PTB Requirements

Physikalisch-Technische Bundesanstalt

Radiation Protection Instruments	PTB-A 23.2
Personal dosemeters for measuring the personal dose equivalent at 10 mm depth, $H_p(10)$ and the personal dose equivalent at 0.07 mm depth, $H_p(0.07)$	**November 2013**

The PTB Requirements (PTB-A) regarding the approval of personal dosemeters for national verification and for approval in accordance with Section 2, subsection 3 of the Verification Ordinance are in compliance with the accepted rules of technology. These requirements have been adopted by the *Plenary Assembly of the Physikalisch-Technische Bundesanstalt (PTB) for Verification Matters 2013* and replace the PTB Requirements PTB-A 23.2, edition of November 2007, which have been valid so far.

The approval is granted by PTB if the type of the radiation protection instrument meets the requirements of the Verification Ordinance, including Appendix 23, section 2, as well as the requirements specified below. Information regarding practical test applications can be obtained in the Internet under http://www.ptb.de/en/org/6/63/bap/bap.htm. Approval is granted exclusively for photon radiation.

The approval test is performed by type examination at PTB. Exceptions are possible for the dosemeters mentioned in Section 2, subsection 3 of the Verification Ordinance which – according to Section 2, subsection 3 of the Verification Ordinance – may also be approved on the basis of extended comparison measurements which are performed once.

The type of a radiation protection instrument that differs from these requirements is approved if the same measurement reliability is ensured in another way. In this case, the requirements to be met by the instrument type are defined upon type approval (Section 16, subsection 3 of the Verification Ordinance).

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1 REQUIREMENTS FOR THE CONSTRUCTION AND ASSEMBLY

1.1 Functionality and stability

The dosemeter must work in accordance with the *instructions for use*. If the indicated measurement values do not meet the requirements outlined below (e.g. in the warm-up phase, or due to functional errors of the dosemeter such as high-voltage failure, or if additional probes are connected), this must be clearly recognizable for the user.

It must be possible to assign warnings and alarms unambiguously to their source.

In the case of dosemeters which evaluate a great number of dosemeter probes automatically, without actions of the operating staff, the evaluation process must be interrupted automatically when a functional error occurs, and the evaluation of any more dosemeter probes must be stopped.

1.2 Change of the response

Users must not be able to change the response. For dosemeters in accordance with Section 2, subsection 3 of the Verification Ordinance it must be ensured that all adjustments which may influence the response may be performed only in a defined way, e.g. via calibration measurements, and that the adjusted values are reproducible and revisable.

Published by Physikalisch-Technische Bundesanstalt (PTB)

1.3 Display

1.3.1 Uncertainty of reading in the case of non-alpha-numerical displays

It must be possible to indicate each value within the measurement range automatically, i.e. without manual range-switching, with an uncertainty of reading of 2 %, at maximum, of the indicated value.

Exception: For dose values smaller than 100 µSv, an uncertainty of reading of 10 % of the indicated value is permitted.

1.3.2 Checking of alpha-numerical displays

It must be possible for the user to check the proper functioning of the display. Malfunctions (e.g. no glowing, or permanent glowing, of single segments of a segment display) must be recognizable during checking.

1.4 Alarm thresholds

Direct-reading dosemeters must be provided with dose alarm thresholds. It must be possible to set these thresholds to at least one value per decade of the measurement range for the dose.

The alarm must be inactive as long as the measurement value indication amounts to less than 80 % of the indication at the set alarm threshold. The alarm must be triggered when the measurement value indication exceeds 120 % of the indication at the set alarm threshold. Dose rate alarms are permitted; they are not, however, checked within the scope of the type approval.

1.5 Alarm devices

Direct-reading dosemeters must have at least one alarm device which enables an alarm without looking on the display.

At any time, at least one approved alarm device must be active.

A functional check of the alarm devices must be provided.

1.6 Behaviour in the case of overload (dose or dose rate)

1.6.1 The measurand "dose"

The exceeding of the upper limit of the measurement range of the dose must be recognizable up to 10 times the amount of this value - at maximum, up to 50 Sv. If the display of the overload can be reset, then the dosemeter must continue to meet the PTB Requirements after the reset.

