2) the linear displacement(s) of the axis of rotation of the WEDGE FILTER from the axis of rotation of the BLS.

Compliance is checked as follows:

a) *SITE TEST grade B – Procedure: attempt IRRADIATION without selecting a SPECIFIC WEDGE FILTER or "no WEDGE FILTER".*

f) and g) *TYPE TEST grade A – Statement regarding identification, selection and coding of* OPERATOR*-mounted WEDGE FILTERS, and of the associated INTERLOCKS providing for the correct DISPLAYS and preventing IRRADIATION when selection or positioning is incorrect.*

d) *SITE TEST grade B – Verify that the* OPERATOR*-selected WEDGE FILTER is displayed before and during IRRADIATION.*

c) and g) *SITE TEST grade B – Verify that the IRRADIATION cannot be started if the WEDGE FILTER is incorrectly affixed or is not the selected WEDGE FILTER.*

f) *TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION.*

g) *TYPE TEST grade A – If two independent systems to monitor the correct fixation are not used, verify that the analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.*

h) *TYPE TEST grade C – Demonstrate that a* VERIFICATION *of the WEDGE FILTER position is performed during IRRADIATION and that the IRRADIATION would be stopped in case WEDGE FILTER becomes improperly affixed.*

i) *SITE TEST grade B – Procedure: inspect the WEDGE FILTERS for identity markings; verify that DISPLAYS agree.*

k) *SITE TEST grade B – Procedure: verify that the indication of the thin end of the WEDGE FILTER can be seen clearly and that the orientation is correct.*

m) *SITE TEST grade B – Procedure: verify, for all angles of insertion and for three positions of displacement, that the indication of the orientation of the thin end of the WEDGE FILTER and its displacements are displayed in both locations.*

b) and l) *SITE TEST grade B – Procedure: verify operation of the DISPLAYS.*

201.10.101.1.13 Selection, VERIFICATION, and DISPLAY of ACCESSORIES supplied by RESPONSIBLE ORGANISATION

Where the MANUFACTURER provides a coded interface for attaching a RESPONSIBLE ORGANISATION's supplied ACCESSORIES to the ME EQUIPMENT, the following applies.

a) An unambiguous code corresponding to the RESPONSIBLE ORGANISATION's supplied and installed ACCESSORIES, if they affect the dose distribution, shall be displayed at the TCP before and during IRRADIATION.

b) Means shall be provided to prevent INITIATION OF IRRADIATION if the installed ACCESSORIES do not match the ACCESSORIES selected at the TCP.

c) The INSTRUCTIONS FOR USE in the ACCOMPANYING DOCUMENTATION shall warn the OPERATOR of the RISK of incorrect selection of ACCESSORIES if the ACCESSORIES are not coded.

d) If the installed OPERATOR-selected ACCESSORIES are incorrectly affixed, INITIATION OF IRRADIATION shall be prevented.

e) If the installed OPERATOR-selected ACCESSORIES become incorrectly affixed during IRRADIATION, then IRRADIATION shall be TERMINATED.

f) The ACCOMPANYING DOCUMENTATION shall contain the interface description and conditions of use.

Compliance is checked as follows:

a) *TYPE TEST grade B – Verify that the codes for the OPERATOR-selected ACCESSORIES are displayed before and during IRRADIATION.*

b) and d) *SITE TEST grade B – Verify that the IRRADIATION cannot be initiated unless the OPERATOR installed ACCESSORIES are correctly affixed and are the selected ACCESSORIES.*

c) *TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION.*

e) *TYPE TEST grade A – Demonstrate through analysis that* VERIFICATION *of each ACCESSORY position is performed during IRRADIATION and that* TERMINATION OF *IRRADIATION occurs when the ACCESSORY becomes incorrectly affixed.*

f) *TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION.*

201.10.101.1.14 Control of ME EQUIPMENT operation

NOTE 1 201.14.101 f) permits designated PASSWORDS or biometric security as alternatives to key control when control is effected by PESS.

a) Key control shall

1) control unlocking and switching on of the ME EQUIPMENT to the STAND-BY STATE, and from there to the PREPARATORY STATE; after selection of all TREATMENT PARAMETERS has been completed, the READY STATE may be achieved without further operation of the key; IRRADIATION or a sequence of IRRADIATIONS shall be prevented until enabled by PASSWORD or dedicated mechanical key;

