Physikalisch-Technische Bundesanstalt

Medical metrology

Guidelines for metrological verifications of medical devices with a measuring function (Edition 3.0)

Part 2

Therapy dosimeters for the external treatment of patients

Therapy dosimeters for the external treatment of patients
with photon radiation in the energy range of up to 1.33 MeV

Therapy dosimeters for the external treatment of patients
with photon radiation in the energy range from 1.33 MeV and upwards and with electron radiation from accelerators with metrological examinations in the form of comparison measurements

Dosimeters for radiodiagnostics for metrological and testing procedures which are not subject to the Measures and Verification Act according to section 34, paragraph 3 of the X-ray Ordinance

Stephan Mieke and Thomas Schade (eds.)

Preamble

These guidelines are the translation of the German „Leitfaden zu messtechnischen Kontrollen von Medizinprodukten mit Messfunktion (LMKM)“. The document describes the correct metrological verification of several medical devices with a measuring function. The present translation has no other purpose than to inform about the requirements in Germany and may serve as a technical resource for interested parties in the field. While in Germany, the original document has a certain legal relevance, the translation has no legal status, neither inside nor outside Germany.

Explanatory notes

With the Ordinance on the installation, operation and use of medical devices (Medical Devices Operator Ordinance; MPBetreibV) entering into force on 7 July 1998, the group of persons authorised to verify medical devices (medical devices with a measuring function) was extended compared to the provisions of the Verification Ordinance applying until then.
To maintain uniform requirements and quality standards regarding the practical implementation of the metrological verifications, PTB's Advisory Board for Medical Metrology, which includes representatives from industry, the scientific community, users and public authorities, decided that PTB's specialised laboratories would, in cooperation with the verification authorities, elaborate a guide for metrological verifications.
The product of this cooperation project, which was coordinated by Dr. S. Mieke (PTB) and T. Schade (from the Bavarian Office for Weights and Measures), entitled

Guidelines for metrological verifications of medical devices with a measuring function,

has been amended, **and its 3rd edition is now available.**

For practical reasons, these guidelines have been divided into two parts. Part 2 describes the metrological verification of therapy dosimeters and dosimeters for radiodiagnostics; part 1 addresses all the other measuring instruments listed in Annex 2 of the Medical Devices Operator Ordinance (MPBetreibV).

Following the decision of the General Assembly on Verification on the 23rd of November 1998, this guidelines were published and can be accessed and downloaded at:

http://www.ptb.de/cms/presseaktuelles/wissenschaftlich-technische-publikationen/publikationen-zum-medizinproduktegesetz.html.
The second ordinance revising the provisions applying to medical devices dated 27 September 2016, in section 14, paragraph 1, clause 3 of the Medical Devices Operator Ordinance (MPBetreibV) regulates that the currently valid version of the guidelines is to be made available and maintained on the website of the Physikalisch-Technische Bundesanstalt (PTB).

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Guidelines for metrological verifications
of medical devices with a measuring function

(Requirements for institutions, persons, measuring and testing facilities
as well for the contents and scope of the verification procedures for medical devices
according to Annex 2 of the Medical Devices Operator Ordinance)

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Foreword

The Council Directive 93/42/EEC concerning medical devices was transposed at the national level with the adoption of the Medical Devices Act on the 2nd of August 1994. Thus, German legislation does not prevent placing medical devices on the market and putting them into operation if they bear the CE marking confirming that these products have been subjected to a conformity assessment procedure in accordance with the above-mentioned Directive.

By affixing the CE marking, the manufacturer declares that such labelled products comply with all relevant provisions of the Directive concerning medical devices.

The general terms of the Directive concerning medical devices stipulate the manufacturer's duty of indicating on a case-by-case basis the type and frequency of maintenance measures and calibrations to ensure that the devices operate properly and safely at all times. The information provided is the manufacturer's responsibility and usually applies to medical devices of the same type.

In the case of medical devices for which measurement reliability is of particular significance, the relevant EU member state is obliged to ensure that these products will also meet the applicable requirements over their entire utilisation period after they have been put into operation. This is the reason why, in Germany, the legislator prescribes metrological verifications at regular intervals for certain medical devices with a measuring function as per the Medical Devices Operator Ordinance dated 29 June 1998, promulgated on 21 August 2002 (Federal Law Gazette I, p. 3396), last revised by the second ordinance amending the provisions relating to the legal aspects of medical devices dated 27 September 2016 (Federal Law Gazette I, p. 2203). The compliance with maximum permissible errors is checked by competent persons by means of suitable and traceable test equipment. The metrological verifications are carried out in the form of tests for each individual medical device and shall be independent of external interference (e.g. from manufacturers or operators). Persons in charge of the verifications shall notify the competent authorities before starting their activities; at the authorities' request, they shall provide the proof that the requirements have been met. This also includes the availability of the documents required for the proper execution of the metrological verification.

To ensure the uniform implementation of the regulations on metrological verifications of medical devices with a measuring function according to the provisions of the Medical Devices Operator Ordinance throughout Germany, the use of the following guidelines is recommended to the competent authorities and all other persons carrying out such verifications.
Pursuant to section 14, paragraph 1, clause 1 of the Medical Devices Operator Ordinance, the metrological verifications shall be deemed to have been performed correctly if the guidelines have been taken into account. In its 3rd version, that is currently available, the guidelines were elaborated by the editors after consultations with the relevant parties.
Pursuant to section 14, paragraph 2 of the Medical Devices Operator Ordinance, the verifications are conducted to determine if the medical device complies with the maximum permissible errors (MPEs). Furthermore, the guidelines also list suitable requirements and measures to ensure compliance with these MPEs. These may require additional tests and place additional specifications on the properties and the availability of necessary documents such as instructions for use. These guidelines do not affect the current regulations in the fields of safety technology and radiation protection. Property rights of any kind are not covered by the guidelines.

A General legal requirements placed on medical devices

Requirements to be met by persons

Section 14 of the Medical Devices Operator Ordinance (MPBetreibV) [1] contains the following requirements to be met by persons conducting the verifications:

Section 14, paragraph 5: The operator may entrust only the following persons with metrological verifications:

1. authorities responsible for metrology, or

2. persons, companies or institutions that fulfil (themselves or through their employees) the prerequisites mentioned in section 5 with regard to the metrological verifications of the individual medical devices.

Section 5 (Specific requirements): If the present ordinance demands specific requirements for a given task, this task may only be performed by persons who:

1. have up-to-date skills with regard to the task required based on appropriate training and relevant professional activities;

2. in terms of technical expertise, are independent from external interference from directly involved or third parties;

3. have the means, in particular capacities, instruments and other work equipment such as appropriate measurement and test equipment, that are necessary in order to properly and traceably carry out the respective task.

The proof that a person can guarantee the proper execution of the metrological verification according to section 5, No. 1 of the Medical Devices Operator Ordinance (MPBetreibV) can, for example, be provided by:

- practical experience of a minimum of one year in the field of metrological verification of such medical devices on which the metrological verifications are to be performed,
- completed professional training in the relevant field,
- training conducted by the manufacturer on the medical devices to which metrological verifications are to be performed.

Section 14, paragraph 6: Persons intending to conduct metrological verifications in the future, must notify the competent authority prior to conducting the first metrological verification and, upon request of the competent authority, deliver the proof that they meet the requirements according to section 5.

Requirements placed on measurement and test equipment

Section 14 of the Medical Devices Operator Ordinance (MPBetreibV) contains the following requirements with regard to the metrological standards that are used for metrological verifications:

Section 14, paragraph 3: Unless otherwise stated in Annex 2, only metrological standards are to be used for metrological verifications that are traceable to a national or international standard and that comply with sufficiently small maximum permissible errors and measurement uncertainties. The maximum permissible errors and measurement uncertainties shall be regarded as sufficiently small if they comply with the requirements in paragraph 1, clause 2 of said guidelines or if they do not exceed one third of the maximum permissible errors and measurement uncertainties of the medical device to be verified.

The metrological standards used for verifications must be metrologically traced on an annual basis. The metrological standards referenced here are working standards as defined in legal metrology, i.e. those standards that are directly employed for metrological verification. The

general reverification deadline of one year corresponds to that in legal metrology. Exceptions to this rule are listed in Annex 1 of these guidelines. The traceability can be proven by a calibration certificate that is issued by a DAkkS-certified calibration laboratory that is accredited for the relevant measurand, by a verification authority or by PTB. Calibrations that are recognized by PTB or DAkkS due to bilateral or multi-lateral agreements (e.g. within the scope of the European Cooperation for Accreditation (EA)) are equivalent to this calibration.

The traceability of metrological standards can also be established by a calibration that does not fulfil the aforementioned requirements. In this case, however, the metrological standard must be traceable as described above and the traceability must be clearly defined in the quality management handbook of the party performing the traceability check. The regulations must comply with those in the DAkkS Instruction Sheet 71 SD 0 005 (http://www.dakks.de/doc_allgemein) for the metrological traceability as amended.

Measuring and testing devices complying with the requirements listed in Part B of these guidelines, are considered as suitable in principle when they are metrologically traced as described. This does not exclude the possibility that also other measuring devices may be suitable, e.g. measuring and testing devices recommended by the manufacturers of the medical products to be tested. The suitability of the measurement and test equipment, however, must be verified according to section 5 of MPBetreibV in conjunction with section 14, paragraph 6 of MPBetreibV upon request by the competent authority.

Maximum permissible errors to be complied with

Section 14 of the Medical Devices Operator Ordinance (MPBetreibV) contains the following specifications with regard to the maximum permissible errors to be complied with:
Section 14, paragraph 2: The metrological verifications are a means to determine if the medical product complies with the maximum permissible deviations (error limits) indicated in the guidelines according to paragraph 1, clause 2.

According to Annex I, No. 10.1, clause 2 of the European Council Directive 93/42/EEC concerning medical devices, "the accuracy limits selected by the manufacturer" must be specified for medical products that are placed on the market in the Federal Republic of Germany according to the regulations of the Medical Devices Act (MPG) [2] or according to a comparable law that implements Directive 93/42/EEC in a member country of the EU. If these limits deviate from the specifications in these guidelines, and if a metrological verification is conducted on this basis, the presumption of conformity does not apply pursuant to section 14, paragraph 1, clause 2 of MPBetreibV, and the party that carried out the metrological verification must, if applicable, justify the reasons for this deviation to the competent authorities.

If the manufacturer has, in addition, also provided specifications or requirements (test procedures) for the performance of metrological verifications, it must be borne in mind that the requirements for the performance of metrological verifications are contained in section 14, paragraph 1 of the Medical Devices Operator Ordinance (MPBetreibV). According to these requirements, the metrological verifications must be conducted based on the recognised state-of-the-art.

The outcome of the metrological verification

Section 14 of the Medical Devices Operator Ordinance (MPBetreibV) places the following requirements on the documentation of the results of the metrological examination:

Section 14, paragraph 7 No. 1: Those conducting the metrological verifications must
1. draw up a protocol on the metrological verification containing the date of the execution and

the results of the metrological verification including the measurement values determined, the measurement procedure and other evaluation results. […]

Pursuant to clause 1, the protocol must be kept by the operator at least until the next metrological verification.

The marking of the metrological verification

Section 14 of MPBetreibV contains the following specifications with regard to the marking after the metrological verification has been successfully completed:

Section 14, paragraph 7, No. 2: Those conducting the metrological verifications must […] attach a marking to the medical device after the metrological verification has been successfully completed; this marking must state in a clearly identifiable and traceable way the year of the next metrological verification and the authority or person that has conducted the metrological verification.