Continuous radiation:

The exceeding of the permissible range for the influence quantity "dose rate" must be recognizable up to 10 times the upper range limit – at maximum, up to 10 Sv/h. The indication of the overload must not be deleted until the dose indication is being reset. After the reset, all requirements must continue to be fulfilled.

1.6.2 The measurand "dose rate"

Omitted.

1.7 Service life and re-usability of detectors

The service life is the time during which the detectors fulfil the PTB Requirements without any restriction.

If detectors with a limited service life or with limited re-usability are used, the manufacturer must provide suitable measures which rule out measurements with detectors which are no longer usable, i.e. with detectors whose service life has been exceeded. A limited service life or the limited re-usability must be documented in the *instructions for use*.

If the re-usability of a dosemeter depends on the dose of the previous measurements or on the accumulated total dose, then the dose value for the limit up to which a dosemeter is re-usable must amount to at least 10 mSv.

1.8 Minimum operating time without interruption of direct-reading dosemeters

The minimum operating time is the uninterrupted time of operation with a primary battery or with a fully charged secondary battery at a dose rate of 0.1 mSv/h without the occurrence of a battery alarm, which must be provided. The minimum operating time must be indicated by the applicant and must amount to at least 24 hours.

With new batteries, or directly after charging, the capacity must be sufficient for an alarm of 15 minutes if all the alarm devices provided are switched on simultaneously.

In the case of a minimum operating time of more than 120 hours, a check is made as to whether the minimum operating time amounts to at least 120 hours after a primary battery change or after a charging process of the secondary battery.

In the case of a minimum operating time of less than 120 hours, a check is made as to whether the battery alarm is triggered after the indicated time, at the earliest, after a battery change or after a charging process. After the triggering of the battery alarm, the residual capacity must be sufficient for at least 8 further hours at a dose rate of 0.1 mSv/h and an uninterrupted operation.

The battery alarm may be reset only after the primary battery has been replaced or after the secondary battery has been charged. An acoustic alarm may be acknowledgeable if an optical warning remains.

1.9 Information on further constructional requirements

Further constructional requirements are to be found in the Verification Ordinance, especially in the following sections: Section 25 (Application of the approval mark), Section 36 (Correctness of measurement), Section 37 (Durability), Section 39 (Ancillary equipment), Section 40 (Protection against tempering and operating errors), Section 41 (Representation of measured values and data) and Section 43 (Stamping locations) as well as Appendix 23, subsection 2 to the Verification Ordinance.

1.10 Software

The requirements which are placed on the software have to be taken into account in accordance with WELMEC Software Guide 7.2 in the version being valid at the time of application. Dosemeters belong to Risk Class C.

The software requirements according to WELMEC 7.2 depend on the design of the overall system. The term "system" hereby means: Arrangement of the detector(s), measurement probe(s), reader(s) and control unit(s) (such as, e.g., PC or microprocessor with EPROM), as well as the design of the software and of the interfaces of the system.

The main requirements are distinguished as follows:

- The system can only be used for the purpose for which it is intended;

or:

- The system can also be used for purposes other than those for which it is intended.

Additional requirements arise from further properties of the system in the following way:

- With the system, measured values are stored.
- Within the system, the measured values are transmitted between the different components (both conducted and without conduction).
- Within the system, the software parts for the processing of the measured values and the software parts for other functions are separate from each other.
- It is envisaged that it will be possible for the users of the dosemeter to download new versions of the software.

In particular, the following applies:

The internal software (firmware) and, if applicable, the external software as well as, in particular, the calibration parameters must be secured against changes. The check as to whether changes have been made must be carried out in the dosemeter or by the software itself, respectively.

If a change is found, no measurement values may be displayed which are marked as being admissible for verification.

2 METROLOGICAL REQUIREMENTS

2.1 General

According to Appendix 23, subsection 2 of the Verification Ordinance, whole-body dosemeters are approved only for the radiation protection quantity "personal dose equivalent" $H_p(10)$, and extremity dosemeters are approved only for the radiation protection quantity "personal dose equivalent" $H_p(0.07)$.