2) select the mode for NORMAL USE, all service modes, all other modes and the locked-off condition.

b) The condition of external INTERLOCKS shall be indicated at the TCP.

c) Means shall be provided to connect an aural indication of the READY STATE to be given in the TREATMENT ROOM, and for an indication of the READY STATE to be given at other locations.

d) During IRRADIATION, in addition to the DISPLAY of RADIATION TYPE required by 201.10.101.1.4 b), there shall be a DISPLAY at the TCP to indicate IRRADIATION; means shall be provided for this DISPLAY to be given at other locations. The aural indication of the READY STATE in the TREATMENT ROOM and its indication elsewhere, as stated in c) above, shall continue during IRRADIATION; the tone may be changed.

e) The INSTRUCTIONS FOR USE shall contain the following:

1) details of the facilities provided for the connection of external INTERLOCKS that prevent, TERMINATE, or INTERRUPT IRRADIATION from selected locations, for example if TREATMENT ROOM doors or other means of access to CONTROLLED AREAS have not been closed, or are opened; and also the facilities required by d) above;

2) advice that the resetting of the external INTERLOCKS required in 1) above should be possible only from inside the CONTROLLED AREAS that they protect, for example by using a time delay device to permit exit and door closure after checking that, apart from the PATIENT, no one remains in the CONTROLLED AREAS;

3) a list of the INTERLOCKS that can be reset only by the use of removable dedicated mechanical key(s);

NOTE 2 Any dedicated mechanical key in e) 3) above is additional to that required by a) 1) above.

4) the conditions to be complied with by the RESPONSIBLE ORGANIZATION to ensure the correct functioning of

- the external INTERLOCKS,
- the aural indications in the TREATMENT ROOM during the READY STATE and IRRADIATION, and
- the DISPLAY, at other locations, of the indications of the READY STATE and of IONIZING RADIATION.

Compliance is checked as follows:

a) *SITE TEST grade B – Procedure: for 1) and 2), verify that key control is provided and that each selected state and condition is indicated in turn at the TCP; verify the functioning of the dedicated mechanical key.*

b) c) d) SITE TEST grade B – Procedure: verify, as appropriate, visual and aural indications.

e) TYPE TEST grade A – Statement regarding connection of the INTERLOCKS, conditions for RESPONSIBLE ORGANIZATION compliance, advice regarding resetting external INTERLOCKS and the list of INTERLOCKS that can be reset only by dedicated mechanical keys.

e) SITE TEST grade B – Procedure: verify functioning and resetting of external INTERLOCKS.

201.10.101.1.15 Starting conditions

It shall be possible to start IRRADIATION in NORMAL USE only by OPERATOR action at the TCP when the READY STATE is indicated and after enablement by PASSWORD or by the dedicated mechanical key – see 201.10.101.1.14 a) 1).

NOTE 1 201.14.101 f) permits designated PASSWORDS as alternatives to key control when control is effected by PESS.

NOTE 2 The same starting condition can be used for megavoltage X-IGRT EQUIPMENT.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding IRRADIATION in NORMAL USE initiated only from the TCP.

201.10.101.1.16 INTERRUPTION OF IRRADIATION

a) It shall be possible TO INTERRUPT IRRADIATION and movements of the ME EQUIPMENT simultaneously, at any time, from the TCP and from other locations as SPECIFIED in the INSTRUCTIONS FOR USE.

b) After an INTERRUPTION OF IRRADIATION, without any change to, or re-selection of, the TREATMENT PARAMETERS existing immediately before the INTERRUPTION OF IRRADIATION, it shall be possible to re-start IRRADIATION. If the movement is restricted to PATIENT POSITIONER motion to re-align the TARGET VOLUME to the planned location in relation to the ME EQUIPMENT, then it shall also be possible to re-start IRRADIATION.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding INTERRUPTION OF IRRADIATION from other locations and recommended SITE TESTS particular to individual ME EQUIPMENTS.

a) SITE TEST grade B – Procedure: at one ENERGY for each RADIATION TYPE:

1) verify the simultaneous INTERRUPTION OF IRRADIATION and movements from

- *the TCP, and*
- *any other location provided;*

2) perform other tests as may be recommended by the MANUFACTURER.

b) SITE TEST grade B – Procedure: at one ENERGY for each RADIATION TYPE, verify the restart of IRRADIATION after INTERRUPTION OF IRRADIATION.