The marking may also include the month if this is supported by the organization conducting the metrological examination. This type of marking must, however, not lead to ambiguities regarding the identification of the year. In addition to the month, the marking must clearly state the year of the next metrological verification. The deadline for the next verification is, in this case, determined by the month specified on the marking. The identity of the person (a natural or a legal person) who conducted the metrological verification shall likewise be shown in a clear way.

Markings of previously conducted metrological verifications shall be removed.

As a general rule, the marking should be indelibly affixed to the medical device. The removal of the marking should only be possible by using mechanical tools and by destroying the marking.

Section 14 of MPBetreibV does not regulate the protection of a metrologically verified medical device against tampering that might have negative effects on the metrological properties.

It is acceptable to attach security seals or similar seals to the devices – especially in the case of devices that were presented without any protection or similar security seals – if such seals will prevent misadjustments or modifications of metrologically important properties. If security seals are provided by the manufacturer, such seals must be affixed or renewed.

Legal ramifications will not ensue when security seals are missing or have been destroyed.

Devices requiring metrological verification

Section 14 of MPBetreibV contains the following statements:

Section 14, paragraph 1, clause 1: For the medical devices specified in Annex 2, the operator shall conduct directly or by way of delegation metrological verifications in accordance with the generally accepted state-of-the-art pursuant to paragraph 4 of the aforementioned Annex 2.

With the changes introduced in 2007, the Medical Devices Act (MPG) has extended the field of application of the metrological verification regulations:

Section 2, paragraph 2: This Act shall also apply to the use, operation and maintenance of devices that have not been placed on the market as medical devices but are used with the intended purpose of a medical device within the sense of Annexes 1 and 2 of the Medical Devices Operator Ordinance. These are deemed to be medical devices within the sense of this Act.

This affects, for example, the foot crank ergometers that were placed on the market as non-medical devices ("training devices") but are employed in the field of medical science for diagnosing and for therapy purposes.

References

[1] Medical Devices Operator Ordinance (*Medizinprodukte-Betreiberverordnung*) as promulgated on 21 August 2002 (Federal Law Gazette I, p. 3396), last revised by article 1 of the Ordinance of 27 September 2016 (Federal Law Gazette I p. 2203)

[2] Medical Devices Act (*Medizinproduktegesetz, MPG*) in the version as promulgated on 7 August 2002 (Federal Law Gazette I p. 3146), last revised by article 2 of the law of 18 July 2016 (Federal Law Gazette I p. 1666)

B Additional requirements placed on special devices

6 Therapy dosimeters for the external treatment of patients

Note 1: Therapy dosimeters for the external treatment of patients whose detectors are not ionization chambers are calibrated pursuant to the state of the art at the operator's premises and on the day of use according to the manufacturer's specifications. Consequently, they are subject to item 2 of Annex 2 (relating to Section 14, paragraph 1) of the Medical Devices Operator Ordinance (MPBetreibV) (decision of the Working Committee "Therapy Dosimeters" of PTB's Advisory Board for Medical Metrology).

Note 2: According to Annex 2, No. 1.5 of the Medical Devices Operator Ordinance (MPBetreibV), two different forms of metrological verifications are specified, depending on the radiation sources with which the dosimeters are used in radiation therapy. For therapy dosimeters that are used for the external treatment of patients with photon radiation in the energy range of up to 1.33 MeV, the metrological verification according to No. 1.5.1 refers only to the measuring device. Pursuant to No. 1.5.2, therapy dosimeters that are used for the external treatment of patients with photon radiation in the energy range of 1.33 MeV and upwards and with electron radiation from accelerators, must be subjected to comparison measurements as a special form of the metrological verification.

While a measuring office has to be appointed by a competent authority to carry out comparison measurements, all other offices intending to conduct metrological verifications of a certain measuring device are obliged to notify the competent authorities.

6.1 Therapy dosimeters with ionization chambers for the external treatment of patients with photon radiation in the energy range of up to 1.33 MeV

6.1.1 Scope of application

The scope of application for the requirements comprises only therapy dosimeters with ionisation chambers that are used for radiation therapy with photon radiation in the energy range of up to 1.33 MeV.

The application of these requirements is recommended to persons and institutions (in the following referred to as measuring offices) conducting metrological verifications on therapy dosimeters according to Annex 2 No. 1.5.1.

Measurement facilities deviating from these requirements in respect of their measurement and test equipment as well as in their test methods must furnish proof that their measurement results are comparable to those determined according to the state of the art.

6.1.2 Definitions

Therapy dosimeters that are used for the external treatment of patients with photon radiation are dosimeters that are intended to be used for the determination of the value of the dose or of the dose rate generated at the measuring point by the X-ray and gamma radiation. They must indicate this value in legal units, and their measurement uncertainty and reliability should comply with the harmonized European standards or with the international standard IEC 60731 [1].

The measurands are the absorbed dose to water in a water phantom (DIN 6800-2 [2], DIN 6809-4 [3]) and the absorbed dose rate to water in a water phantom.

6.1.3 Preliminary notes on the scope of the metrological verifications

A therapy dosimeter of the type described in this guide usually consists of two components: the chamber unit (ionization chamber) and the indicating device (electrometer with indicating unit); there may be an additional control device.

One indicating device can be used for several ionization chambers.

A chamber unit may also be metrologically verified as a separate assembly without the associated indicating device if a calibration certificate for the chamber unit is available.

The calibration certificate for a chamber unit without a radioactive control device must indicate at least the calibration factor for the reference radiation quality (in Gy/C) and correction factors for other radiation qualities of the rated range of use.

The calibration certificate for a chamber unit with a radioactive stability check device must additionally indicate the stability check measurement value or the stability check current including its reference date and the identification of the stability check device including the radionuclide and its half-life.

An indicating device of a dosimeter without a chamber unit can only be metrologically verified alone if an indication in electrical units is possible.

A therapy dosimeter is deemed metrologically verified if all components have been subjected to a successful metrological verification.

6.1.4 Content and scope of the metrological verification

The metrological verification consists of an initial verification, a functional performance test and the metrological verification.

6.1.4.1 Initial verification

The initial verification must include the following checks:

a) whether specific requirements by the manufacturer have been adhered to, provided adherence can be determined by a visual inspection;

b) the labelling and marking of all parts of the dosimeters and its accessories;

c) the scales and indicating devices;

d) whether all components that are necessary for the operation of the dosimeter, e.g. chamber units, stability check devices, instructions for use as well as calibration certificates, are available;

e) whether all detachable parts belong together according to the technical documents and device numbers;

f) whether exterior damage has occurred (especially the thin-walled radiation entrance windows of the flat chambers must be examined for any possible damage);

g) the information on the calibration certificate associated with the dosimeter (especially when the calibration factor of the electrometer is internally stored, a verification must be conducted to establish that the calibration factor corresponds to the information in the calibration certificate; the same applies to the list of correction factors if radiation qualities deviate from the reference quality, provided these correction factors are also stored internally in the electrometer).

6.1.4.2 Functional performance test

The functional performance test is to examine whether the test object can reasonably be expected to allow a proper execution of the metrological verification. The functional performance test includes:

a) the verification of the settings of the dosimeter or of the auxiliary device according to the instructions for use;

b) the verification of the voltages, provided they are described in the instructions for use;

c) the verification of the zero indication or zero adjustment;

d) the determination of the instrumental drift (does not apply to dose-rate measuring instruments).

6.1.4.3 Metrological verification

6.1.4.3.1 Verification of the dosimeter (chamber unit and indicating device)

The accuracy of the indication of the dosimeter is verified under reference conditions at the reference radiation quality and at least at one additional radiation quality.

The accuracy of the indication in the measurement ranges that cannot be verified in this way with X-ray or gamma radiation must be established by determining the relative response by means of a current source.

In all the aforesaid cases, the calibration factor, the corrections and uncertainties must be recorded and entered in the medical devices book of the operator. The dosimeter must be adjusted to the new calibration values, if possible. If the modification of the calibration factor exceeds the maximum permissible errors, the metrological verification is considered as failed.

If the metrological verification has been successful, a new calibration certificate must be issued.

6.1.4.3.2 Verification of the chamber unit of a dosimeter

The accuracy of the measurement value of the output quantity (output charge or current) of a chamber unit is verified by means of an electrometer or ammeter regarding the measurand and the influence of the radiation quality according to clause 6.2.3.1.

6.1.4.3.3 Verification of the radioactive stability check device

If the dosimeter is equipped with a radioactive stability check device, the check response value or the check current must be verified.

6.1.4.3.4 Verification of the electrical stability check device

If the dosimeter is equipped with an electrical stability check device for the verification of its relative response in the different measurement ranges, the relations of the output voltages or output currents in the different ranges of the stability check device must be verified.

6.1.4.3.5 Additional verification tests pursuant to specific requirements

In addition to the above-mentioned metrological verifications, the effects of further parameters or characteristics of the device on the measurement value must be examined if specific requirements are placed on the device.

A verification test pursuant to specific requirements may be required:

a) due to the manufacturer’s requirements;

b) due to a directive issued by the competent authority, if the experiences made with the properties of the individual dosimeters of a certain type require these tests.

6.1.5 Test equipment for measurement facilities

6.1.5.1 Radiation sources and attachments

6.1.5.1.1 X-ray equipment and attachments

X-ray equipment

X-ray equipment for the low-energy X-ray range and for the medium-energy X-ray range are required for the verification. This equipment is to fulfil the minimum requirements listed in Table 1.

Table 1: Minimum requirements placed on X-ray equipment

	Low-energy X-ray range	Medium-energy X-ray range
Tube voltage	At least 10 kV to 100 kV, as continuously adjustable as possible, constant potential, voltage ripple ≤ 10 % at max. tube current.	At least 100 kV to 280 kV, as continuously adjustable as possible, constant potential, voltage ripple ≤ 10 % at max. tube current.
Tube current	At least up to 5 mA, as continuously adjustable as possible.	At least up to 10 mA, as continuously adjustable as possible.
Anode material	Tungsten	Tungsten
Quality equivalent filtration of tube and tube housing (inherent filtration)	≤ 1.5 mm beryllium	≤ 3.5 mm aluminium

To verify the high voltage that is applied to an X-ray tube, a connection on the secondary side must be provided for a high-voltage measuring device (e.g. a voltage divider) to be able to conduct an on-site verification at the laboratory if needed. This connection can be omitted if the high voltage is determined according to another procedure, e.g. from the spectrum of the radiation.

For the voltage variations of the power supply, the following should apply: $\Delta U < 0.3$ %. This voltage regulation can be achieved by means of a power stabilizer.

X-ray beam shutter

The diameter of the opening of the X-ray beam shutter must not limit the field size determined by the diaphragm. The shutter should decrease the radiation intensity to at least 0.1 %. This requires approximately 2 mm of lead in the low-energy X-ray range (tube voltage up to 100 kV) and approximately 15 mm of lead in the medium-energy X-ray range (tube voltage up to 300 kV). The time for the opening and closing process should be below 0.1 s.

Diaphragms

The apertures of the diaphragms must be selected, taking into account the diaphragm distance from the focal spot of the X-ray tube, so that the distances specified in Table 2 for the diameters of the radiation field are achieved. The openings of the diaphragms should be circular. The outer diameter of the diaphragms must be sufficiently dimensioned so that only the parts of the chamber to be irradiated are directly exposed.

In the medium-energy X-ray range, the diaphragms must be made of lead and coated by stainless steel or brass to protect them from damage. The lead diaphragms B_1 and B_2 (see Fig. 1) or B (see Fig. 2) should have a thickness of at least 4 mm each.