In the metrological tests it is investigated whether the response or the indication of the dosemeter varies by no more than the permitted maximum values if an influence quantity is changed from its reference value to any other value within its rated range of use (see section 2.5 of these Requirements).

The requirements in Table 2 (1 to 4) only relate to photon radiation which impinges on the dosemeter in addition to the natural environmental radiation. The portion of the indication caused by the instrument-internal (apparative) background and the natural environmental radiation must be subtracted.

The test procedures and the evaluation of the results comply with the accepted rules of technology.

The tests are carried out in test fields and on phantoms according to ISO 4037-1 or ISO 4037-3, respectively, and by means of procedures according to ISO 29661:2012. The reference point must be indicated by the applicant.

2.2 Maximum possible measuring time

The maximum possible measuring time of a dose measurement t_0 is indicated by the applicant. Within this period of time, the dosemeter must meet the PTB Requirements without any restriction.

According to Section 2, subsection 3 of the Verification Ordinance, the maximum measuring time (wearing time) for dosemeters must amount to at least 1 month and may, in general, amount to 3 months at the most. This corresponds to the SSK Recommendation "Tragezeiten von Personendosimetern " published in the Federal Gazette No. 175 of 19.11.2009.

2.3 Apparative background and natural environmental radiation

2.3.1 General

The *"apparative background"* is the change of the indicated dose with time or the change of the indicated dose rate with time, respectively, in the absence of external ionizing radiation.

2.3.2 Dose measurement

In order to check the lower limit of the measurement range (H_u), the apparative background is determined in PTB's underground laboratory for dosimetry.

Thereby, the following must apply to the lower limit of the measurement range H_u at the maximum measuring time t_0:

$$\frac{\left|H_{\text{indication}} - H_{\text{environment}}\right|}{t_{\text{meas}}} \times t_0 \quad \leq \quad H_u \,.$$

Hereby, $H_{\text{indication}}$ is the display of the dosemeter after the measuring time t_{meas} in PTB's underground laboratory for dosimetry and $H_{\text{environment}}$ is the conventional quantity value of the dose determined by PTB in the underground laboratory, approx. 2 nSv/h times t_{meas}.

In addition, this relation must be fulfilled at natural environmental radiation. This is checked on PTB's reference measuring station for environmental radiation.

Note:
According to Section 2, subsection 2 of the Verification Ordinance, the lower limit of the measurement range, H_u, must be larger than or equal to 10 µSv.

It is possible to indicate several different lower limits of the measurement range with the associated maximum measuring times.

2.3.3 Dose rate measurement

Omitted.

2.4 Coefficient of variation

When a measurement is repeated several times with the same dosemeter under unchanged environmental and irradiation conditions, the coefficient of variation v must not exceed the maximum values v_{max} stated in Table 1. The measurement is repeated with the same dosemeter or, in the case of dosemeters with a great number of dosemeter probes, with different probes.

The influence of the maximum measuring time must be taken into account, if necessary by storing the dosemeters over this period of time.

Table 1: Maximum value v_{max} of the coefficient of variation.

Dose range	v_{max} in %
$1 \cdot H_u \le H < 11 \cdot H_u$	$16 - H / H_u$
$11 \cdot H_u \le H$	5

Note: H_u is the lower limit of the measurement range of the dosemeter.

2.5 Measuring range and rated ranges of use

The measuring range and the rated ranges of use must be indicated by the applicant. They must completely cover the minimum rated ranges of use (column 3 in Table 2).

