

MEMORANDUM FOR THE TYPE TESTING OF RADIATION PROTECTION DOSEMETERS

As of: August 2021

0 PRELIMINARY REMARK AND SCOPE

This Memorandum provides information about the type testing of radiation protection dosimeters. General information concerning type tests is given in the “General Terms and Conditions of Certification (Allgemeine Zertifizierungsbedingungen (AZB)).

https://www.ptb.de/cms/fileadmin/internet/dienstleistungen/zertifizierungsstelle/General_Terms_and_Conditions_of_Certification_Mar_2020.pdf.

Dosimeters used for radiation protection purposes must have been type tested by PTB (§ 14 section 4 Measurement and Verification Act) if they are to be used for official measurements (§ 1 section 1 No. 13 Measures and Verification Ordinance (MessEV)).

This is valid for dosimeters, if,

1. their rated range of photon energy lies completely or partly in the range of 5 keV to 7 MeV, and
2. their measuring range lies completely or partly within the ranges that are mentioned in the last line of table 1 of this memorandum.

1 RESPONSIBILITIES AND REGULATIONS IN FORCE

Table 1 provides detailed information about the regulations in force and the responsibilities at PTB.

Table 2 gives a survey of the regulations in force.

Application forms and further information of department 6.3

For the application forms and further information select “more information” – “Radiation protection instruments”.

<https://www.ptb.de/cms/en/ptb/fachabteilungen/abt6/fb-63/information/conformity-assessment-according-to-module-b-type-examination-of-area-and-individual-dosimeters-for-photon-radiation-in-compliance-with-the-measures-and-verification-act.html>

Application forms and further information of the Conformity Assessment Body

For the application forms and further information select “Metrology Services” – “Conformity Assessment Body” – “Sector 4: Measuring Instruments – National and EEC Approvals”.

<http://www.ptb.de/cms/en/metrological-services/kbs/kbs4.html>

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Bundesallee 100

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Phone: ++49-(0)531-592-0

Web: <https://www.ptb.de/cms/de.html>.

General information about the putting into circulation of measuring instruments according to the Measurement and Verification Act is given in the “Memorandum for manufacturers to the putting into circulation measuring instruments in compliance with the Measurement and Verification Act” (only in German).

https://www.ptb.de/cms/fileadmin/internet/dienstleistungen/zertifizierungsstelle/Instruction_sheet_for_manufacturers_placing_measuring_instruments_on_the_market_in_accordance_with_German_MessEG_160307.pdf

Table 1: Detailed Information

	Personal dosimeters	Stationary radiation protection measuring instruments and Area dosimeters	Diagnostic dosimeters
PTB Department	6.3		6.2
Contacts	<p>Dr. Zutz ++49-(0)531-592-6310 Dr. Ketelhut ++49-(0)531-592-6341 Mrs. Olzem ++49-(0)531-592-6311</p>		<p>Dr. Büermann ++49-(0)531-592-6250 Dr. Pajtinger ++49-(0)531-592-6217 Mrs. Buchmann ++49-(0)531-592-6211</p>
Quantities	<p>Personal dose equivalent at 0.07 mm depth $H_p(0.07)$</p> <p>Personal dose equivalent at 3 mm depth $H_p(3)$</p> <p>Personal dose equivalent at 10 mm depth $H_p(10)$</p>	<p>Directional dose equivalent (rate) at 0.07 mm depth $H'(0.07), \dot{H}'(0.07)$</p> <p>Directional dose equivalent (rate) at 3 mm depth $H'(3), \dot{H}'(3)$</p> <p>Ambient dose equivalent (rate) $H^*(10), \dot{H}^*(10)$</p>	<p>Air kerma (rate) K_a, \dot{K}_a</p> <p>Air kerma-length product $(K_a \cdot L)$</p>
Rule Determination Committee	Ermittelte Regeln und Erkenntnisse des Regelermittlungsausschusses nach § 46 des Mess- und Eichgesetzes		
	13.1	13.2	13.3
PTB Requirements / Standard	<p>PTB-A 23.2 Personal dosimeters for measuring the personal dose equivalent at 10 mm depth, $H_p(10)$ and the personal dose equivalent at 0.07 mm depth, $H_p(0.07)$</p> <p>and Complement of PTB-A 23.2 Personendosimeter zur Messung der Tiefen-, Augenlinsen und Oberflächen-Personendosis</p>	<p>PTB-A 23.3 Area dosimeters for measurement of the ambient and directional dose equivalent and of the ambient and directional dose equivalent rate</p> <p>and Complement of PTB-A 23.3 Ortsdosimeter zur Messung der Umgebungs- und Richtungs-Äquivalentdosis und der Umgebungs- und Richtungs-Äquivalentdosisleistung</p>	<p>DIN EN 61674 Diagnostic dosimeters</p>
Range of validity of the MessEV	$10 \mu\text{Sv} \leq H \leq 10 \text{ Sv}$	$100 \text{ nSv} \leq H \leq 10 \text{ Sv}$ $100 \text{ nSv/h} \leq \dot{H} \leq 10 \text{ Sv/h}$	$1 \mu\text{Gy} \leq K_a \leq 0.3 \text{ Gy}$ $100 \text{ nGy/s} \leq \dot{K}_a \leq 10 \text{ mGy/s}$ $(K_a \cdot L) \geq 5 \mu\text{Gy} \cdot \text{m}$