In the low-energy X-ray range, these diaphragms may consist of steel or brass. The lead diaphragms B_1 and B_2 (see Fig. 3) should have a thickness of at least 3 mm each.

Filters

The thickness of the required filters is specified in the tables of radiation qualities according to DIN 6809-4 [3], a German national standard, i.e. in Table 2 (low-energy X-ray therapy) and in Table 5 (medium-energy X-ray therapy).

The filter materials used should have a purity grade of 99.99 % for radiations with a 1st half-value thickness of s1(Al) < 0.2 mm.

The purity grade for radiations with s_1(Al) ≥ 0.2 mm should be at least 99.8 %. The tolerance of the thickness of the individual filter materials must not exceed ± 5 µm or ± 2 %.

The filters must be homogeneously manufactured (in particular, they must be free of air inclusions).

6.1.5.1.2 Gamma radiation sources

To keep the uncertainty of the current measurement sufficiently low, a ^{60}Co gamma radiation source with a sufficiently high activity is necessary for the metrological verification of therapy dosimeters. Especially the radiation-induced ionization current must be substantially larger than the leakage current. As a rule, an activity of less than 2 TBq is not sufficient.

The radiation shielding provided by the working tank must offer sufficient radiation protection. The radioactive source must be made of material with a high specific activity to keep its dimensions and, consequently, the penumbra region as small as possible.

To reduce the dose rate of the scattered radiation that is generated at the collimator edges, the collimator should consist of several disks that are separated from each other by approximately 2 cm wide gaps. The total thickness of a collimator must be dimensioned in such a way that its material reduces the radiation intensity by at least a factor of 10^2. The collimator should have a circular or square cross-section (see Table 2) and must be built in such a way that the penumbra region is as small as possible.

6.1.5.2 Measuring instruments

6.1.5.2.1 Standard measuring instruments

Dosimeters

The dosimeters used as reference standards for the metrological verification of therapy dosimeters must fulfil the requirements of the international standard IEC 60731 [1] for therapy dosimeters of the reference class.

They must be monitored by means of a radioactive stability check device that also fulfils the requirements of standard DIN IEC 60731 [1]. Should this stability check device not allow a verification of the accuracy of the reading in all measurement ranges of the dosimeter, an additional electrical stability check device is necessary.

It is preferable to conduct the monitoring in the radiation field of a ^{60}Co source rather than conducting the monitoring by means of a radioactive stability check device.

Electrometers, ammeters, voltmeters

The following requirements are placed on electrometers, ammeters and voltmeters that are used for the verification of a chamber, a radioactive stability check device or an electrical stability check device (see clauses 6.1.4.3.2, 6.1.4.3.3 and 6.1.4.3.4):

1) Electrometers

a) Measurement ranges: 10^{-7} C to 10^{-11} C;

b) Repeatability: relative standard deviation of the individual test result $s_r \leq 0.2$ %;

c) Temperature influence: max. 0.2 % in the temperature range between 20 °C and 30 °C.

2) Ammeters

a) Measurement ranges: 10^{-9} A to 10^{-12} A;

b) Repeatability: relative standard deviation $s_r \leq 0.2$ % for currents $I \geq 10^{-11}$ A, $s_r \leq 0.3$ % for currents $I < 10^{-11}$ A;

c) Temperature influence: max. 0.2 % in the temperature range between 20 °C and 30 °C.

3) Voltmeters

a) Measurement ranges: 10^{-3} V to 10^{3} V (DC voltage);

b) Repeatability: relative standard deviation of the individual test result $s_r \leq 0.2$ %;

c) Internal resistance: larger than 500 MΩ for voltages smaller than or equal to 20 V;

d) Temperature influence: max. 0.1 % in the temperature range between 20 °C and 30 °C.

Voltage sources

To supply the chamber units with the operating voltage (chamber voltage), voltage sources must be available (often integrated in the indicating device).

Setting ranges:	at least 100 V up to 400 V (positive and negative polarity);
Temperature influence:	max. 0.01 % in the temperature range between 20 °C and 30 °C;
Ripple:	max. 0.01 %.

Current source

To verify an indicating device in the different decades of the measurement range, a current source covering the respective current range (setting range: approx. 10^{-6} A up to 10^{-14} A) is necessary.

6.1.5.2.2 Verification of the accuracy of the standard measuring instruments

Traceability of the standard measuring instruments

The reference standards for the measurand absorbed dose to water must be calibrated against a national standard at intervals of 2 years. Furthermore, subsequent measurements of this type must also be conducted after repairs have been carried out.

Other measuring instruments (electrometers, voltmeters and ammeters) that are used for the verification, must be traced to a national standard at intervals of 2 years.

Intermediate verification of the accuracy of the standard and secondary dosimeters

All dosimeters used as standards must be continually monitored:

The stability check readings of the dosimeters that are determined in the radiation field of a ^{60}Co source or by means of their radioactive stability check devices must be measured and

recorded at reasonable intervals, at least, however, once every three months. During these measurement procedures, the decrease in the activity of the radionuclide must be corrected. If the stability check indication that is recalculated to reference conditions changes by more than ± 1 %, the standard dosimeter – if necessary after it has been repaired – must be again traced back to a national standard. The standard dosimeter must be accompanied by the associated stability check device and the results of the recordings of the verification.

6.1.5.2.3 Dose monitor

To take temporal fluctuations of the dose rate in the radiation field into account, the indications M_n of the standard dosimeter and M of the test object are referenced to the indication M_m of a dose monitor that appears simultaneously. The quotients M_n/M_m and M/M_m are independent of the temporal variations of the dose rate. The radiation field should be modified as little as possible by the detector of the dose monitor (monitoring chamber), and in particular inhomogeneities must not be caused in the effective part of the radiation field (shadow formation) by the detector.

This specification is met by a transmission ionization chamber with electrodes consisting of thin plastic foils (thickness < 50 μm). The diameter of the electrodes must be larger than the largest intended diameter of the radiation field at the measurement point. Both the holder of the monitoring chamber and the holder of the diaphragms B_1 and B_2 (see Fig. 1) surrounding the chamber must be rigidly connected with each other and with the tube housing in order to avoid substantial errors that may occur when these parts are out of alignment. The filtration effect of the monitoring chamber that is especially noticeable in the low-energy X-ray range, must be taken into account for the total filtration. For the repeatability, a relative standard deviation of the individual test result of $s_r \leq 0.2$ % is required.

6.1.5.2.4 Auxiliary measuring instruments

The following auxiliary measuring instruments are necessary:

- a chronometer to determine the measurement time (resolution 0.1 s);
- a thermometer (0.1 °C-scale division); measurement range 15 °C to 30 °C;
- a precision barometer: The measurement range must cover all climatic air pressure variations at the location of the test laboratory (resolution and measurement uncertainty ≤ 1 hPa);
- a hygrometer (measurement uncertainty of max. 5 % relative humidity);
- distance meters, e.g. measuring tapes, graduated scales, tactile probes.

As these auxiliary measuring instruments contribute significantly to the measurement uncertainty, they must be traced back to the national standards and be subject to the inspection and measuring equipment within the scope of the quality management system of the measuring office.

6.1.5.3 Auxiliary devices

Phantoms

a) Water phantom with chamber mounting sleeves (waterproof) at medium-energy X-ray radiation and gamma radiation:

   The dimensions of the phantom must be 30 cm x 30 cm x 30 cm.

The thickness of the wall of the water phantom facing the radiation source must be 5 mm in the part through which the radiation enters the phantom (entrance window). The other phantom walls must have a thickness that is so large that it does not allow the occurrence of measurement errors caused by a deformation of the phantom when filling in the water. The chamber mounting sleeve that contains the chamber in the water phantom must have a thickness of 1 mm in the area of the chamber volume. The construction material for the phantom vessel and for the chamber mounting sleeve in the part where the effective radiation hits the material, must be made of PMMA (Plexiglas). The position of the chambers and/or their mounting sleeves must be adjustable.

b) PMMA phantom in the case of low-energy X-ray radiation:

At the front, the PMMA phantom must be able to house each ionization chamber (parallel-plate chamber) to be verified so that it is flush with the surface.

The dimensions of the phantom must be at least 12 cm x 12 cm vertical to the beam and 6 cm in the beam direction.

6.1.6 Measuring set-up (typical set-up)

6.1.6.1 Verification in the case of X-rays

6.1.6.1.1 Verification with monitoring chamber

The measuring set-up (see Fig. 1 and 2 for medium-energy X-ray radiation and Fig. 3 for low-energy X-ray radiation) consists of the radiation source R, the tube shutter V, the diaphragms B1 and B2, the filter F, the dose monitor M and of the dosimeter (standard dosimeter N or test object P) at the measurement point in the water phantom in the case of medium-energy X-ray radiation and in the PMMA phantom in the case of low-energy X-ray radiation.

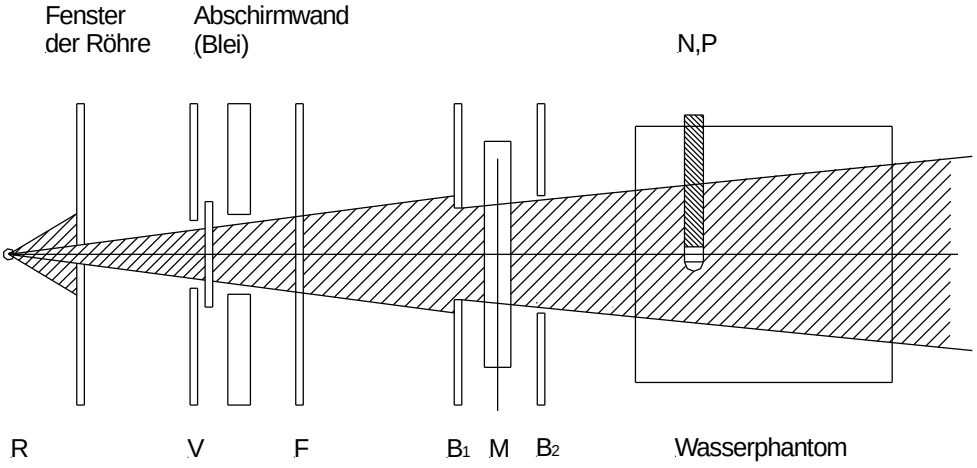

Figure 1: Measuring set-up for the metrological verification of therapy dosimeters with medium-energy X-ray radiation (100 kV to 300 kV tube voltage) while using a dose monitor. Legend: R = X-ray tube assembly, B = diaphragms, V = tube shutter, F = filter, M = monitoring chamber, N = chamber of the standard dosimeter, P = chamber of the test object

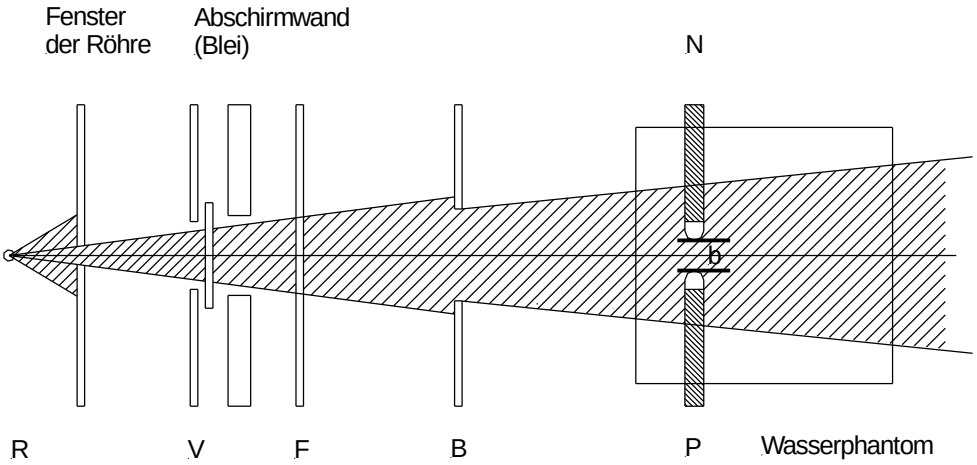

Figure 2: Measuring set-up for the metrological verification of therapy dosimeters with medium-energy X-ray radiation without using a dose monitor.
b: Distance standard to test object, other symbols as in Fig. 1.