A distinction is made between influence quantities of *type F* and influence quantities of *type S*:

Influence quantities of type F cause a change of the response (factor; multiplicative influence)

Influence quantities of type S cause a change of the display, independent of the value displayed (summand; additive influence)

Table 2, influence quantities of type F: If the quantity changes (column 2) within the rated range of use or within the measuring range indicated for it by the applicant, the response A ($A = M/H$ with M: indication of the dosemeter and H: conventional quantity value of the dose due to the irradiation), related to the response at reference conditions A_0 (see column 4), is allowed to change only by the values given in column 5:

$$f_{min} \le \frac{A}{A_0} - 1 \le f_{max}$$

Table 2 and Table 4, influence quantities of type S: The change of the indication ΔM (hereby, $\Delta M = M - M_0$, with M being the indication of the dosemeter in the case of an influence of the quantity, and M_0 being the indication of the dosemeter without the influence of the quantity) must be within the following limits:

$$s_{min} \le \Delta M \le s_{max} .$$

At each test, the values of the other quantities which are not the subject of the test are kept as unchanged as possible in the vicinity of their reference values according to Table 2, column 4.

Table 2: Test requirements for personal dosemeters

1	2	3	4	5	6
	Quantity	**Minimum rated range of use**	**Reference value**	**f_{min} … f_{max} or s_{min} … s_{max}**	**Remarks**
1.	For $H_p(0.07)$: Mean photon energy $\overline{E}$ and angle of radiation incidence α	30 keV to 250 keV and $-60° \le \alpha \le +60°$	65 keV ($\overline{E}$ of N-80) and 0° (reference orientation)	Type F: -29 % …+67 %	2.5.1a 2.5.1b 2.5.1c
	For $H_p(10)$: Mean photon energy $\overline{E}$ and angle of radiation incidence α	80 keV to 1250 keV and $-60° \le \alpha \le +60°$	662 keV ($\overline{E}$ of ^{137}Cs) and 0° (reference orientation)	Type F: -29 % …+67 %	
2.	Mean photon energy and angle of radiation incidence at lateral irradiation	Photon energy as in line 1 and angles of radiation incidence from α_{max} to 180°- α_{max}	Respective photon energy and reference orientation	Type F: -100 % …+20 % (without phantom)	2.5.2
3.	For $H_p(0.07)$: Dose and dose rate	1 mSv to 10 Sv and 0.1 µSv/h to 1 Sv/h	3 mSv and 1 mSv/h	Type F: -13 %...+18 %	2.5.3
	Für $H_p(10)$: Dose and dose rate	0.1 mSv to 1 Sv and 0.1 µSv/h to 1 Sv/h	1 mSv and 1 mSv/h	Type F: -13 %...+18 %	
4.	Radiation pulse duration and peak pulse dose rate	1 ms to 10 s and 0 Sv/h to 1 Sv/h	Response at continuous radiation	Type F: -20 % … +20 %	2.5.4
5.	Ambient temperature and relative air humidity	-10 °C to +40 °C (+15 °C to +30 °C) and 40 % to 90 % (30 % to 75 %), non-condensing	+20 °C and 65 %	Type F: -13 % ... +18 % Type S: $-0.7 \cdot H_u$ …$+0.7 \cdot H_u$ at a dose of $H = 7 \cdot H_u$	2.5.5
6.	Light	0 to 1000 W/m^2	0 W/m^2	Type F: -9 % … +11 % Type S: $-0.7 \cdot H_u$ …$+0.7 \cdot H_u$ at a dose of $H = 7 \cdot H_u$	2.5.6
7.	Free fall onto concrete	Falling height: 1 m	0 m	$-0.7 \cdot H_u$ …$+0.7 \cdot H_u$	2.5.7
8.	Storage in water	0 to 24 h	0 h	$-0.7 \cdot H_u$ …$+0.7 \cdot H_u$	2.5.8

Note: H_u is the lower limit of the measurement range of the dosemeter

Notes to Table 2:

2.5.1a During the test of the energy dependence and of the angular dependence, the combined influence of the two quantities is measured. The test is performed with reference radiation fields in accordance with ISO 4037-1 and with procedures according to ISO 29661. The mean energy (fluence-related) and the angle of incidence of the photon radiation must lie within the rated range of use stated for the dosemeter. Mixtures of these reference radiation fields are permitted. Tests with mixed radiation fields can be performed especially when the dosemeter is composed of several detectors, evaluates several signals, or uses a non-linear algorithm for signal processing.