201.10.101.1.17 TERMINATION OF IRRADIATION

a) It shall be possible TO TERMINATE IRRADIATION and movements at any time from the TCP and from other locations as SPECIFIED in the INSTRUCTIONS FOR USE. This control shall be HARD-WIRED or have equivalent safety switching function and be independent of any PESS.

b) The values of TREATMENT PARAMETERS may only be adjusted during RADIOTHERAPY as a result of having been pre-programmed before the start of IRRADIATION or except as may be permitted in 201.108.3. During RADIOTHERAPY, if any TREATMENT PARAMETER is manually adjusted, TERMINATION OF IRRADIATION shall occur. If the movement is restricted to PATIENT POSITIONER motion to re-align the TARGET VOLUME to the planned location in relation to the ME EQUIPMENT then, instead of TERMINATION OF IRRADIATION, it shall also be possible TO INTERRUPT IRRADIATION and re-start IRRADIATION (see also 201.10.101.1.16).

c) For ME EQUIPMENT that has the capability to move during IRRADIATION, TERMINATION OF IRRADIATION shall occur if the actual position of a moving part differs by more than 10 mm at RTD, or 5°, from the position required by calculation using the actual DOSE MONITOR UNITS delivered; information sufficient to enable the continuation of IRRADIATION shall be available for a minimum of 20 min – see also 201.10.101.1.1.4 c).

d) The INTERLOCKS implicit in c) shall include two position sensors or other means to ensure that any single fault failure of the sensors implicit in c) shall prevent IRRADIATION or, in the event of position monitoring failure during TREATMENT, to TERMINATE IRRADIATION.

e) For ME EQUIPMENT that has the capability of BEAM HOLD, TERMINATION OF IRRADIATION shall occur before an additional ABSORBED DOSE of 0,25 Gy is delivered if the TREATMENT IRRADIATION continues after a BEAM HOLD is applied.

f) If there is movement outside of defined tolerances as stated in 201.10.101.1.7, 201.10.101.1.8 and 201.10.101.1.10 of the GANTRY, RADIATION HEAD, or PATIENT POSITIONER during IRRADIATION that is not part of the pre-programmed movement or autonomous movement during REAL-TIME ADAPTIVE RADIOTHERAPY, TERMINATION OF IRRADIATION shall occur.

g) For ME EQUIPMENT that has the capability to change TREATMENT PARAMETERS during IRRADIATION, information sufficient to enable the continuation of IRRADIATION shall be available for a minimum of 20 min after an abnormal TERMINATION OF IRRADIATION or INTERRUPTION OF IRRADIATION – see also 201.10.101.1.1.4 c).

h) The tolerances stated in g) shall be provided in the ACCOMPANYING DOCUMENTATION.

Compliance is checked as follows:

a) *TYPE TEST grade A – Statement regarding TERMINATION OF IRRADIATION from other locations.*

a) *SITE TEST grade B – Procedure: verify, at one NOMINAL ENERGY for each RADIATION TYPE, TERMINATION OF IRRADIATION and movements from the TCP and any other location provided.*

b) *SITE TEST grade B – Procedure: verify TERMINATION OF IRRADIATION when any one of the operating parameters is adjusted during RADIOTHERAPY.*

c) f) *TYPE TEST grade C – Verify functioning of the means to TERMINATE IRRADIATION in the case of unintended movement.*

c) f) *SITE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION for a description and results of the TYPE TESTS performed.*

d) *TYPE TEST grade C – Verify independent functioning of each position sensor.*

e) *TYPE TEST grade C – Verify TERMINATION OF IRRADIATION within 0,25 Gy when TREATMENT IRRADIATION continues to occur after application of a BEAM HOLD.*

g) *SITE TEST grade B – Procedure: verify at one NOMINAL ENERGY for one RADIATION TYPE, INTERRUPTION OF IRRADIATION preserves the parameters needed to continue IRRADIATION for 20 min. Repeat for TERMINATION OF IRRADIATION.*

h) *TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION.*

201.10.101.1.18 Abnormal TERMINATION OF IRRADIATION

If TERMINATION OF IRRADIATION has occurred by any means other than normal operation of the DOSE MONITORING SYSTEM, the following applies.