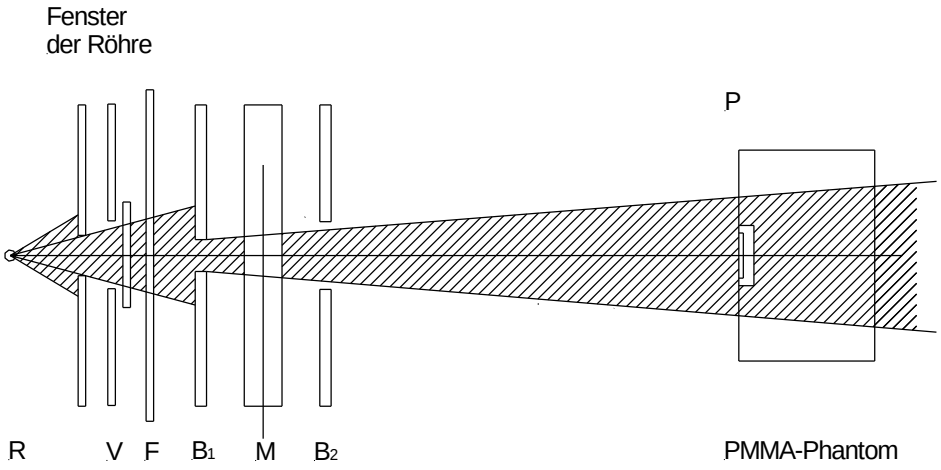

Figure 3: Measuring set-up during the metrological verification of therapy dosimeters with low-energy X-ray radiation (10 kV to 100 kV tube voltage). Symbols as in Fig. 1.

The X-ray beam shutter is used to interrupt the irradiation without having to switch off the tube voltage. It should be as close as possible to the front of the X-ray tube.

The diaphragms are used to limit the radiation field at the lateral position to the field size that is desired at the point of measurement. In the case of medium-energy X-ray radiation, the effective size of the tube window should be confined by a lead diaphragm so that, at a distance of 100 cm from the focal spot, the radiation field without penumbra has a diameter of approx. 10 cm; in the case of low-energy X-ray radiation, it should be confined so that, at a distance of 30 cm from the focal spot, the diameter of the radiation field is approx. 3 cm. To reduce the radiation background at the point of measurement, a radiation protection screen can be put up. Its opening should not confine the radiation field that is screened out by the

lead diaphragm at the tube window. The interchangeable diaphragm B_1 is used to create the desired field size at the point of measurement. The diameters of diaphragms in a set must be selected in such a way that the values for the field sizes correspond to the values specified in Table 2. For each diaphragm B_1, a diaphragm B_2 must be used, the diameter of which must be selected in such a way that diaphragm B_2 blocks the penumbra but does not confine the direct radiation field.

The filters are used to generate the desired radiation quality. The materials of filters consisting of aluminium and copper (see DIN 6809-4 [3] Table 5) must be arranged in such a way that the aluminium parts are facing the point of measurement. This will reduce the dose contribution of the fluorescence radiation from copper.

The monitoring chamber must be positioned in the radiation field in such a way that the electrodes (foils) are perpendicular to the central beam.

Table 2: Information on the measuring set-up and on the reference conditions

Type of chamber	Material of the phantom	Range of tube voltages U_R, radionuclide	Distance from focus to surface in cm (SSD)	Size of field	Depth in the phantom in cm
Parallel-plate chamber	PMMA	10 kV $\leq U_R \leq$ 100 kV	30[1]	3 cm ∅ circular (at the face area of the phantom)	Flush with the surface
Cylindrical ionisation chamber	Water	100 kV $\leq U_R \leq$ 300 kV	98	10 cm ∅ circular (at the point of measurement)	2[2]
		^{60}Co	95	9.5 cm x 9.5 cm	5

The tube voltage of non-voltage-stabilized X-ray equipment can noticeably change due to voltage variations in the grid. This variation can significantly influence the measurement value of a dosimeter, whose chamber is located in a phantom. If a measuring authority works without a power stabilizer, this body must render the proof that it remains within the maximum permissible errors.

6.1.6.1.2 Verification without monitoring chamber

If no monitoring chamber is available, cylindrical farmer chambers with similar dimensions can be verified according to the measuring set-up in Fig. 2. During this verification, the chambers in the water phantom must be set up antiparallel to each other in a plane perpendicular to the central beam, so that their reference points have the same distance from the central beam and

[1] Optionally, also 50 cm are possible

[2] Optionally, also 5 cm are possible. In this case, the distance of focus to surface is 95 cm

their connecting line cuts the central beam in an orthogonal angle. The distance b between the chamber walls facing each other must not be smaller than 10 mm.

In a second measurement, the chambers must be transposed. The measured value is obtained from the mean value of these two individual measurements, each with transposed chambers.

6.1.6.2 Verification by means of gamma radiation

The measuring set-up (see Fig. 4) consists of the radioactive source S in a shielding tank A, the collimator Ko and the dosimeter at the point of measurement (standard dosimeter N or test object P) in a water phantom at a depth of 5 cm (measured from the phantom face wall in a horizontal radiation field).

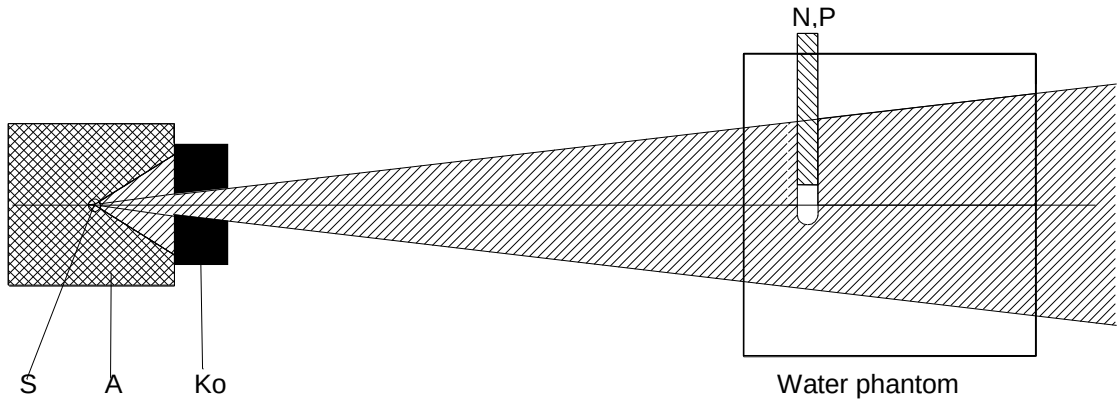

Figure 4: Measuring set-up for the metrological verification of therapy dosimeters with ^{60}Co gamma radiation. Definition: S = radioactive source, A = shielding tank, Ko = collimator, N = chamber of the standard dosimeter, P = chamber of the test object.

The metrological verification of therapy dosimeters in gamma radiation can, if necessary, also be carried out at the ^{60}Co gamma radiation source at the site of the operator of the dosimeter if the reference conditions can be met.

6.1.7 Testing conditions for the metrological verification

The measurement conditions to be met during the verification are:

1) radiation qualities: according to DIN 6809-4 [3] Tables 4 and 5;
2) angle of radiation incidence: reference orientation (marking);
3) dose: determined by the manufacturer if necessary;
4) dose rate: determined by the manufacturer if necessary;
5) ambient temperature: 18 °C to 22 °C;
6) pressure of the outside air: existing air pressure;
7) relative air humidity: 30 % to 75 %.

If different measuring conditions are applied during the verification, the measuring office must deliver the proof that the influence on the measurement result is negligible.

6.1.8 Maximum permissible errors (MPEs)

The maximum permissible errors specified in the manufacturer's instructions for use were taken as a basis. If the instructions for use do not contain any information on maximum

permissible errors, the maximum permissible measurement errors specified in harmonized standards must be met. If no harmonized standards are available, the state of the art must be assumed.

The international standard IEC 60731 [1] represents the current state of the art for therapy dosimeters with ionization chambers. This standard stipulates, for example, that therapy dosimeters must meet the requirements for long-term stability. For this purpose, a differentiation is made between field dosimeters and reference dosimeters. Table 3 specifies the maximum permissible errors for long-term stability taken from this standard.

The compliance or non-compliance with the specified maximum permissible errors must be reliably established during a metrological verification. It must be substantiated with a measurement uncertainty budget that has to be established in accordance with EA-4/02 [4].

Table 3: Maximum permissible errors according to IEC 60731 [1] (requirements for long-term stability)

Range of tube voltages U_R, radionuclide	Reference radiation quality	Type of ionisation chamber	Maximum permissible errors %	
			Application class	Reference class
10 kV < U_R < 100 kV	TW 30	Parallel-plate chamber	$\pm$1.0*)	$\pm$0.5*)
100 kV < U_R < 300 kV	^{60}Co	Cylindrical farmer chamber	$\pm$1.0*)	$\pm$0.5*)
^{60}Co	^{60}Co	Cylindrical farmer chamber	$\pm$1.0*)	$\pm$0.5*)

*) maximum permissible variation p.a. for this type

6.1.9 Implementation of the metrological verification

6.1.9.1 General

In the case of therapy dosimeters (especially older, analogue indicating devices), the measured value that is indicated in the display is often not yet the measurement result that is relevant to the therapy. This measurement result, the actual value of the absorbed dose to water or the absorbed dose rate to water, is obtained by multiplying the indicated measured value M with the calibration factor $N_{D\mathrm{w}}$ that is valid for the prevailing measurement conditions for the reference radiation quality. In principle, corrections are to be applied (e.g. corrections for the air density influence, the influence of the radiation quality, etc.) if the measurement conditions deviate from the reference conditions (for the calibration factor). The absorbed dose to water D_{W} is therefore:

$$D_{\mathrm{W}} = M \; N_{D\mathrm{w}} \; k \,,$$

where k is the product of all necessary correction factors (see DIN 6800-2 [2]).

The calibration certificate must contain the calibration factor for the reference radiation quality, the other reference conditions applicable to the calibration factor such as the focus to skin distance (FSD), the field size on the phantom face surface (surface) and the measurement depth in the phantom as well as the correction factors for the different radiation qualities. In addition, information about the radiation entry wall of the water phantom vessel and the chamber mounting sleeve for the chamber in the phantom is required.

During the metrological verification, the measurement conditions are to be selected such that they deviate as little as possible from the reference conditions that apply to the calibration factor $N_{D\mathrm{w}}$ specified on the calibration certificate and that is used for the calculation of the measurement result. Table 2 specifies the reference values for the measurement distance and for the field size according to the DIN standards. The measurement point is the place where the reference point of the chamber is located during the measurement. The measurement point in the phantom should be located on the central beam (axis of the radiation field). The Source-Surface Distance (SSD) represents the distance of the front surface of the phantom to the centre of the focal point of an X-ray tube or to the geometrical centre of the source capsule containing the radioactive material.