The applicant may also select another reference value of the photon energy, provided that this value lies within the rated range of use of the photon energy.

2.5.1b The requirement regarding the angle of radiation incidence comprises all directions with an angle α from 0° to ± α_{max} to the reference orientation of the dosemeter. The reference orientation and the value for the angle α_{max} must be indicated by the applicant.

2.5.1c If the design of the dosemeter allows the user to wear the dosemeter in various orientations (e.g. one in which the reference orientation points towards the body of the user and one in which the reference orientation points away from the body – this is, for example, the case for flat dosemeters), the dosemeter must meet the requirements for both orientations, unless clear and unequivocal information for the user is given on the dosemeter and in the *instructions for use* as to in which orientation the dosemeter is to be worn.

2.5.2 Hereby, the response of the dosemeter is tested at all lateral angles of radiation incidence in the angular section from α_{max} to 180°- α_{max} (as regards the value for the angle α_{max}, see section 2.5.1b above). The dosemeter is irradiated free in air, i.e. without phantom, and the reference quantity is the *"ambient dose equivalent" H**(10). The response is averaged over the different angles of radiation incidence. The mean response, divided by the response at the reference orientation, must not exceed the value 1.2 at any photon energy. This test is omitted if compliance with the requirement is ensured by the design.

2.5.3 For practical reasons, the test of the dose indication regarding the dependence on the measurand *"dose"* (linearity test) and the test regarding the influence quantity *"dose rate"* are carried out jointly.

2.5.4 In the case of pulsing of the radiation field, the response of the dosemeter must not change by more than ± 20 %, compared to the response in the case of continuous radiation (see also IEC/TS 62743:2012, as well as section 2.9 in these Requirements).

The upper limit of the minimum rated range of use for the pulse dose results from the upper limit for the radiation pulse duration and the peak pulse dose rate.

2.5.5 The limited temperature range and the limited humidity range apply only to devices which are intended exclusively for interior use (e.g.: TLD readers). To the dosemeter probe, always the whole unrestricted ranges apply.

2.5.6 This test is carried out only for those personal dosemeter probes in the case of which photosensitivity cannot be safely ruled out by the design. The total irradiance is 1000 W/m^2 with a spectrum corresponding to bright sunlight: at least 45 W/m^2 in the wavelength range between 300 nm and 400 nm, and at least 630 W/m^2 in the wavelength range between 400 nm and 900 nm. The values originate from the AM-1.5 spectrum of IEC 60904-3.

2.5.7 During this test, the dosemeter is dropped from a height of 1 m down to a plane, hard concrete surface. A total of 10 fall tests is carried out with different dosemeter orientations. The tested dosemeter must continue to meet the PTB Requirements, and no dose information may get lost. This test is omitted for components which are not firmly connected to the detector (e.g.: TLD readers).

2.5.8 This test is only performed with finger-ring dosemeter probes. Prior to the evaluation, these must be dried in accordance with the information given in the *instructions for use*.

2.6 Response time for dose rate measurement

Omitted.

Table 3: Omitted.

2.7 Electromagnetic compatibility

The electromagnetic compatibility of the dosemeter is tested with procedures and test quantities in accordance with DIN EN 61000-6-2 (VDE 0839 part 6-2) "Electromagnetic compatibility (EMC) – Part 6-2: Generic standards – Immunity for industrial environments".

Within the scope of the approval test, the single tests are carried out in accordance with Table 4. In each single test, the indication may change by a maximum of $0.7 \cdot H_u$ with a residence time of 6 min or 10 pulses/discharges. Thereby, H_u is the lower limit of the measurement range according to section 2.3.

If it is guaranteed by the instrument type that the indication of the dosemeter will not change as a result of the respective component test, this test is omitted. This applies, in particular, to dosemeter probes in accordance with Section 2, subsection 3 of the Verification Ordinance. The other components of these dosemeters are only checked according to the single tests in lines 3 to 6 of Table 4.

