Czech Metrology Institute
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1. ------IND- 2018 0339 CZ- EN- ------ 20180803 --- --- PROJET

Executive summary for the EC (not part of this legislation)

Non-spectrometric activity meters and dosimeters used to monitor compliance with limits in the area of radiation protection or nuclear safety and for emergency measurement – electronic personal dosimeters for measuring gamma radiation and X-rays are placed on the market and put into use in the Czech Republic in accordance with Act No 505/1990 on metrology, as amended.

The subject of this notified regulation is to lay down metrological and technical requirements for these measuring instruments. The legislation establishes further tests for purposes of type approval and verification.

(End of executive summary.)

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PUBLIC DECREE

As the authority with substantive and territorial jurisdiction in the matter of laying down metrological and technical requirements for specified measuring instruments and stipulating the testing methods for type approval and verification of specified measuring instruments pursuant to § 14(1) of Act No 505/1990, on metrology, as amended (hereinafter the 'Metrology Act'), and in accordance with the provisions of § 172 et seq. of Act No 500/2004, the Code of Administrative Procedure (hereinafter the 'CAP'), the Czech Metrology Institute (hereinafter the 'CMI') commenced ex officio proceedings on 4 April 2016 pursuant to § 46 of the CAP, and, based on supporting documents, issues the following:

I.

DRAFT MEASURE OF A GENERAL NATURE

number: 0111-OOP-C078-16

laying down the metrological and technical requirements for specified measuring instruments, including testing methods for type approval and verification of the following specified measuring instruments:

'non-spectrometric activity meters and dosimeters used to monitor compliance with limits in the area of radiation protection or nuclear safety and for emergency measurement – electronic personal dosimeters for measuring gamma radiation and X-rays'

1 Basic definitions

For the purposes of this General Measure of a General Nature, terms and definitions pursuant to VIM and VIML[1)] as well as the following terms and definitions apply:

1.1

personal dose equivalent $H_p(d)$

The dose equivalent in soft tissue, at a specified point in the human body at a depth of *d.* For penetrating radiation, a depth of 10 mm is recommended and for non-penetrating radiation, a depth of 0.07 mm is recommended.

The unit of personal dose equivalent is Sv (J/kg).

1.2

personal equivalent dose rate $\dot{H}_p(d)$

The proportion of $dH_p(d)/dt$, in which $dH_p(d)$ is the increase in spatial dose equivalent at a temporal interval of d*t*.

The unit of personal equivalent dose rate is Sv/s (mSv/h).

1.3

measuring instrument for personal dose equivalent

A device intended for measuring personal dose equivalent with a digital dose indicator.

1.4

reference point of measuring instrument

A physical mark or marks on the external surface of the measuring instrument intended for positioning the measuring instrument on the test point.

1.5

test point

The point at which the reference value of the measured quantity is set and into which the measuring instrument's reference point is positioned for the purpose of the tests.

1.6

measuring instrument response

Response for the reference value of the quantity $H_{r,0}$ measured under specific conditions:

$$R_0 = \frac{G_{r,0}}{H_{r,0}} \qquad (1)$$

in which $G_{r,0}$ is the corresponding specification of the measuring instrument.

1.7

reference response

the ratio given under reference conditions by the relationship:

$$R = \frac{G}{H} \qquad (2)$$

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1) TNI 01 0115 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM) and International Vocabulary of Terms in Legal Metrology (VIML) are part of the technical harmonisation compendium 'Terminology in the Area of Metrology', which is publicly accessible at www.unmz.cz.

in which *G* is the measuring instrument's specification and *H* is the reference value of the measured quantity under reference conditions.

1.8
relative response

Ratio of *R* and reference response R_0:

$$R = \frac{G}{H} \tag{3}$$

in which *G* is the measuring instrument's specification and *H* is the reference value of the quantity

1.9
effective measurement range

The range of values of the measured quantity that meets the requirements of the standard.

1.10
lower limit of effective measurement range H_0

The lowest value of dose equivalent or dose rate that falls within the effective measurement range.

1.11
upper limit of effective measurement range H_0

The highest value of dose equivalent or dose rate that falls within the effective measurement range.

1.12
coefficient of variation v

A measure of the relative dispersion of the data determined as a proportion of standard deviation to the arithmetical mean in percent.

1.13
relative expanded uncertainty U_{rel}

The sum of the standard measurement uncertainty and the coefficient of expansion *k* (*k* = 2 corresponds to a probability of coverage of approximately 95 %).

1.14
conventional true value of dose equivalent

The best estimate of the true value of the dose equivalent

2 Metrological requirements

2.1 Categorisation of measuring instruments

The categorisation of measuring instruments is specified in Table 1.

Table 1 – Categorisation of measuring instruments

Main category	Symbol	Minimum required range of use	Energy range	For dose equivalent	For equivalent dose rate
$H_p(10)$ gamma radiation	**G**	**energy:** 80 keV – 1.5 MeV **equivalent dose rate:** 0.5 µSv/h – 1 Sv/h	**m:** lower limit 60 keV **l:** lower limit 20 keV **h:**	**f:** lower limit 10 µSv	**a:** emergency upper limit 10 Sv/h **e:** environment

		dose equivalent: 100 µSv – 10 Sv	including 6 MeV		lower limit 0.05 µSv/h
$H_p(10)$ X radiation	**X**	**energy**: 20 keV – 150 keV **equivalent dose rate:** 0.5 µSv/h – 1 Sv/h **dose equivalent:** 100 µSv – 10 Sv	**l:** lower limit 10 keV **h:** including 300 keV	**f:** lower limit 10 µSv	**a:** emergency upper limit 10 Sv/h **e:** environment lower limit 0.05 µSv/h
$H_p(0.07)$ gamma and X radiation	**S**	**energy:** 20 keV – 150 keV **equivalent dose rate:** 5 µSv/h – 1 Sv/h **dose equivalent:** 1 mSv – 10 Sv	**l:** lower limit 15 keV **n:** lower limit 10 keV	**g:** lower limit 100 µSv	**a:** emergency upper limit 10 Sv/h **e:** environment lower limit 0.5 µSv/h

2.2 Reference conditions and standard test conditions

Reference conditions and standard test conditions are specified in Table 2 and apply unless the manufacturer states otherwise.