a) A SPECIFIC DISPLAY shall be given at the TCP. In ME EQUIPMENT with a visual DISPLAY terminal, data shall be displayed regarding the cause of each TERMINATION OF IRRADIATION; the INSTRUCTIONS FOR USE shall contain details of warnings of associated potential safety HAZARDS.

b) The ME EQUIPMENT shall record the TREATMENT data. In the case where TREATMENT data are designed to be stored on equipment other than the ME EQUIPMENT, the ME EQUIPMENT shall store the information locally until VERIFICATION of the data transfer has occurred.

c) Further IRRADIATION shall not be achievable without resetting the INTERLOCK causing the abnormal TERMINATION OF IRRADIATION by the use of a designated mechanical key at the TCP.

NOTE 1 201.14.101 f) permits designated PASSWORDS as alternatives to key control when control is effected by PESS.

NOTE 2 The designated mechanical key is additional to that referred to in 201.10.101.1.14 a) 1).

d) When restarting after abnormal termination, the consistency, correctness and completeness of the data set required for completing the TREATMENT shall be checked by the ME EQUIPMENT before it can be accepted for TREATMENT.

In the case of inconsistency, incorrectness or incompleteness of the data set being loaded, TREATMENT shall not be allowed to commence without

1) explicit DISPLAY of the identified deficiencies to the OPERATOR,

2) requirement of the OPERATOR to change or accept the identified deficiencies, and

3) recording of the ID of the OPERATOR performing the operation in 2).

NOTE 3 As long as the information in d) is saved to allow association with the other information pertaining to the IRRADIATION, it is not required that the information all exist on the ME EQUIPMENT. For example, recording of data can be performed by another system, such as a RECORD AND VERIFY SYSTEM, which is in communication with the ME EQUIPMENT.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding warnings given of potential safety HAZARDS.

a) TYPE TEST grade C – Verify the DISPLAY informs the OPERATOR of the cause of TERMINATION OF IRRADIATION by activation of INTERLOCKS to cause unplanned TERMINATION OF IRRADIATION. Repeat using a different cause and verify that the DISPLAY shows the new cause of TERMINATION OF IRRADIATION.

b) TYPE TEST grade B – Comparison of the recorded TREATMENT *data to the IRRADIATION conditions.*

b) TYPE TEST grade B – When the TREATMENT *data are designed to be stored on equipment other than the ME EQUIPMENT, interrupt the remote storage on the receiving equipment and verify that the* TREATMENT *data is stored locally until such time the data are verified as having correctly transferred.*

c) TYPE TEST grade A – Statement regarding INTERLOCKS that can be reset only by use of the designated mechanical key.

c) TYPE TEST grade C – Cause a TERMINATION OF IRRADIATION by SPECIFIED means, followed by attempted INITIATION OF *IRRADIATION without the use of a designated mechanical key.*

d) SITE TEST grade B – Attempt to import a data set that fails the consistency, correctness and completeness test and verify that TREATMENT *cannot commence. If the design is such that a data set with a fault cannot be created on-site, then this test shall be a TYPE TEST.*

201.10.101.2 Protection against STRAY RADIATION in the RADIATION FIELD

201.10.101.2.1 STRAY X-RADIATION during ELECTRON IRRADIATION

The percentage ABSORBED DOSE on the REFERENCE AXIS due to X-RADIATION at a depth of 100 mm beyond the practical ELECTRON range shall not exceed the values as set out in Figure 201.102[3].

The measurement shall be made in a water or water-equivalent PHANTOM, the incident surface being normal to the REFERENCE AXIS at RTD and dimensioned such that the PHANTOM extends at least 5 cm beyond each edge of the RADIATION FIELD; its depth shall be at least 5 cm more than the depth of measurement.

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3 See ICRU Report 35:1984, 3.3 (Energy); 3.3.2.3 (Range measurements); 9.2.6.1 (X-ray contamination); etc.

