authority of appropriately licensed or QUALIFIED PERSONS by OPERATORS having the required skills for a particular medical application, for particular SPECIFIED clinical purposes maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE,
 - subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

NOTE 1 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION's premises.

NOTE 2 In this particular standard, all references to NEUTRON FLUENCE refer to NEUTRON FLUENCE in water or substance equivalent to water.

NOTE 3 Information regarding x-ray image guidance can be found in IEC 60601-2-68.

NOTE 4 IEC 61217 gives guidance on the designation of ME EQUIPMENT movements, the marking of scales, their zero positions and the direction of movement with increasing value (see 201.7.4.101).

¹ The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for NCT ME EQUIPMENT and to SPECIFY tests to check compliance to those requirements.

NOTE The adoption of this standard helps to ensure that the ME EQUIPMENT

- maintains PATIENT safety during ME EQUIPMENT movements and failure of the SUPPLY MAINS;
- delivers the pre-selected NEUTRON FLUENCE;
- delivers NEUTRON BEAM to the PATIENT, by utilizing NEUTRON BEAM modifying devices, etc., without causing unnecessary risk to the PATIENT, the OPERATOR, other persons or the environment.

201.1.3 Collateral standards

Addition:

Collateral standards published after the date of publication of this standard shall only apply subject to further amendment to this standard.

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-6 applies as modified in Clause 206. IEC 60601-1-3, IEC 60601-1-8, IEC 60601-1-9² IEC 60601-1-10³, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE Collateral standards published after the date of publication of this standard will only apply subject to further amendment to this standard.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard or collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral

² IEC 60601-1-9, Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design

³ IEC 60601-1-10, Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed loop controllers

standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.154, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:2014/AMD1:2020, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1: 2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-2-1:2020, *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 60601-2-64:2014, *Medical electrical equipment – Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment*

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

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

CISPR11, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

NOTE Informative references are listed in the bibliography.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005/AMD1:2012/AMD2:2020, IEC 60601-2-1:2020, IEC 60601-2-64:2014, and IEC TR 60788:2004 apply, except as follows:

Additional definitions:

201.3.201

EQUIPMENT REFERENCE POINT

ERP

point in space used for referencing dimensions and positions of equipment and performing dosimetry measurements

Note 1 to entry: Typically, the EQUIPMENT REFERENCE POINT is coincident with ISOCENTRE. If the beam delivery equipment is not ISOCENTRIC, then the centre of the PATIENT alignment system may be used.

Note 2 to entry: The corresponding note to entry in the French text indicates that the abbreviation "ERP" stands for "EQUIPMENT REFERENCE POINT" in English.

[SOURCE: IEC 60601-2-1:2020, 201.3.218]

201.3.202

EXTERNAL BEAM EQUIPMENT

external RADIATION equipment utilizing electron accelerators, LIGHT ION beam equipment or radionuclide beam therapy equipment, NEUTRON CAPTURE THERAPY ME EQUIPMENT

[SOURCE: IEC 60601-2-68:2014, 201.3.207, modified]

201.3.203

FLUENCE

The fluence, ϕ , is the quotient of dN by da , where dN is the number of particles incident on a sphere of cross-sectional area da , thus

$$\phi = \frac{dN}{da}$$

Unit: m^{-2}

where, N is the number of particles that are emitted, transferred, or received and the unit is 1.

Note to entry 1: unit cm^{-2} is frequently used instead of unit m^{-2}

[SOURCE: ICRU Report 85a: 2011, modified]

201.3.204**FLUENCE RATE**

The fluence rate, $\dot{\phi}$, is the quotient of $d\phi$ by dt , where $d\phi$ is the increment of the fluence in the time interval dt , thus

$$\dot{\phi} = \frac{d\phi}{dt}$$

Unit: $\text{m}^{-2}\text{s}^{-1}$

Note to entry 1: $\text{cm}^{-2}\text{s}^{-1}$ is frequently used instead of unit $\text{cm}^{-2} \text{s}^{-1}$.

[SOURCE: ICRU Report 85a: 2011]

201.3.205**FLUX**

The flux, $\dot{N}$, is the quotient of dN by dt , where dN is the increment of the particle number in the time interval dt , thus

$$\dot{N} = \frac{dN}{dt}$$

where, N is the number of particles that are emitted, transferred, or received and the unit is 1.

Unit: s^{-1}

[SOURCE: ICRU Report 85a: 2011, modified]

201.3.206**INTERRUPTION OF IRRADIATION****TO INTERRUPT IRRADIATION**

stopping of/to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

[SOURCE: IEC 60601-2-1:2020, 201.3.227, modified]

201.3.207**LIGHT ION BEAM DISTRIBUTION SYSTEM**

system of components and a control system used to transport the LIGHT ION FLUX from a RADIATION SOURCE to several TREATMENT stations or beam dumps or etc.

NOTE 1 to entry: Examples of components include vacuum pipes, magnets, and steering coils.