For measurements in the phantom, the field size is the area of the surface that encloses the 50% isodose curve free in air (when there is no phantom) in the plane of the front surface of the phantom facing the radiation source. The 50% isodose curve is the curve that contains all points in a certain plane at which the value measured with a detector that is as small as possible (e.g. a small ionization chamber) is 50% of the largest measured value within that plane. The response of this detector should depend as little as possible on the photon energy and the radiation incidence.

Each dose or dose measurement must be repeated at least five times after sufficient pre-irradiation. The mean value of the measured individual values shall be the measured value. If there is no radiation at the test object, at the standard dosimeter and, where applicable, at the dose monitor, the leakage current (for dosimeters) or a zero-point display (for dose-rate measuring instruments) must be taken into account in the measurement result.

In the case of open ionization chambers, the air density during the measurement must be taken into account by the correction factor

$$k_{\rho} = (p_0 / p)(T/T_0)$$

This also applies to the monitoring chambers. *p* is the air pressure in hPa, T is the absolute temperature in K, p_0 = 1013.25 hPa and T_0 = 273.15 K. In the case of measurements in the water phantom, the temperature of the air volume in the chamber is defined by the temperature of the surrounding water and is to be determined as close as possible to the measurement point.

Notes

1) The dosimeter to be verified must be operated in accordance with the instructions for use (e.g. zero adjustment, consideration of the calibration factor and of the air density correction).
2) Measuring instruments are ready to perform measurements only after the stabilization time. The indicated measurement values must be read after the response time has lapsed (see instructions for use).

3) When selecting the measuring time, it must be taken into account that short measurement times may lead to time measurement errors and long measurement times may lead to temporal variations of the leakage current, which may distort the measurement value.
4) If the measured values change continuously in the same way when the measurement is repeated, the chamber must be pre-irradiated before further measurements are conducted to avoid this adjusting procedure (ionization induced charging). For the pre-irradiation, a dose of several Gy is to be generated in the chamber, unless otherwise specified in the instructions for use.
5) The temperature at the location of the chamber of the test object or of the standard dosimeter may differ markedly from the temperature at the location of the monitoring chamber, especially if the monitoring chamber is located near the X-ray tube and is influenced by its heating. The temperature of the dose monitor may change here, although there is no noticeable change in temperature at the more distant location of the test object or standard dosimeter chamber. It is therefore necessary to measure the temperature at the location of the test object or standard dosimeter chamber and at the location of the monitoring chamber separately and to consider the influence of these temperatures on the charge or current measurement values in the case of open chambers.
6) X-ray and gamma radiation fields are always inhomogeneous in a plane perpendicular to the radiation axis in the phantom. The free-in-air plateau of the dose rate distribution in a plane perpendicular to the axis of the radiation field disappears in the phantom. The approximately rectangular dose distribution free in air transforms into a bell shape. To avoid errors caused by this process, the dimensions of the chamber of the standard dosimeter used for the metrological verification should deviate only slightly from those of the chamber of the test object, if possible.
7) When the radiation passes through solid or liquid material, its properties change to a much greater extent due to attenuation and scattering than they do when it passes through air. The dose rate heavily decreases with the increasing depth in the phantom, depending on the radiation quality and field size.

6.1.9.2 Radiation qualities

6.1.9.2.1 Characterization of the radiation quality

The radiation quality of X-rays in clinical use is generally characterized by the following information:

tube voltage, anode material, total filtration, first aluminium or copper half-value-layer thickness for low-energy and medium-energy X-rays.

In the case of gamma radiation, details about the radionuclide are sufficient to characterize the radiation quality.

In the case of X-rays, the dependence of the correction factors on the radiation quality is described by their dependence on the first half-value-layer thickness s_1, and in the case of gamma radiation by the dependence on the photon energy *E*.
(For the determination of s_1 in the case of X-rays see ref. [5].)

6.1.9.2.2 Verification of the radiation qualities

For the metrological verifications, the radiation qualities in accordance with the national standard DIN 6809-4 [3] Table 2 (low-energy X-ray therapy) or Table 5 (medium-energy X-ray therapy) must be applied. For the verification of the radiation quality, the first half-value layer thickness s_1 must be measured [4]. If the deviation of a value of s_1 from the value specified in the standard is greater than 10 %, the X-ray equipment should be examined. Radiation quality control is to be performed on each X-ray unit for at least two radiation qualities at intervals of one year and for all radiation qualities after a repair which may influence the radiation quality, e.g. after a tube change.

6.1.9.2.3 Determination of radiation qualities for metrological verification

In accordance with the standards DIN 6800-2 [2] and DIN 6809-4 [3] and the international standard IEC 60731 [1], the reference radiation quality for the calibration of therapy dosimeters used with medium-energy X-ray radiation, gamma radiation and high-energy photon radiation is ^{60}Co gamma radiation. For this reason, metrological verifications of therapy dosimeters should always be performed at this radiation quality. In addition, at least at a second radiation quality in the field of medium-energy X-ray radiation between 200 kV and 300 kV, the tube voltage must be verified.

Furthermore, the polarity effect must always be checked at ^{60}Co (determination of the response of the dosimeter with positive and negative chamber voltage).

In the case of low-energy X-ray radiation, the reference radiation quality was defined as the quality with the abbreviated designation TW 30 (see DIN 6809-4 [3] and DIN IEC 60731 [1]).

6.1.9.3 Metrological verification of a dosimeter

6.1.9.3.1 Implementation of the metrological verification

6.1.9.3.1.1 Dosimeter with compact chambers

Dosimeters with farmer-type chambers which indicate the absorbed dose to water or the absorbed dose rate to water are tested under medium-energy X-rays at a depth of z = 2 cm and under gamma rays of ^{60}Co at a depth of z = 5 cm in the water phantom. The reference conditions specified in Table 2 must comply with the measurement conditions in the metrological verification. If the phantom contains layers of elements other than water, e.g. a PMMA entrance window, during the calibration in ^{60}Co, the thickness of the layers scaled with

the electron density relative to that of the water must be taken into account when calculating the positioning depth in the phantom. For more information, see DIN 6800-2 [2].

During the metrological verification in the water phantom, the absorbed dose to water or the absorbed dose rate to water are to be determined. For this purpose, the calibration factors for the standard dosimeter and the test object which apply to the measurement conditions during this test must be used. The chamber of the standard dosimeter and that of the test object must be irradiated under the same conditions in the water phantom of the measuring office. Both chambers should be inserted into their respective mounting sleeve, unless otherwise specified in the calibration certificates or in the instructions for use. The mounting sleeve used by the applicant should be used as the mounting sleeve for the test object. The phantom should be positioned in the radiation field in such a way that the central beam is perpendicular to the front wall of the phantom in the centre of the intended beam entry area.

Notes:

1) Often, the water phantom vessel used by the measuring office differs in material and dimensions from that in which the test object was calibrated. The difference in the material, in the dimensions and in the thickness of the front wall of the phantom vessel has only a negligible influence on the result of the metrological verification if the materials are made of organic plastics (such as Plexiglas).
2) If the ambient temperature deviates from the water temperature in the phantom, the water temperature adjusts only slowly to the ambient temperature. Due to the cooling by evaporation, however, there is no complete temperature stabilization. It is, however, always necessary to wait until the water temperature has sufficiently stabilized.
3) In the case of water phantoms, the phantom vessel may be subject to deformation over time, which can lead to measurement errors in the measuring depth. It is therefore necessary to check the set measuring depth on a regular basis.

6.1.9.3.1.2 Dosimeters with parallel-plate chambers

The PMMA phantom associated with the chamber is to be used for the metrological verification of dosimeters with parallel-plate chambers which are used to determine the absorbed dose to water or the absorbed dose rate to water at the surface of a water phantom at X-ray radiation up to 100 kV tube voltage. The chamber is to be positioned in the phantom according to the specifications of the calibration certificate or the instructions for use in such a way that it is flush with the front surface of the phantom and its reference point lies on the central beam. The dosimeter is calibrated to indicate the absorbed dose to water value at the surface of a water phantom. The phantom used in the metrological verification for the standard of the measuring office, must also be made of PMMA material.

Notes:

1) The following applies also in this case: If the ambient temperature deviates from the temperature of the phantom, the phantom temperature will only slowly adjust to the ambient temperature. If there is a difference in temperature between the phantom and its environment, the measurement must be postponed until the difference is less than 0.5 °C. This is particularly important because the parallel-plate chamber that is aligned flush with the surface in the phantom is, on the one hand, thermally connected with the ambient air

through its thin entrance window and, on the other hand, it is connected with the PMMA phantom through its plastic body.

2) Particular care must be taken to ensure that the reference field size of 3.0 cm diameter is maintained as accurately as possible under the measurement conditions, since the field size correction may not be negligible.

6.1.9.3.2 Electrical verification of the indicating device

For the purpose of verification, a current source is connected to the display device to be tested instead of the chamber unit. This current source must meet the requirements of a standard according to section 14, paragraph 3 of the Medical Devices Operator Ordinance (MPBetreibV).

The zero-point setting, or indication must be checked in each measurement range. For this purpose, the input is to be shielded, unless otherwise stated in the instructions for use. Before connecting the current source to the test object (indicating device of the dosimeter), it is necessary to ensure that no difference in potential exists between the ground wires of the two devices. Proper grounding and shielding must be ensured to discharge parasitic currents and eliminate the influence of external voltages. Caution is advised when the input amplifier is at chamber voltage potential. In this case, special connecting cables may have to be used. In addition, interconnection should only take place when the indicating device has been switched off temporarily.

After the devices have been interconnected, the zero-point indication is first controlled in all measurement ranges. Zero offsets that may occur in the sensitive measurement ranges must be taken into account during measurements with the current source. The internal resistance of the current source should be as large as possible in order to minimize the influence of the offset voltage of the test object.

The response of the indicating device is to be checked in each decade of the rated operating range.

6.1.9.4 Verification of a chamber unit without an associated indicating device

6.1.9.4.1 Requirements

A chamber unit may be subjected to a metrological verification without the associated indicating device if a current calibration certificate is available for the chamber unit, specifying at least the reference quality calibration factor in Gy/C and the reference conditions.

6.1.9.4.2 Implementation of the metrological verification

The chamber must be traceable to a calibrated electrometer (see clause 6.1.5.2.1).

The chamber unit must be operated with the chamber voltage and voltage polarity applied by the user or with those chamber voltages and voltage polarities specified in the instructions for use.

If an indicating device with an integrated power supply is connected, the indicating device must supply the chamber voltage specified for the chamber in the appropriate polarity. If this is not the case, the chamber voltage must be taken from a voltage source (see clause 6.1.5.2.1).

Note:

When interconnecting the chamber unit, the indicating unit and the chamber voltage source, ground loops must be avoided. Ground loops can lead to zero shifts and greater leakage currents. The indication of the interconnected measuring system (chamber unit, indicating unit, chamber voltage source) must be examined in the absence of X-rays or gamma radiation. The leakage current of the measuring system is to be measured after the pre-irradiation of the chamber.

Caution has to be taken when the touchable electrically conductive parts of the chamber unit are not at earth potential (if necessary, the applicant has to request appropriate plugs and circuit diagrams).

6.1.9.5 Verification of a radioactive stability check device

A radioactive stability check device is primarily used to verify the long-term stability of a therapy dosimeter. As an attachment to a medical device, it is also treated as a medical device.