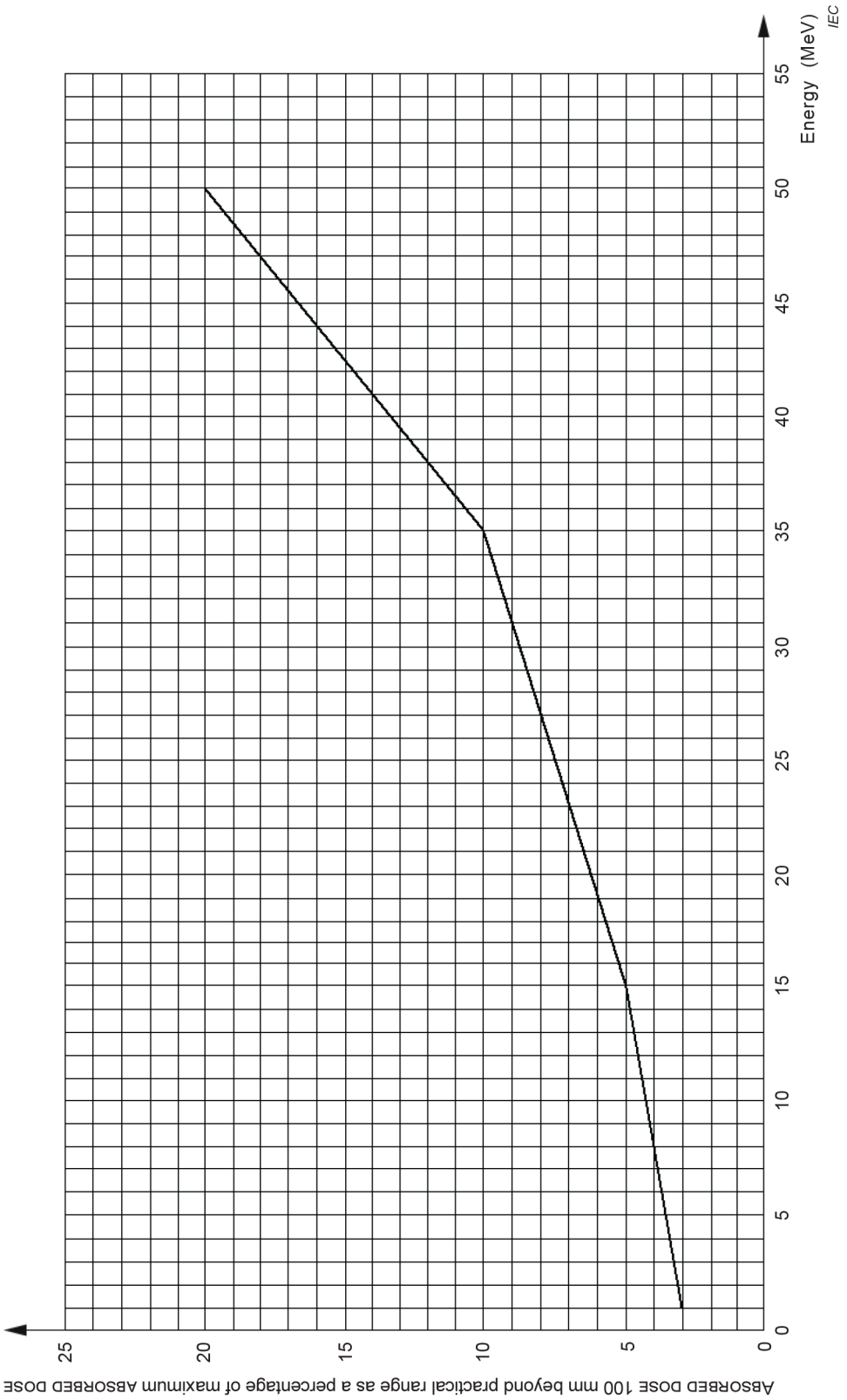


Figure 201.102 – Limits of STRAY X-RADIATION during ELECTRON IRRADIATION

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding percentage stray X-RADIATION during ELECTRON IRRADIATION for all ELECTRON BEAM APPLICATORS and ENERGIES.

SITE TEST grade B – Procedure: perform measurements, as described, for a 10 cm × 10 cm RADIATION FIELD size and the MANUFACTURER's stated RADIATION FIELD size that gives the worst values. Repeat for all ENERGIES.