201.3.208**LIGHT ION FLUX**

The FLUX of the LIGHT ION BEAM from RADIATION SOURCE incident upon NEUTRON PRODUCTION TARGET

201.3.209**LIGHT ION FLUX MONITOR**

system to monitor the LIGHT ION FLUX

201.3.210**NEUTRON BEAM**

collection of NEUTRONS travelling in the same general direction

374 **201.3.211**
375 **NEUTRON FLUENCE MONITOR UNIT**
376 a parameter, reported by the NEUTRON FLUENCE MONITORING SYSTEM, from which, through a
377 calibration procedure and with additional information, the NEUTRON FLUENCE delivered can be
378 calculated

379 **201.3.212**
380 **NEUTRON FLUENCE MONITOR UNIT RATE**
381 NEUTRON FLUENCE MONITOR UNIT per unit time

382 **201.3.213**
383 **NEUTRON FLUENCE MONITOR UNIT RATE MONITORING SYSTEM**
384 system of devices for the measurement and DISPLAY of a RADIATION quantity related to NEUTRON
385 FLUENCE MONITOR UNIT RATE

386 **201.3.214**
387 **NEUTRON FLUENCE MONITORING SYSTEM**
388 system of devices for the measurement and DISPLAY of a RADIATION quantity related to the
389 NEUTRON FLUENCE

390 **201.3.215**
391 **NEUTRON FLUX MONITOR**
392 system to monitor the NEUTRON FLUENCE

393 **201.3.216**
394 **NEUTRON PRODUCTION SYSTEM**
395 system for production of NEUTRON that includes NEUTRON PRODUCTION TARGET, heat load
396 reduction system, water cooling system and etc.

397 NOTE 1 to entry: Heat load reduction systems include expanding the LIGHT ION FLUX with electromagnets, scanning
398 the LIGHT ION FLUX, and NEUTRON PRODUCTION TARGET rotators.

399 **201.3.217**
400 **NEUTRON PRODUCTION TARGET**
401 device that generates neutrons by the collision of an incident beam of a specified energy from
402 RADIATION SOURCE

403 **201.3.218**
404 **NON-PRIMARY RADIATION**
405 RADIATION emitted from the NEUTRON CAPTURE THERAPY ME EQUIPMENT that is not intended to
406 treat the PATIENT

407 **201.3.219**
408 **NORMAL USE**
409 operation, including routine inspection and adjustments by any OPERATOR, and stand-by,
410 according to the INSTRUCTIONS FOR USE

411 Note 1 to entry: NORMAL USE should not be confused with intended use. While both include the concept of use as
412 intended by the MANUFACTURER, intended use focuses on the medical purpose while normal use incorporates not
413 only the medical purpose, but maintenance, transport, etc. as well.

414 Note 2 to entry: NORMAL USE is all functions performed by the OPERATOR. This includes warmup, calibration and other
415 testing "physics" modes.

416 [SOURCE: IEC 60601-1:2005/AMD1:2012, 3.71, modified]

417 **201.3.220**
418 **PATIENT POSITIONER**
419 <RADIOTHERAPY> assembly of equipment upon which the PATIENT is placed and positioned for
420 RADIOTHERAPY

421 Note 1 to entry: PATIENT POSITIONER includes a PATIENT POSITIONER TOP.

422 [SOURCE: IEC 60601-2-1:2020, 201.3.235, modified]

423 **201.3.221**

424 **PATIENT POSITIONER TOP**

425 component of the PATIENT POSITIONER to which registration and immobilization devices are
426 attached and upon which PATIENT is placed

427 Note 1 to entry: PATIENT POSITIONER TOPS are often exchangeable to hold PATIENTS or equipment in different
428 orientations, for instance, a flat board or seat.

429 **201.3.222**

430 **PRIMARY/SECONDARY NEUTRON FLUENCE MONITORING COMBINATION**

431 utilization of two NEUTRON FLUENCE MONITORING SYSTEMS where one is arranged to be the
432 PRIMARY and the other the SECONDARY NEUTRON FLUENCE MONITORING SYSTEM

433 **201.3.223**

434 **PRIMARY NEUTRON FLUENCE MONITORING SYSTEM**

435 NEUTRON FLUENCE MONITORING SYSTEM which is intended TO TERMINATE IRRADIATION when a pre-
436 selected value is reached

437 **201.3.224**

438 **RADIATION HEAD**

439 structure from which the RADIATION BEAM emerges

440 Note to entry: RADIATION HEAD for NCT is often called a "beam shaping assembly" or "moderator and includes
441 moderator, gamma ray filter, shielding and etc.

442 [SOURCE: IEC TR 60788:2004, rm-20-06, modified]

443 **201.3.225**

444 **REDUNDANT NEUTRON FLUENCE MONITORING COMBINATION**

445 utilization of two NEUTRON FLUENCE MONITORING SYSTEMS where both systems are arranged to
446 TERMINATE IRRADIATION according to the pre-selected number of NEUTRON FLUENCE MONITOR
447 UNITS

448 **201.3.226**

449 **SECONDARY NEUTRON FLUENCE MONITORING SYSTEM**

450 NEUTRON FLUENCE MONITORING SYSTEM which is intended TO TERMINATE IRRADIATION in the event
451 of failure of the PRIMARY NEUTRON FLUENCE MONITORING SYSTEM

452 **201.3.227**

453 **TERMINATION OF IRRADIATION**

454 stopping of stop IRRADIATION and movements, with no possibility of restarting without the
455 reselection of all operating conditions

456 Note 1 to entry: I.e., returning to the PREPARATORY STATE.

457 Note 2 to entry: Events that TERMINATE IRRADIATION and stop movements include the following:

458 – normal TERMINATION OF IRRADIATION:

- 459 • when the pre-selected value of NEUTRON FLUENCE MONITOR UNITS is reached;
- 460 • when the pre-selected value of elapsed time is reached;
- 461 • when the pre-selected value of an angular or linear dimension is reached;

462 – abnormal TERMINATION OF IRRADIATION:

- 463 • a deliberate manual act;
- 464 • the operation of an INTERLOCK which is not due to a pre-selected value being reached;
- 465 • when the pre-selected value of an angular or linear dimension is exceeded.