These tests do not need to be carried out for readers for which the manufacturer declares that the respective influence quantity does not influence the display by more than $0.7 \cdot H_u$ when the dosemeter is evaluated, or that the influence is detected and accompanied by a corresponding error message, or that the influence is corrected (e.g. by software). One error message at most is permitted (see above). This declaration must include the required justification. As a justification, either a physical cause may be given - for the fact that the device is not influenced by the electromagnetic interference - or a reason may be given for the fact that this electromagnetic interference does not occur. This justification must be given for each single electromagnetic interference. An example of this is that mobile phones are not permitted in the room in which the reader is located.

Note:

The requirements for the application of the CE mark comply with the regulations of the "Law on the Electromagnetic Compatibility of Devices" of November 9, 1992 (Federal Law Gazette I, p. 1864) in its currently valid version. Compliance with this law is not an object of the approval test in accordance with the Verification Act.

Table 4: Single tests to investigate the influence of electric and magnetic disturbances. The values shown here are basic data, the tests are performed in accordance with the state of the art of the standards stated.

	Influence quantity	Test in accordance with standard	Minimum rated range of use	In the case of dosemeters acc. to Section 2, subsection 3	Crite-rion*
1.	HF voltage, voltage	IEC EN 61000-4-6	150 kHz to 80 MHz 0 to 10 V (rms, unmodulated) 80 % AM (1 kHz)	no	A
2.	Electromagnetic HF field, field strength	IEC EN 61000-4-3	80 MHz to 2 GHz 0 to 30 V/m (rms, unmodulated) 80 % AM (1 kHz)	no	A
3.	Electrostatic discharge, charging voltage	IEC EN 61000-4-2	0 to ± 8 kV air discharge 0 to ± 4 kV contact discharge	yes	B
4.	Fast transients unsymmetrical, peak voltage	IEC EN 61000-4-4	0 to ± 2 kV (current conductors) 0 to ± 1 kV (signal conductors)	yes	B
5.	Surges, peak voltage	IEC EN 61000-4-5	0 to ± 2 kV unsym. 0 to ± 1 kV sym.	yes	B
6.	AC mains voltage dips, duration	IEC EN 61000-4-11	20 ms (100 % reduction) 200 ms (60 % reduction) 500 ms (30 % reduction) 5000 ms (>95 % reduction)	yes	B C C C
7.	50 Hz magnetic field, field strength	IEC EN 61000-4-8	0 to 30 A/m	no	A

*The criteria indicate the permitted behaviour during and after the disturbance in accordance with IEC EN 61000-6: A: unrestricted functionality; B: temporary device failure (followed by automatic resetting) is permitted, but no loss of data or instrument settings is permitted; C: device failure is permitted, but no loss of stored data is permitted

2.8 Documentation of the influence of beta and/or neutron radiation

2.8.1 General

The influence of beta and/or neutron radiation on the photon indication of the dosemeter is investigated if the *instructions for use* do not expressively restrict the use of the dosemeter to pure photon radiation fields or if the dosemeter is recognisably intended for use in such fields (e.g. if an indication for beta or neutron radiation is provided).

The results determined in these tests are documented in the approval certificate and must be included into the *instructions for use*.

2.8.2 Beta radiation

The response of the photon indication of the dosemeter with respect to the beta radiation is determined with suitable radiation sources, e. g. ^{147}Pm, ^{85}Kr and ^{90}Sr/^{90}Y. The $H_p(10)$ indication must, at maximum, amount to 10 % of the conventional quantity value of $H_p(0.07)$.

2.8.3 Neutron radiation

The response of the photon indication of the dosemeter with respect to neutron radiation or mixed neutron-photon fields is determined with suitable radiation sources, e.g. ^{252}Cf and ^{252}Cf (D_2O-mod.).

2.9 Requirements for pulsed radiation

Note: The aim of this test is to determine the parameter range in which measurements can be reliably performed, and to ensure that also radiation pulses outside this parameter range can be detected up to 100 times the range limit of the peak pulse dose rate.

Similar to the influence quantity *"mean photon energy"*, the approval only specifies the permitted range. Depending on the parameters of the measurement task, the user must decide whether the dosemeter can be used.