Table 1a: Classification of personal dosimeters

Type of dosimeter	Extremity dosimeter		Whole body dosimeter
Quantity	Personal dose equivalent at 0.07 mm depth $H_p(0.07)$	Personal dose equivalent at 3 mm depth $H_p(3)$	Personal dose equivalent at 10 mm depth $H_p(10)$
Representative wearing position	Extremity or eye proximity	Eye proximity	Trunk
Measuring purpose	Measurement of the local skin dose or the organ dose of the lens of the eye, hands, lower arms, feet or ankle	Measurement of the organ dose of the lens of the eye	Estimation of the effective dose
Calibration phantom	ISO rod phantom ($\varnothing = 19$ mm), made of PMMA	Water-filled cylinder phantom ($\varnothing = 200$ mm, high 200 mm) made of PMMA	ISO water slab phantom (30 cm x30 cm x15 cm)

Table 2: Regulations in force for type testing of radiation protection dosimeters and the source of supply

Regulations	To be obtained from:
Measurement and Verification Act	Gesetz über das Inverkehrbringen und die Bereitstellung von Messgeräten auf dem Markt, ihre Verwendung und Eichung sowie über Fertigpackungen https://www.gesetze-im-internet.de/messeg/index.html
Measures and Verification Ordinance	Verordnung über das Inverkehrbringen und die Bereitstellung von Messgeräten auf dem Markt sowie über ihre Verwendung und Eichung https://www.gesetze-im-internet.de/messev/index.html
Rule Determination Committee	Ermittelte Regeln und Erkenntnisse des Regelermittlungsausschusses nach § 46 des Mess- und Eichgesetzes https://www.ptb.de/cms/en/metrological-services/rea/rules-decisions-documents.html
PTB Requirements	Personal dosimeters and Complement: https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_6/6.3/bap/ptb23_2e.pdf https://oar.ptb.de/files/download/5c0686124c93902d0c000832 Area dosimeters and Complement: https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_6/6.3/bap/ptb23_3e.pdf https://oar.ptb.de/files/download/5c0686e04c93902d0c00086c
WELMEC Softwareleitfaden	https://www.welmec.org/guides-and-publications/guides/
Merkblatt der AG 8.51	Requirements for the documentation for software testing, according to WELMEC Guide 7.2 https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_8/8.5_metrologische_informtionstechnik/8.51/PTB-8.51-MB01-AnfDoku-EN-V09.pdf More leaflets: https://www.ptb.de/cms/en/ptb/fachabteilungen/abt8/fb-85/ag-851.html
DIN EN 61674	Beuth Verlag GmbH 10772 Berlin https://www.beuth.de/de

Additional information concerning legal metrology is offered on the following PTB website:
<https://www.ptb.de/cms/de/ptb/fachabteilungen/abt9/fb-92.html>.

2 FLOWCHART

On Application the application forms available from PTB Department 6.3 must be filled in (also possible by electronic means) also the required application forms available from the Conformity Assessment Body must be filled in (also possible by electronic means). By this, it is made sure that all the necessary information are available at the beginning of the type test.

The complete type test will normally be carried out at PTB. All components and devices which belong to the dosimetry system and which are necessary for the determination of the measurement value, as well as the Operating Instructions, must be made available to PTB, the latter in the version which will be marketed together with the system.

An exception from this are dosimetry systems comprising dosimeters which components are already routinely used by dosimetry services or for which a type examination cannot be carried out for other reasons. In this case the type test can, as before, be carried out in the form of extended comparison measurements.

After examination of the documents and performance of a simple functional test, the metrological test will be carried out. This test will go off smoothly if the system to be tested functions properly and if all measurement results lie within the permissible error limits. If inadequate measurement results are obtained during the test, the applicant will be informed immediately. Modifications of the dosimetry system may be possible. Whether the modification is possible during the current type test or not is decided by the evaluator. Tests already carried out will have to be repeated, where appropriate, if it appears that the modifications made affect the measurement results already on hand. If successful modification of the dosimetry system is not to be reckoned with within four weeks, the test procedure will be discontinued. A new application for type test will have to be filed for new processing. If possible, the results of previous measurements will be taken over for this new procedure.

According to § 29 Measures and Verification Ordinance, dosimetry systems must participate in regular comparison measurements. The relevant rules are available from PTB department 6.3 https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_6/6.3/vergl/reg_photon.pdf.