201.10.101.2.2 RELATIVE SURFACE DOSE during X-IRRADIATION

The RELATIVE SURFACE DOSE shall not exceed the values given in Table 201.105 and as set out in Figure 201.103 for

a) a RADIATION FIELD of 30 cm × 30 cm, or the largest available RADIATION FIELD less than 30 cm × 30 cm, and

b) a RADIATION FIELD of 1 cm × 1 cm, or the closest available RADIATION FIELD.

The measurement shall be made in a PHANTOM dimensioned and positioned as in 201.10.101.2.1. All RADIATION BEAM modifying devices removable without the use of tools shall be removed from the RADIATION BEAM. All FIELD FLATTENING FILTERS, if provided, shall remain in their SPECIFIED positions per intended use.

Table 201.105 – Limits of RELATIVE SURFACE DOSE during X-IRRADIATION (see Figure 201.103)

NOMINAL ENERGY, MV	1	2	5	8 to 30	40 to 50
RELATIVE SURFACE DOSE, %	80	70	60	50	65

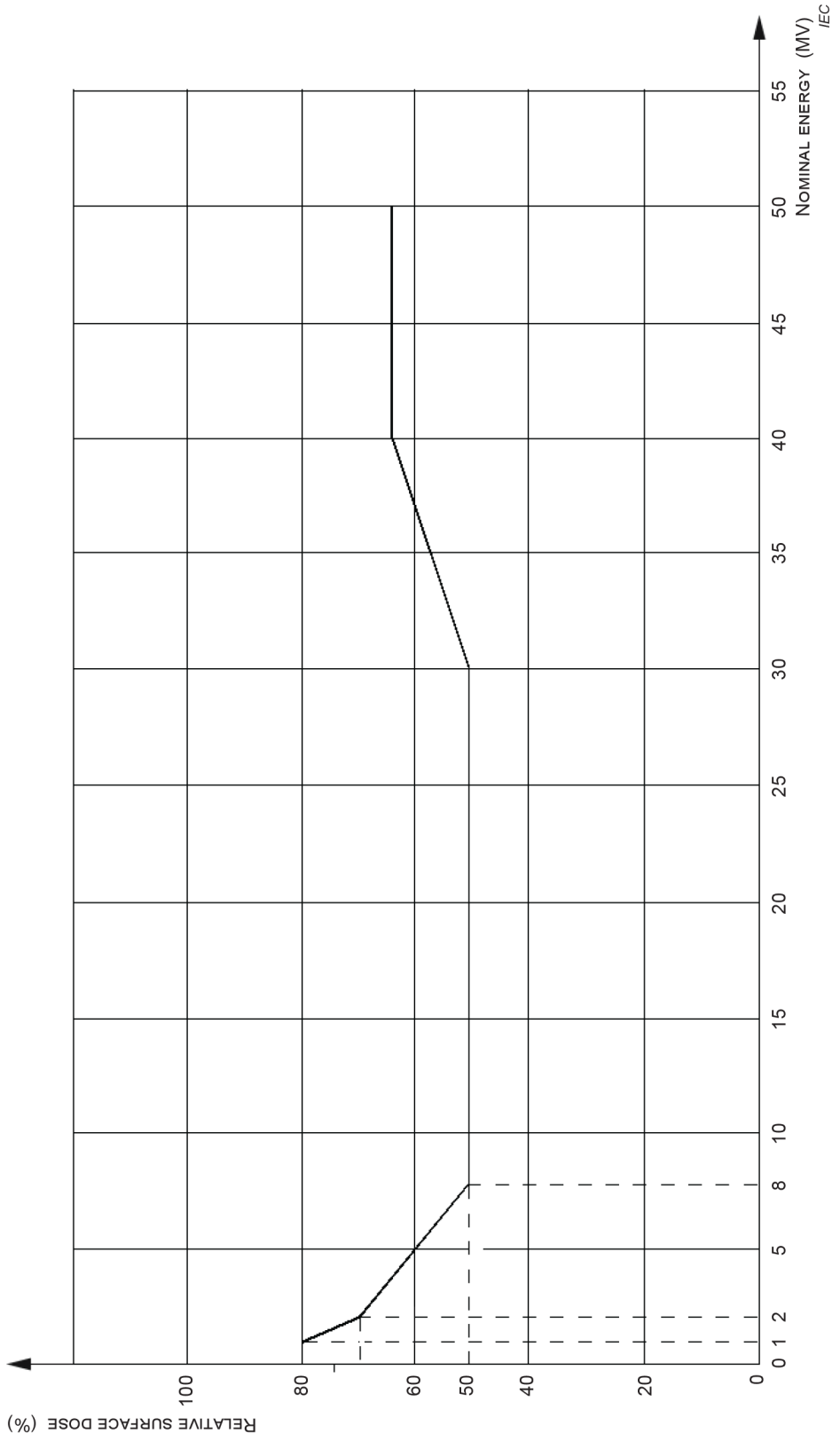


Figure 201.103 – Limits of RELATIVE SURFACE DOSE during X-IRRADIATION

Compliance is checked as follows:

TYPE TEST grade B – Procedure: verify RELATIVE SURFACE DOSE for all NOMINAL ENERGIES, as SPECIFIED above.

SITE TEST grade B – Procedure: verify RELATIVE SURFACE DOSE for all NOMINAL ENERGIES, as SPECIFIED above.

201.10.101.2.3 Stray NEUTRON RADIATION

This requirement shall apply only when the maximum ENERGY of the ELECTRONS in the LINAC exceeds 10 MeV.