When a radioactive stability check device is metrologically verified, the verification measurement value of the chamber unit in this stability check device is determined. This value must be referenced to 20 °C and 1013.25 hPa as well as to a reference date.

6.1.9.5.1 Implementation of the metrological verification

The chamber unit in the radioactive stability check device must either be connected to the indicating device supplied by the operator to determine the verification measurement value $M_{k_0}^{P}$ or be connected to a calibrated ammeter or charge meter (see clause 4.2.1.2) to determine the stability check current $I_{k_0}^{P}$. The measured value of the indicator M_k can be used to determine the verification measurement value according to the relation

$$M_{k_0}^{P} = M_k \exp\left(t \ln(2) / T_{1/2}\right).$$

Likewise, the stability check current can be determined from the measured current I_k (equal to the measured charge divided by the measurement time) according to the relation

$$I_{k_0}^{P} = I_k \exp\left(t \ln(2) / T_{1/2}\right).$$

Here:

$T_{1/2}$ is the half-life of the radionuclide in the stability check device.

t is the time difference between the date of measurement of M_k or I_k and the reference date to which the verification measurement value or the stability check current is to refer (taking into account the sign of t).

The stability check indications M_k and $M_{k_0}^{P}$ or the stability check currents I_k and $I_{k_0}^{P}$ must always be corrected to 20 °C and 1013.25 hPa and referred to the same measuring time.

Notes

1) Care must be taken that no objects fall into the opening of the stability check device. Since the distance between the radioactive emitter and the chamber in the stability check device

is usually very small, even minor changes of the position of the chamber in the stability check device can lead to errors.

2) Due to its large mass, a radioactive stability check device takes a longer time to reach the new temperature after a temperature change. Therefore, a stability check device must be kept at the temperature prevailing during the measurement for a longer period of time before the stability check reading is taken. The adjustment of the temperature of the stability check device to the ambient temperature is to be determined by measuring the temperature in the stability check device. The temperature of the stability check device should not deviate from the ambient temperature by more than 0.5 °C when measuring the stability check readings.

6.1.9.6 Verification of an electrical stability check device

An electrical stability check device is verified by a comparative measurement of the currents or charges emitted from the stability check device in all range settings. The deviations of the range ratios must not exceed the maximum permissible errors specified by the manufacturer or in the standard IEC 60731 [1].

6.1.9.7 Measurement uncertainties in metrological verification

A measurement uncertainty budget in accordance with EA-4/02 [6] has to be established. The measurement uncertainty must be stated in the calibration certificate or in the medical devices book.

6.1.10 Returning dosimeters

A dosimeter is to be returned without a test result if the initial inspection, and the functional test indicate that the metrological verification cannot be conducted properly or if calibration is no longer possible taking into account the maximum permissible errors specified in clause 6.1.8. Any existing markings left from the previous metrological verification must be removed or invalidated.

6.1.11 Records

6.1.11.1 Protocol of the verification

The protocol must contain all information about the test that is necessary for its unambiguous description and for a comparison of various verification results.

6.1.11.1.1 Information on the test object

The following information is required:

1) manufacturer, type designation and identification number for all components of the test object.

2) indication of the length of the measuring cable attached to the test object during calibration and its length during the measurement of the stability check indicator if this could influence the measurement value.

6.1.11.1.2 Information on other measuring instruments

Information on the standard dosimeter, the dose monitor and the electrical measuring devices (current source, electrometer, etc.) as listed in clause 6.1.11.1.1.

Information on the dose monitor is only required if it can be replaced by other dose monitors.

6.1.11.1.3 Information about the verification

The following information is required:

1) date of the verification,
2) name of the person responsible for the verification,
3) data on the measurement set-up (e.g. dimensions of the phantom, material and thickness of the phantom front wall in the radiation entrance area, material and dimensions of the chamber mounting sleeve, distance of the phantom surface from the focal point of the X-ray tube or the geometrical centre of the source capsule containing the radioactive material, field size at the phantom surface, measurement depth in the phantom, etc.),
4) radiation qualities used

   a) for X-rays: tube voltage, total filtration (inherent and adaptive filters as well as added filters), 1st half-value-layer thickness, tube current;

   b) for gamma radiation: radionuclide, characterization of the source,
5) climatic conditions in the measuring room: ambient temperature, air pressure, air humidity range.

6.1.11.1.4 Measurement results of the verification

Measurement results of the verification are:

1) measuring ranges of the test object, standard dosimeter and, if applicable, the dose monitor and the electrical testing equipment used in the test;
2) measured values on the test object and standard dosimeter as well as the measurand;
3) stability check indication of the radioactive stability check device;
4) measured values of the electrical test.

6.1.11.1.5 Calibration certificate

The results of the calibration must be recorded in a calibration certificate. In addition to the calibration factor N_{Dw} for the measurand and the reference conditions to which the calibration factor applies, the calibration certificate must also include information on the calibrated dosimeter, the time of calibration, the conditions under which the calibration was performed (measurement distance, field size and depth in the phantom, climatic conditions) and the radiation quality. If the device is calibrated in the phantom, additionally, the phantom material, the dimensions of the phantom and, if applicable, those of the chamber mounting sleeve must also be specified.

6.1.11.2 Marking of the verified therapy dosimeter

According to section 14, paragraph 7 of the Medical Devices Operator Ordinance (MPBetreibV), a marking must be attached to the therapy dosimeter after the metrological verification has been successfully completed. This marking must state, in a uniquely identifiable and traceable way, the year of the next metrological verification and the authority or person that has conducted the metrological verification.

6.1.12 Quality assurance

The quality assurance of the measuring office concerns especially the workflow, the accuracy as well as the realization and the documentation of the measurement results. This is done by internal controls and by regularly tracing the measuring instruments to national standards. Detailed written work instructions must be available for all steps of the workflow.

The content of the quality management system (QM system) must meet the requirements of ISO / IEC 17025 [6].

6.1.13 References

[1] IEC 60731: Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy (2014-10)

[2] DIN 6800-2: Procedures of dosimetry with probe type detectors for photon and electron radiation - Part 2: Ionization chamber dosimetry of high-energy photon and electron radiation (2008-03)

[3] DIN 6809-4: Clinical dosimetry - Part 4: X-ray therapy with X-ray tube voltages between 10 kV and 300 kV (2016-06)

[4] EA-4/02: (previously EAL-R2, EAL-R2-S1 and EAL-R2-S2): Expression of the Uncertainty of Measurement in Calibration (1999); German translation: DKD-3 (of EAL-R2) and DKD-3-E1 (of EAL-R2-S1)

[5] H. Reich: Kalibrierung von Dosimetern - Messung von Halbwertschichtdicken bei Röntgenstrahlen, in "Dosimetrie ionisierender Strahlung" (ed. H. Reich), B.G. Teubner Stuttgart 1990, p. 238

[6] ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories (2005-08)

6.2 Therapy dosimeters for photon radiation in the energy range from 1.33 MeV and upwards and with electron radiation from accelerators

6.2.1 Scope of application

These requirements are directed at measurement facilities appointed by the competent authority in accordance with No. 3 of Annex 2 of the Ordinance on the Production, Operation and Use of Medical Products (Medical Devices Operator Ordinance; MPBetreibV) to conduct comparison measurements. According to No. 1.5.2 of Annex 2 of the MPBetreibV, comparison measurements are mandatory as metrological verification for therapy dosimeters that are used in therapy for the external treatment of patients with photon radiation in the energy range from 1.33 MeV and above and with electron radiation from accelerators.

For therapy dosimeters that are used exclusively for ^{60}Co gamma radiation, No. 1.5.3 of Annex 2 MPBetreibV provides the option to select a metrological verification according to No. 1.5.1 or to participate in comparison measurements according to No. 1.5.2 of Annex 2 MPBetreibV.

According to section 14, paragraph 1 in conjunction with Annex 2, No. 1.5.2 of the MPBetreibV, operators of therapy dosimeters are under the obligation to participate in comparison measurements. The obligations to cooperate are to be contractually agreed between the measuring office and the operators.

The quality assurance for the external treatment of patients with photon radiation in the energy range from 1.33 MeV and above and with electron radiation from accelerators includes a basic dosimetry based on the application of the dose measurement procedure described in DIN 6800-2 [1].

Through the comparison measurements as a special form of metrological control according to section 14 MPBetreibV, both the correct function of the measuring instrument (the therapy dosimeter) and the correct application of the procedure according to DIN 6800-2 [1] are subject to verification.

It is recommended to use these requirements as a basis for comparison measurements when appointing a measuring office for comparison measurements to prove the competence in accordance with section 14 (5) of the MPBetreibV.

These requirements are intended to contribute:

- to carrying out measurements and evaluations in accordance with the state of the art in science and technology;
- to ensuring the comparability of the results and their uniform recording and transmission;
- to ensuring the quality of the comparison measurements.

The requirements cover:

- the measurement procedure;
- the performance of the measurements and their evaluations;
- the recording and transmission of the results;
- the implementation of quality assurance;
- the equipment of the measuring office with technical, as well as those relating to room capacities and personnel resources.

They also regulate the procedure in the event of unsuccessful participation in the comparison measurements.

6.2.2 Criteria for appointing the measuring office

According to No. 3 of Annex 2 of the MPBetreibV, comparison measurements (according to clause 1.5.2 of this Annex) can only be carried out by a measuring office appointed by the competent authority. Only an office that fulfils the mandatory requirements which have to be complied with according to section 14, paragraph 5 MPBetreibV and – in addition – also fulfils the recommended requirements in accordance with section 5 of the MPBetreibV, should be appointed as a measuring office. Both a private company and an institution under public law can be appointed to establish and maintain a measuring office.

The measuring office must prove the existence of a liability insurance to cover the risks arising from the tasks assigned to it.

The appointment of a measuring office may be revoked in whole or in part or suspended temporarily if the measuring office does not comply with the content-related restrictions of the appointment or if it commits grossly negligent or intentional violations of its obligations; this applies in particular if it fails to perform measurements and their evaluation in an objective and impartial manner, or if the statutory requirements for the appointment are no longer fulfilled. In this case, the competent authority should take measures to ensure the continuity of the prescribed comparison measurements. This can be done, for instance, by appointing another measuring office.

6.2.3 Tasks of the measuring office

The measuring office must be able to perform and organize the prescribed comparison measurements in accordance with the requirements in Nos. 6.2.3.1 to 6.2.3.5.

6.2.3.1 Availability of the measuring office

The measuring office must be able to perform the prescribed comparison measurements in accordance with clause 6.2.3.2 continuously. It is at the discretion of the measuring office to pool the comparison measurements that are to be conducted at regular intervals by a large number of participants for reasons of rationalization at a previously fixed and announced date. However, it must be available at any time, for first-time participants and for operators who have to repeat a comparative measurement due to inconsistent results (see clause 6.2.3.3), i.e. within a reasonable period of no more than four weeks after the submission of the application.

6.2.3.2 Carrying out the comparison measurements

The standard and reference conditions according to DIN 6800-2 [1] shall apply.

When multiple ionization chambers and multiple indicating devices are used, at least each chamber and each indicating device must be tested with at least one radiation quality. For this purpose, the dose at which the detectors were irradiated by the operator is determined in the measured quantity of absorbed dose to water. Necessary corrections are derived from the information in the measurement protocols. The measuring office must – by contractual agreement – be able to request further information at any time in compliance with set deadlines if the information supplied is not sufficient. This may be necessary in particular in cases where measures for clarifying and eliminating the causes of faults have to be proposed

in accordance with clause 6.2.3.3. Similarly, the protocols and measurement results must be communicated to PTB without delay so that it can fulfil its advisory obligation.