Definition of terms according to ISO TS 18090-1:

The peak pulse dose rate is the mean dose rate in the time interval in which a radiation pulse reaches 80 % of the peak pulse dose rate.

2.9.1 General

It is investigated whether the dosemeter is suited to measure the dose in pulsed radiation fields. The minimum rated range of use and the permissible deviation are shown in Table 2. The influence quantities to be taken into account are the peak pulse dose rate, the pulse dose, the pulse duration and the pulse repetition frequency. The definition of terms which are used as a basis can be found in ISO TS 18090-1. The test and the requirements have been defined on the basis of IEC/TS 62743.

If the requirements for pulsed radiation are not met, a warning must be included in the *instructions for use* with the corresponding content: "The dosemeter is not suited for measurements in pulsed radiation fields".

2.9.2 Behaviour in the case of overload (dose or dose rate, respectively)

2.9.2.1 The measurand "dose"

An exceeding of the range which has been permitted for the influence quantity *"peak pulse dose rate"* must be recognizable up to 100 times its value – at maximum up to 1000 Sv/h. The warning may not be deleted until a reset takes place. After the reset, all requirements must continue to be met.

If an overload is not recognizable, a corresponding warning must be included in the *instructions for use*.

2.9.2.2 The measurand "dose rate"

Omitted.

2.9.3 Measurement range and rated ranges of use

see Table 2.

3 DESIGNATIONS AND INSCRIPTIONS

Each dosemeter must bear the following information (see also Verification Ordinance Section 42 and Appendix 23 of the Verification Ordinance):

- Approval sign
- Company logo or name of the manufacturer
- Type designation of the dosemeter
- Serial number
- Measurand and measuring range
- Rated range of use of the photon energy and of the angle of radiation incidence
- If applicable: Brief *instructions for use*
- If applicable: Further information (which is determined during the approval)

4 RADIOACTIVE CHECKING DEVICES

4.1 Half-life time

The half-life time of the radionuclide of a checking device must be longer than 5 years. The documents must specify the control indication or the control time for the respective date with an uncertainty of less than ± 1 %.

4.2 Coefficient of variation of the control measurements

When measurements are performed with a checking device which belongs to the dosemeter, the coefficient of variation must not exceed the value 0.05 under repeatability conditions.

4.3 Minimum indication value

During the approval, a minimum indication value is laid down which may not be fallen short of during the control measurement.

5 REFERENCE CONDITIONS AND TEST VALUE RANGES DURING THE VERIFICATION

5.1 General

The reference conditions during verification are laid down by PTB in the approval certificate. The test value ranges during verification are laid down in the PTB Testing Rules "Radiation Protection Dosemeters for Photon Radiation with Energies between 5 keV and 3 MeV" and are in accordance with ISO 4037.

5.2 Verification at the place of operation

If the verification is carried out at the place of operation (e.g., in the case of radioactive checking devices), the measurement conditions mentioned above must be complied with as far as possible. In cases where deviations from these conditions are indispensable, PTB will specify new reference conditions and test value ranges. These will be specified in the approval certificate.

6 INSTRUCTIONS FOR USE

6.1 General

The *instructions for use* must be enclosed with each dosemeter. The *instructions for use* must be written in German and must be marked in such a way that they can be unequivocally assigned to the dosemeter described.

The *instructions for use* must describe the construction and the mode of operation of the dosemeter and its components and contain all information required for their normal operation and maintenance. Technical data which are determined during type approval must be clearly separated from data which have not been confirmed by the type approval.

The *instructions for use* must contain at least the following information:

6.2 Content

6.2.1 General indications

- Type designation as well as the manufacturer and the holder of the approval certificate
- Type of dosemeter
- Number of the PTB type approval
- Dose quantity $H_p(10)$ or $H_p(0.07)$ and measurement range for the dose
- Radiation type for which the dosemeter is intended

6.2.2 Construction and way of operation

- External dimensions and mass of the dosemeter
- Position of the reference point and of the reference orientation relative to external markings
- Information regarding the consideration of natural environmental radiation
- For dosemeters in accordance with Section 2, subsection 3 of the Verification Ordinance: description of the evaluation procedure:
  The procedure for the determination of the personal dose equivalent from the indication of the display unit must be described consistently and completely so that the dose can be calculated from the indicated value also at a later time. In addition, all steps of the evaluation procedure which are relevant to practical applications must be described (for example: information regarding the reader, such as stabilization time, required calibrations including a detailed description of the calibration procedure, gas purging, correction of non-linearity, etc.).