An estimate of the NEUTRON energy distribution and a value for STRAY NEUTRON RADIATION shall be derived from measurements, averaged over a cross-sectional area not exceeding 800 cm^2, of either:

- the NEUTRON ABSORBED DOSE at the REFERENCE TREATMENT DISTANCE, as a percentage of the X-RADIATION REFERENCE ABSORBED DOSE measured at the REFERENCE TREATMENT DISTANCE in a 20 cm × 20 cm RADIATION FIELD, or
- the maximum NEUTRON FLUENCE RATE to be expected at the REFERENCE TREATMENT DISTANCE for a stated X-RADIATION ABSORBED DOSE RATE.

When a 20 cm × 20 cm RADIATION FIELD size is not available, the RADIATION FIELD size closest to it shall be used when determining the values for 201.10.101.2.3.

The values determined will be included in the ACCOMPANYING DOCUMENTATION.

Compliance is checked as follows:

TYPE TEST grade C – For all NOMINAL ENERGIES of X-RADIATION or, if X-RADIATION is not available, for the NOMINAL ENERGY of ELECTRON RADIATION producing the maximum ABSORBED DOSE or maximum FLUENCE RATE due to STRAY NEUTRON RADIATION, perform measurements to obtain the data required. The method, conditions and results for the chosen alternative shall be stated; account shall be taken of the pulsed nature of the RADIATION, the NEUTRON ENERGY spectrum, the effects of the accompanying X-RADIATION and of NEUTRON RADIATION scattered from surrounding structures. The measurements shall be made with the BLDs fully closed and fully opened.

TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION.