The minimum range of radiation qualities prescribed for the comparison measurements depends on the respective field of application of the radiation in the therapy performed by the operator. The following regulation applies to the selection of the radiation qualities: For both high-energy photon radiation and electron radiation, the irradiations should be carried out at the lowest and at the highest energy used by the operator in the therapy.

Note: When using compact chambers for dosimetry with electron radiation, the radiation quality parameter R_{50} must have a value of at least 4 cm (E~10 MeV).

6.2.3.2.1 Comparison measurement with TLD probes

The measuring office distributes – usually by mail – dosimeter probes with detailed instructions for use for the participating operators (radiation therapy centres, radiation clinics, medical practices). These probes are irradiated by the operator with radiation qualities resulting from the respective field of application of the radiation in therapy. A certain number of the distributed dosimeter probes remain unirradiated at the operator's in order to ensure that no uncontrolled irradiation of the probes has occurred during storage at the operator's or during shipping.

The measuring office must contractually agree with the operator that the irradiated and non-irradiated dosimeter probes with the fully completed measurement protocols are returned to the evaluating measuring office within two weeks of issue. The irradiated dosimeter probes are evaluated at the measuring office.

The operator must be notified of the results of the comparative measurement in writing or by means of a data carrier immediately after the evaluation, but no later than 6 weeks after receipt of the irradiated probes at the measuring office. The measuring office will send a copy of this notification to PTB.

6.2.3.2.2 Comparison measurement with a reference dosimeter

An appointed employee of the measuring office conducts the necessary measurements of the absorbed dose to water for the respective radiation qualities directly at the operator's premises (radiation therapy centres, radiation clinics, medical practices) by means of a dosimeter of the reference class that belongs to the measuring office pursuant to IEC 60731[2]. For this purpose, all necessary auxiliary measuring instruments (thermometers, barometers, distance measuring devices, etc.) must also be provided by the measuring office in order to ensure a determination of the absorbed dose to water that is independent of the operator.

No later than 24 hours before the comparison measurement is performed, the operator must inform PTB of the calibration factors of the monitoring chamber that are to be used for the irradiation of the reference dosimeter of the measuring office for the radiation qualities at which a comparison measurement is to be performed. This is usually done by e-mail. The following address is to be used: mtk@ptb.de.

The measuring office is obliged to inform the operator in an appropriate form that the calibration factor of the monitoring chamber must be communicated to PTB at the latest on the day before the comparison measurement. A notification of the calibration factor after this point of time will result in the non-recognition of the comparison measurement.

The measuring office carries out the evaluation of the irradiation and prepares a protocol of the process in which the calibration factor(s) of the operator's monitoring chamber determined by the measuring office are listed. This protocol is handed over to the operator and transmitted to PTB without delay.
If corrective measures are necessary, they must be recorded in a second protocol, which is also handed over to the operator and PTB.

6.2.3.3 Evaluation of the measurement data

The measurement data should be separately grouped by the respective irradiation types as follows:

- ^{60}Co gamma radiation,
- high-energy photon radiation from accelerators,
- electron radiation from accelerators.

The dose values determined by the measuring office are compared with the data provided by the operator and evaluated according to the following scheme:

Category A: All dose values specified by the operator correspond to the data determined by the measuring office within the specified maximum permissible errors. The comparison measurement is deemed successfully completed.

Category B: At least one dose value specified by the operator is outside the maximum permissible error limit defined for Category A, but still within an interval specified for this category that marks a transition range. In this case, the operator must implement the measures proposed by the measuring office to clarify and eliminate the causes and comply with the requests of the measuring office. If necessary, the measuring office will request repeat comparison measurements.

Category C: Dose values specified by the operator are outside the maximum permissible error indications delimiting the transition range in Category B. In this case, the therapy dosimeters must no longer be used according to section 4, paragraph 8 of the Medical Devices Operator Ordinance (MPBetreibV) until the error has been verifiably eliminated. Evidence must be provided in writing to the appointed measuring office. If necessary, repeat comparison measurements must be conducted.

The following limits for the relative measurement error Δ, shall apply to the individual categories – separated by radiation type:

	Category A	Category B	Category C
^{60}Co gamma radiation	$\Delta \leq 2$ %	2 % < $\Delta \leq 3$ %	$\Delta > 3$ %
High-energy photon radiation	$\Delta \leq 3$ %	3 % < $\Delta \leq 4$ %	$\Delta > 4$ %
Electron radiation	$\Delta \leq 3$ %	3 % < $\Delta \leq 5$ %	$\Delta > 5$ %

6.2.3.4 Communication of the results

If further information is required by the operator for the evaluation of the measurement results according to Categories B and C or if a functional test and, if necessary, the recalibration of the used therapy dosimeter is required for the evaluation of the measurement results according to Category C, the operator must be notified without delay in writing. The same applies if it is necessary to repeat comparison measurements. The date for repeat comparison measurements must also be agreed upon in writing. A protocol must be prepared for the entire causal research.

If the operator does not comply with the requests of the measuring office, the body must inform the competent authority of the operator in writing without delay.

If no improvement can be achieved in a Category C evaluation even after a functional check has been conducted and, if necessary, after a recalibration of the therapy dosimeter, as well as after thorough causal research and after repeated participation in comparison measurements, the competent authority of the operator is to be informed in writing. Furthermore, the data of all participants in the comparison measurements and the respective category evaluation achieved must be transmitted to the competent authority of the measuring office by the end of a calendar year at the latest.

6.2.3.5 Data storage

The measuring office must keep the data obtained from the comparison measurements for a period of at least 5 years. While doing so, the requirements of the data protection law must be observed. If a measuring office discontinues operation, all records of the results that have so far been obtained must be sent to PTB.

6.2.4 Requirements placed on the measurement procedure

The measuring office is to make a suitable measurement procedure available. Written work instructions must be available for the individual steps of the measurement procedure used. In particular, the following information is required:

- details on the instrumentation;
- details on the preparations for the measurements;
- details on the realization of the measurements;
- details on the analytical methods;
- details on the uncertainty and detection limit;
- details on quality assurance.

6.2.4.1 Radiation qualities

The measurement method shall be applicable for $^{Co}60$ gamma radiation, for high-energy photon radiation up to 25 MV generation voltage and for electron radiation with a radiation quality parameter of $1.6 < R_{50}/\text{cm} < 10$ ($4 < E/\text{MeV} < 25$).

6.2.4.2 Dose range

The measurement procedure must cover a dose range that comes close to the operator's irradiation conditions and that allows the dose to be determined with the required accuracy.

The dose range is to be determined by the measuring office and notified to the operators. It must lie within the range of 1 Gy to 40 Gy.

6.2.4.3 Detection limit

For the measurement procedure, a lower detection limit must be determined below which it is no longer possible to determine whether a test object was irradiated or not. The detection limit (in the measurand absorbed dose to water in gray) shall not exceed 1 % of the dose that the operator intends to use for irradiation (in the measurand absorbed dose to water).

6.2.4.4 Capacity

The technical implementation of the measuring method must be carried out in such a way that the following conditions, in particular, can be met for the time required to carry out the comparison measurements:

- The comparison measurements can be evaluated in routine operation.
- The costs incurred by the operator are kept within reasonable limits.

The measuring office must be designed for a throughput of reference measurements in accordance with the requirements pursuant to clause 6.2.3.1.

6.2.4.5 Accuracy

The proportion of relative standard uncertainty in the determination of the dose caused by the measurement procedure and the calibration of the measuring and evaluation equipment must not exceed 1.0 %. This uncertainty does not include the portion that must be attributed to the primary standard.

The competent authority checks the measuring office at regular intervals (e.g. every 2 years) by involving PTB.

For comparison measurement with the TLD procedure, a sufficient sample size of probes irradiated with a certain dose of ^{60}Co gamma radiation or high-energy photon or electron radiation at PTB, which is unknown to the measuring office, must be evaluated by the measuring office. PTB provides the necessary information on the radiation quality used for this purpose. The actually applied dose should not deviate from the nominal dose specified by the competent authority by more than 5 % in the upward or downward range.

The difference between the mean dose value of all probes determined by the measuring point and the applied dose must not exceed 0.3 % when using the radiation quality of ^{60}Co and 0.5 % in fields of high-energy photon and electron radiation; the measurement uncertainty of the PTB dose value is additionally to be taken into account. If this requirement is not met, the measuring device of the measuring office must be recalibrated over the entire dose range.

In comparison measurements with a reference dosimeter, the measuring office is obliged to have the reference dosimeter calibrated traceably to PTB before commencing operation and it has to repeat these calibrations thereafter at intervals of no more than two years. The uncertainty intrinsic to the calibration must not conflict with the requirements placed on accuracy as set out in this guide.

The measuring office is obliged to perform a metrological verification in PTB's radiation fields. With this metrological verification, the measuring office is to provide evidence that the procedures it has used to determine the dose with measurement errors of not more than 0.3 % for ^{60}Co radiation and of not more than 0.5 % in fields of high-energy photon and electron

radiation result; the measurement uncertainty of PTB's dose value must be considered separately.

6.2.5 Quality assurance

The quality assurance of the measuring office relates particularly to the work process, the accuracy as well as the realization and the documentation of the measurement results. It is carried out by internal controls and by regularly tracing the measuring instruments to national standards. Detailed written work instructions must be available for all steps of the workflow.

The content of the quality management system (QM system) must meet the requirements of DIN EN ISO / IEC 17025 [3].

6.2.5.1 Internal controls

The measuring office must regularly ensure the reliability of the results obtained in the measuring procedure by means of internal laboratory measures.

This is done by:

- functional inspections of the measurement devices on a daily basis,
- verifying inspections of the entire measurement procedure on a quarterly basis that include controls of all steps for the acquisition and processing of the measurement data, in particular for their correctness and precision.

If these inspections do not meet the requirements specified in the QM system of the measuring office, then the causes must be identified, the errors remedied, and the inspection repeated.

If the instrumentation or the measurement procedure are changed, it must be ensured without delay that the requirements specified in clause 6.2.4 are met. The competent authority must be informed of these changes.

These internal controls must be documented. The documentation must contain at least the following information:

- the date of the internal controls;
- the name of the inspector and, where appropriate, the names of the employees inspected;
- (operators);
- a list of the inspected devices;
- the result of the verification;
- measures for rectifying errors.

6.2.5.2 Traceability of the standards of the measuring office

The correct dose determination by the measuring office by means of the entire measuring instrumentation must be ensured before the measuring office is appointed and thereafter at regular intervals by comparison with the PTB standards for the measurand absorbed dose to water at ^{60}Co gamma radiation and high-energy photon and electron radiation.

The calibrations of the measuring and evaluation devices required for the respective measuring method must be traceable to national standards. Recalibration cycles correspond to the time intervals specified for the respective instruments or customary in practice.

6.2.6 Equipment of the measuring office

The equipment of the measuring office with its technical and personnel resources as well as those relating to room capacities must satisfy the type and scope of the task assigned by the authority.

6.2.6.1 Technical equipment of the measuring office

For the necessary technical equipment, please refer to Annex A 6.2.1. This equipment must be described to the competent authority. It should be taken into account that changes due to development may occur. It must be ensured that operation can be resumed after one week in the event of equipment failure.

6.2.6.2 Room capacities of the measuring office

The room capacities depend on the measurement procedure used to carry out the task assigned by the authorities in compliance with the requirements of clause 6.2.4. The available room capacities must especially ensure the reliability of shipping and of the execution of the necessary paperwork. Specific requirements are contained in Annex A 6.2.2.