6.2.3 Handling

- Normal position or way of wearing the personal dosemeter, if applicable with a note in accordance with section 2.5.1c above
- Function and handling of all operating elements, connections and displays
- Information must be given as to from when on a dosemeter is no longer usable; if applicable: reference to facilities which may be used to make the dosemeters usable again.
- Information regarding limitations relevant to dosimetry, e.g. regarding re-usability, air humidity, storage, maintenance, after-effects in the case of irradiation with high doses.
- If applicable: information regarding cleaning and drying of the dosemeter
- Information regarding the exchange of wear and tear parts (e.g. batteries) by the user; this information must contain, where applicable: test of the serviceability of the wear and tear parts and type of the wear and tear parts provided as replacement.

6.2.4 Technical data

- Detector type
- If applicable: setting range of dose alarm thresholds
- For direct-reading personal dosemeters: permissible types of primary batteries and/or secondary batteries and minimum operating time
- For mains-powered components (e.g.: readers): rated range of use of the connection voltage and of the frequency, switch-over of the mains voltage, if necessary
- If applicable: additional technical data relevant to dosimetry

6.2.5 Results of the PTB type approval

- Measuring range for the dose
- Coefficient of variation of the response
- Maximum possible measuring time according to sections 2.2 and 2.3
- Rated ranges of use and the associated change of the response or of the indication according to section 2.5 for the following influence quantities:
  - Energy and angular dependence of the response, possibly with a diagram,
  - Linearity and dose rate dependence,
  - Indications concerning the influence of pulsed radiation,
  - Ambient temperature and relative air humidity,
  - If applicable: light,
  - If applicable: free fall onto concrete,
  - If applicable: EMC tests,
  - If applicable: air pressure,
  - If applicable: operating voltage and -frequency,
  - For finger-ring dosemeter probes: storage in water,
  - If applicable: further influence quantities having a significant influence on the indicated value
- Information regarding the influence of beta and neutron radiation according to section 2.8
- Sound pressure level of the acoustic alarm, if provided

6.2.6 Information regarding the radioactive checking device (if provided)

- Type of the associated checking device,
- External dimensions,
- Radionuclide and nominal activity of the associated source,
- Description of the procedure for a prolongation of the period of validity of verification, including all information relevant to dosimetry as, for example, determination of the current activity of the source.

7 OFFICIAL ELECTRONIC PERSONAL DOSEMETERS ACCORDING TO SECTION 2, SUBSECTION 4 OF THE VERIFICATION ORDINANCE

In order to be able to use an electronic personal dosemeter as an official dosemeter in accordance with Section 2, subsection 4 of the Verification Ordinance, this dosemeter must fulfil the following additional type requirements:

7.1 Switching off or change of the dose measurement

By means of a suitable design of the personal dosemeter it must be ensured that the dose measurement cannot be switched off or changed while the dosemeter is worn.

The indication of *additional* dose values (e.g. daily dose counter resettable by the user) is permitted.

7.2 Primay or secondary batteries

If the primary or secondary batteries can be changed by the user, this change may be possible only with special tools or it must be possible to recognize this change afterwards. It is regarded as sufficient if e.g. a screwdriver with a special blade is used for the change or if an adhesive foil must be destroyed.

The dose indication may not be deleted when the battery is changed.

7.3 If the dosemeter is worn by various persons

If it is not ruled out that the dosemeter is worn by various persons, at least the following data must be taken for each measurement (time of wearing) and must be checkable by the monitored person while they are being taken:

- clear marking of the dosemeter used (e.g. dosemeter type and serial No.)
- clear assignment of the monitored person to the dosemeter used
- Start and end of the measurement, including date and time
- Dose value in the required resolution