201.10.101.3 Protection against RADIATION in the PATIENT plane outside the RADIATION FIELD

201.10.101.3.1 General

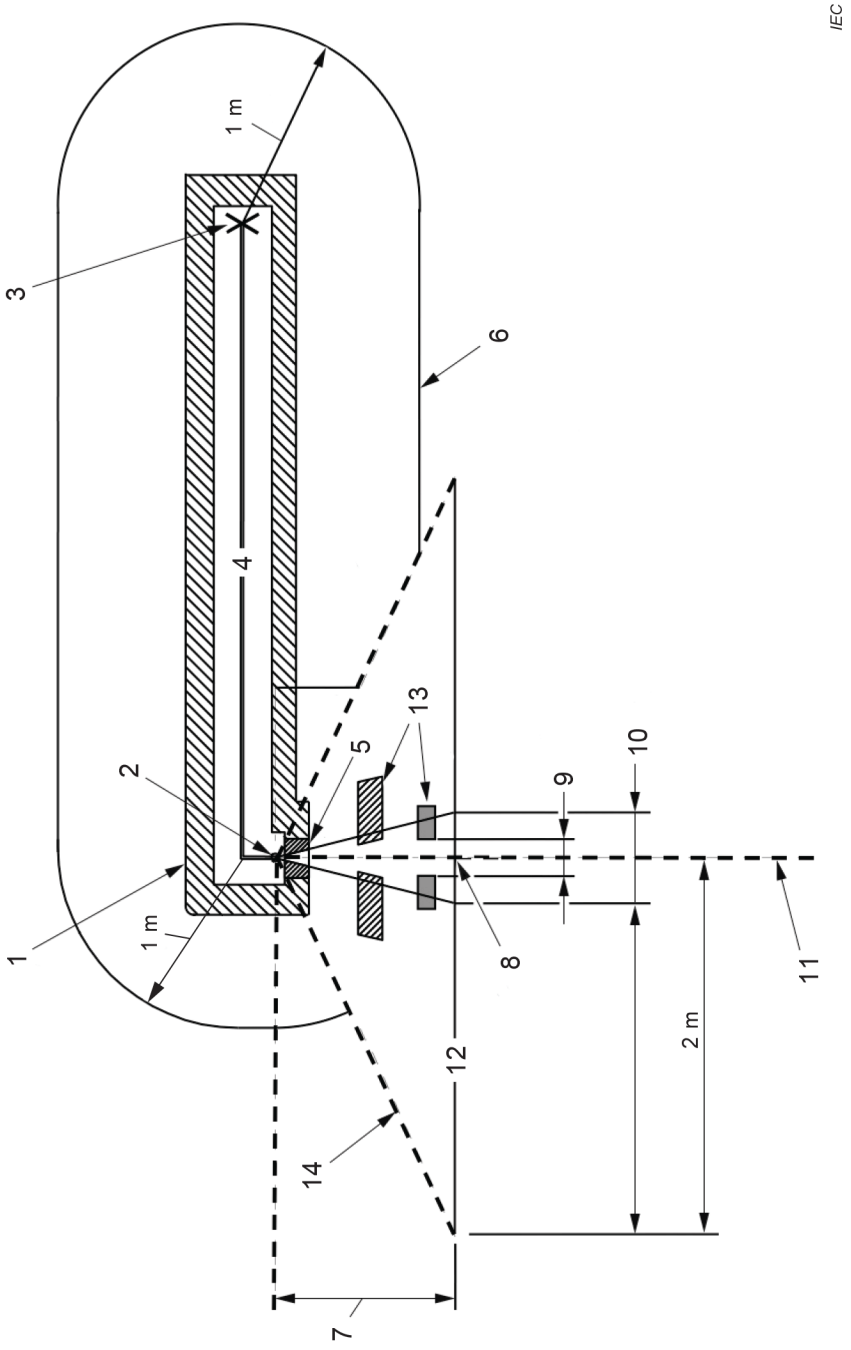
The requirements of 201.10.101.3, unless otherwise stated, shall apply when the ME EQUIPMENT is operating under standard TREATMENT conditions.

For ME EQUIPMENT delivered with an ADDED FILTER, if operation with and without the ADDED FILTER can be achieved, the requirements of 201.10.101.3 shall be satisfied for both conditions.

Unless otherwise specified in 201.10.101.3, a 20 cm × 20 cm RADIATION FIELD size shall be used for measurements. The REFERENCE ABSORBED DOSE shall be used for all LEAKAGE RADIATION calculations. If a 20 cm × 20 cm RADIATION FIELD size is not available, the RADIATION FIELD size closest to it shall be used when determining the values for 201.10.101.3.

The boundaries applying to the requirements of 201.10.101.3 are shown in Figure 201.104.

NOTE The REFERENCE ABSORBED DOSE is an area weighted average (see 201.3.245).



Key

1 PROTECTIVE SHIELDING
2 TARGET/ELECTRON RADIATION window
3 ELECTRON gun
4 ELECTRON path
5 non-adjustable primary BEAM LIMITING DEVICE
6 boundary for measurement of LEAKAGE RADIATION outside the PATIENT TREATMENT PLANE
7 REFERENCE TREATMENT DISTANCE
8 EQUIPMENT REFERENCE POINT
9 GEOMETRICAL RADIATION FIELD due to BEAM LIMITING DEVICE
10 area M (or M_{10})
11 REFERENCE AXIS
12 plane on ERP perpendicular to the REFERENCE AXIS
13 adjustable BEAM LIMITING DEVICE
14 conical surface area

Figure 201.104 – Elevation view – Application of LEAKAGE RADIATION requirements