6.2.6.3 Personnel resources of the measuring office

The following tasks, in particular, must be performed at the measuring office:

- management and organization;
- preparation of probes or reference dosimeters;
- performing the measurements;
- evaluating the measurement results;
- implementation of quality assurance;
- scientific consultation and development;
- administration, reporting and documentation.

The measuring office must have the necessary personnel at its disposal to guarantee the scope of services and their continuous availability:

- head of department with a degree in sciences or engineering (or an equivalent qualification) and at least two years' practical experience in the field of dosimetry of ionizing radiation;
- at least one qualified technical specialist to carry out the measurements.

A substitute must be appointed to stand in for each person while being able to take charge of the tasks if necessary.

6.2.7 Obligation of the participating operators to cooperate

Operators of therapy dosimeters in the sense of clause 1.5.2 of Annex 2 of the Medical Devices Operator Ordinance (MPBetreibV) are obliged to participate in metrological verifications in the form of comparison measurements (see clause 6.2.1).

6.2.7.1 Interaction between measuring office and operator

For the information relevant to the interaction between the measuring office and the operator, please refer specifically to the requirements described under clauses 6.2.3.3 (Evaluation of measurement data), 6.2.3.4 (Notification of the results), 6.2.4.2 (Dose range), 6.2.4.3 (Detection limit) and clause 6.2.4.4 (Capacity).

6.2.7.2 Further requirements placed on the operators

The interaction between the operator and the measuring office is subject to the applicable contractual agreements. These should essentially contain the following points:

- modalities of the detector irradiations,
- documentation of the irradiations carried out (irradiation protocols for the measuring office) as part of the comparison measurements,
- compliance with the requirements, especially in the case of unsuccessful participation in the comparison measurements.

The operators should support the measuring office in their own interest so that the participation can be successfully completed and any discrepancies occurring can be quickly resolved.

6.2.8 References

[1] DIN 6800-2: Procedures of dosimetry with probe type detectors for photon and electron radiation – Part 2: Ionization chamber dosimetry of high-energy photon and electron radiation (2008-3)

[2] IEC 60731: Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy (1997-07)

[3] ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories (2005-08)

Annex

A 6.2.1 Instrumentation of the measuring office

The instrumentation must be specified in detail by the measuring office. At least the following must be available: 1 therapy dosimeter of the reference class according to IEC 60731 [2];
1 copy of the standard DIN 6800-2 [1];
a medical electron accelerator must be available.

A 6.2.2 Radioactive source

A suitable ^{60}Co gamma irradiation system (or, alternatively, a ^{137}Cs gamma irradiator must be available to the measuring office for control irradiations of dosimeter probes or for verifying the stability of the response of the reference dosimeter(s) used.

The activity of the radiation source and the dose rate at the measuring point that can be generated with this source at the measurement location must be high enough to allow all necessary control irradiations (see clause 6.2.3.1) to be performed within the required period. When calibrating or verifying the irradiation of reference dosimeters, the dose rate that can be generated at the measuring point must be within the nominal range of use of the dosimeter.

The stability of the response of the reference dosimeter(s) or probes used is to be checked immediately before and after each series of comparison measurements. The results of these control measurements must be documented.

Prior to the appointment, the measuring office must notify the competent authority of these results in a comprehensible form.

A 6.2.3 Room capacities of the measuring office

A 6.2.3.1 Irradiation room

The room capacities shall include the availability of an irradiation room (or at least access to such a room) in which the necessary irradiations can be carried out by the detectors. The suitability of the irradiation room must be proven to the competent authority prior to the assignment.

A 6.2.3.2 Measuring room

The suitability of the existing measuring room must be established to the competent authority prior to the assignment.

A 6.2.3.3 Cabinets for storing files

The files must be stored in designated cabinets so that they are available at all times without time-consuming searching. Access must be limited to authorized persons only.

7 Diagnostic dosimeters for radiodiagnostics for metrological and testing procedures

7.1 Scope of application

According to clause 1.6 of Annex 2 (to section 14, paragraph 1) of the Medical Devices Operator Ordinance (MPBetreibV), the scope of application refers to diagnostic dosimeters for radiodiagnostics for metrological and testing procedures, unless they are subject to the Measures and Verification Act according to section 34, paragraph 3 of the X-ray Ordinance (RöV).

Consequently, the scope of application refers to diagnostic dosimeters which are not used for measurements according to sections 3, 4 and 16, paragraph 2 of the X-ray Ordinance (RöV). Sections 3 and 4 regulate the "Operation of X-ray equipment requiring approval (section 3) and of that requiring notification (section 4)". Section 16 regulates the "Quality assurance of X-ray equipment for the examination of humans" and paragraph 2 regulates the compliance test. Therefore, diagnostic dosimeters for radiodiagnostics for metrological and testing procedures require a metrological verification when they are used for all other purposes. In this guide, this requirement is interpreted in such a way that only metrological and testing procedures for quality assurance in X-ray equipment for the examination of humans are covered by this definition. Applications of this type are, for example, constancy tests according to section 16, paragraph 3 of the X-ray Ordinance (RöV) and the measurement of the dose area product, a measurand that is also used as a diagnostic reference value in accordance with section 16, paragraph 1 of the RöV.

Diagnostic dosimeters within the sense of this guide are measuring instruments for the measurement of dose measurands according to clause 7.2 in the useful radiation beam of diagnostic X-ray equipment for the examination of humans.

7.2 Measurands

Measurands in the field of application of diagnostic dosimeters are the air kerma and the air kerma rate, the dose length product, the dose area product and the dose area product rate. For definitions and units of these measurands, please refer to the national standard DIN 6814-3 [1]. The national standard DIN 6809-3 [2] defines the so-called application-related measurands in X-ray diagnostics that were derived from these values.

7.3 Requirements placed on measurement and test equipment

The requirements for measurement and test equipment to perform metrological verifications on diagnostic dosimeters are the same as those placed on accredited testing and calibration laboratories pursuant to ISO/IEC 17025 [3]. A detailed description of the necessary technical equipment, the required measuring equipment and the recommended set-ups are described in Chapters 5 and 6 of IAEA Report TRS 457 [4].

7.4 Content and scope of the verification

Since the range of application refers to a large number of different measurement tasks according to the measurands described in clause 7.2, this guide can only offer general information. In principle, the metrological verification consists of the initial inspection of the device and the metrological test.

7.4.1 Initial inspection

The completeness of the diagnostic dosimeter must be examined with regard to its intended use. It must also be checked whether sufficient evidence for the compliance of the diagnostic dosimeter to be tested with internationally harmonized and national standards can be delivered. Important technical standards for the field of application of diagnostic dosimeters are DIN EN 61674 [5] (for devices for measuring the air kerma and air kerma rate as well as for measuring the dose length product) and DIN EN 60580 [6] (for devices for measuring the dose area product).

7.4.2 Metrological verification

During the metrological verification, the accuracy of the indication within the maximum permissible errors specified in clause 7.4.3 must be verified under reference conditions. The measuring procedures correspond to those of the calibration of the device. The tests and the determination of the uncertainty for the respective measurand must be performed according to the range of use as described in Chapter 7 of IAEA Report TRS 457 [4].

7.4.3 Maximum permissible errors

The maximum permissible errors specified in Tables a) to c) below apply to measurements under reference conditions.

a) Maximum permissible errors for measurements behind or in the phantom

Measurand	**Range**	**Maximum permissible error G**
Air kerma K [1)]	$K \geq 1.0$ µGy	G = 5 %
Air kerma rate $\dot{K}$ [1)]	$\dot{K} < 1.0$ µGy/s $\dot{K} \geq 1.0$ µGy/s	G = (10 - 5 $\dot{K}$) %[3)] G = 5 %
Dose length product P_L [2)]	$P_L \geq 5 \cdot 10^{-6}$ Gy · m	G = 5 %

[1)] Measurements behind the phantom

[2)] Measurements in the phantom

[3)] $\dot{K}$ in µGy/s

b) Maximum permissible errors for measurements without a phantom and in mammography

Measurand	**Range**	**Maximum permissible error G**
Air kerma K	$K < 100$ µGy $K > 100$ µGy	G = (10 - 0.05 K) %[1)] G = 5 %
Air kerma rate $\dot{K}$	$\dot{K} < 100$ µGy/s $\dot{K} \geq 100$ µGy/s	G = (10 - 0.05 $\dot{K}$) %[2)] G = 5 %

Dose length product P_L	$P_L \geq 5\ 10^{-6}$ Gy·m	G = 5 %

[1)] K in μGy

[2)] $\dot{K}$ in μGy/s

c) Maximum permissible errors for measurements of the dose area product

Measurand	**Range**	**Maximum permissible error G**
Dose area product P_F	$P_F \geq 10.0$ μGy · m^2	G = 5 %
Dose area product rate $\dot{P}_F$	$\dot{P}_F \geq 1.0$ μGy · m^2/s	G = 5 %

7.5 References

[1] DIN 6814-3: Terms in the field of radiological technique - Part 3: Dosimetry (2016-08)

[2] DIN 6809-3: Clinical dosimetry - Part 3: Diagnostic radiology (2012-09)

[3] ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories (2005-08)

[4] IAEA-Reports TRS 457: Dosimetry in Diagnostic Radiology: An International Code of Practice (2007-09)

[5] DIN EN 61674: Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging (2015-11)

[6] DIN EN 60580: Medical electrical equipment - Dose area product meters (2001-12)

Annex 1: Particular specifications for the reverification intervals of metrological standards

The metrological standards used for metrological verifications (MV) must be traced to a national standard on an annual basis, irrespective of the method of tracing. Exceptions to this rule are listed in Table 1. The reverification extends to all measurement and test equipment, for example also to balances, test spheres, etc.

Table 1: Metrological standards with reverification intervals of more than 1 year. The column "Reverification can be carried out by ..." relates to the German situation.

Standard for MV of	Type of standard	Recalibration intervals (years)	Recalibration can be carried out by		
			PTB	EB*	D-K**
Audiometers	Sound calibrators,	3	x	x	x
	ear simulators and acoustic couplers including pressure microphones;	3	x		x
	Mechanical couplers;	3	x		
	Frequency meters;	3	x	x	x
	Harmonic distortion meters;	3		x	x
	Measuring equipment for pressing forces;	6	x	x	
	Sound level meters with free-field microphones;	3	x	x	x
	Third octave filters.	3	x	x	
Medical thermometers	Mercury-in-glass thermometers	3		x	x
Medical thermometers	Resistance decades	2		x	x
Non-invasive sphygmomanometers	Liquid column manometers;	5		x	x
	Piston manometers	5	x	x	x
Ocular tonometers	Test equipment for indentation, applanation and non-contact tonometers	3	x***	x	

Dosimeters	Dosimeters	3	x	x	x
Foot crank ergometers	Test equipment for ergometers	2	x		x

*) EB: *Eichbehörde* [verification authority] (since not every verification authority is able to perform all calibrations, the details can be obtained from the local verification authority at www.eichamt.de).

**) D-K: Calibration laboratories accredited by the German accreditation body DAkkS (a list of calibration capabilities is available on the internet at: http://www.dakks.de/content/akkreditierte-stellen-dakks)

***) Recalibration is performed by the Czech Metrology Institute (CMI) in Most,
Address: Vladislava Vančury 1428/7, Most 434 01, Czech Republic, phone: +420 476 104 330,
fax: +420 476 105 460, e-mail: oimost@cmi.cz