Table 2 – Reference conditions and standard test conditions

Influencing quantity	Reference conditions	Standard test conditions
Photon radiation energy for: 1 – $H_p(10)$ – personal dose equivalent 2 – $H_p(0.07)$ – directional personal dose equivalent	gamma radiation: ^{137}Cs or ^{60}Co (ISO 4037-3) N-80 or ^{241}Am (ISO 4037-3)	gamma radiation: ^{137}Cs or ^{60}Co (ISO 4037-3) N-80 or ^{241}Am (ISO 4037-3)
Angle of incidence of radiation	reference direction given by the manufacturer	given direction ±5°
Dose equivalent: $H_p(10)$ $H_p(0.07)$	 0.3 mSv 3 mSv	 0.1 mSv to 10 mSv [a)] 0.5 mSv to 50 mSv [a)]
Equivalent dose rate: $H_p(10)$ $H_p(0.07)$	 0.3 mSv/h 3 mSv/h	 0.1 mSv/h to 10 mSv/h [a)] 0.5 mSv/h to 50 mSv/h [a)]
Stabilisation time	15 minutes	≥ 15 minutes
Temperature	20 °C	18 °C to 22 °C [a)]
Relative humidity	65 %	50 % to 75 % [a)]
Air pressure	101.3 kPa	86.0 kPa to 106.6 kPa [a)]
Supply voltage	nominal supply voltage	battery charged up to half of its service life
External electromagnetic field	negligible	less than the smallest value causing the disturbance

External magnetic induction	negligible	less than two times the value of Earth's magnetic field
Measuring instrument orientation	will be specified by the manufacturer	specified orientation ± 5°
Measuring instrument control	settings for ordinary operation	settings for ordinary operation
Radiation background	2 µSv/d	lower than 0.25 µSv/h
Contamination with radioactive particles	negligible	negligible
[a] Actual value determined in test		

2.3 Maximum permissible error

2.3.1 Linearity and statistical response fluctuation

Under standard conditions, the measuring instrument's response deviation over the entire effective measurement range may not exceed −17 % to +25%.

Under standard conditions, the coefficient of variation over the entire effective measurement range may not exceed:

for H_p(10):

for $H_0 \leq H < 11H_0$ $(16 - H/H_0)$ %

for $H \geq 11H_0$ 5 %

for $\dot{H}_p$(10):

for $\dot{H} < 10$ µSv/h 20 %

for 10 µSv/h $\leq \dot{H} < 60$ µSv/h $[21 - \dot{H}/(10\ \mu Sv/h)]$ %

for $\dot{H} \geq 60$ µSv/h 15 %

2.3.2 Energy and directional dependence of response

The measuring instrument's relative response caused by the angle of radiation incidence over a range of 0 ° to ±60 ° (relative to the reference direction of radiation incidence) and over an energy range of 80 keV to 1.5 MeV (for gamma radiation) or 20 keV to 150 keV (for X radiation) must be within 0.71 to 1.67.

2.3.3 Storage of measured dose equivalent data

The measured dose equivalent data must be stored on the device for at least 8 hours. At the same time, this value may not change by more than ±2 %.

Likewise, it is necessary to store the dose equivalent data for 24 hours after a power loss The value stored may not differ by more than ±5 % after battery replacement.

2.3.4 Overload

2.3.4.1 Equivalent dose rate

If the measuring instrument is exposed to a equivalent dose rate the exceeds the maximum measurement range, the measuring instrument must indicate the maximum value of the measurement range and simultaneously indicate an overload.

2.3.4.2 Dose equivalent

If the measuring instrument is exposed to a dose equivalent greater than that of the maximum measurement range, the measuring instrument must indicate the maximum value of the measurement range and simultaneously indicate an overload.

2.3.4 Indication that the set level has been exceeded

2.3.5.1 Response time for equivalent dose rate measurement and alarm

The response time is defined as the period of time after which the measuring instrument's specification reaches the final specification of the equivalent dose rate in the event of a sudden rise or drop in equivalent dose rate. The measuring instrument's required response time limit is 10 seconds. Exceedance of the set level must be signalled within 2 seconds. The requirements apply to a equivalent dose rate ≥ 1 mSv/h.

2.3.5.2 Accuracy of signalling that the set equivalent dose level has been exceeded

Under standard conditions, a measuring instrument exposed to 0.87 times the pre-set value may not signal exceedance of this value.

A measuring instrument exposed to 1.18 times the pre-set value must signal an exceedance of this value.

2.3.5.3 Accuracy of signalling that the set equivalent dose rate level has been exceeded

Under standard conditions, a measuring instrument exposed to $(1 - 2 \cdot v_{max})$ times the pre-set value may not signal exceedance of this value for longer than 5% of the total time.

A measuring instrument exposed to $(1 - 2 \cdot v_{max})$ times the pre-set value must signal exceedance of this value for longer than 95% of the total time.

2.3.6 Response to beta radiation

The measuring instrument must be as insensitive to beta radiation as possible. The indicated equivalent dose (input) must be lower than 10% of the value of equivalent dose (input) to which the measuring instrument is exposed.

2.3.7 Resistance to mechanical shocks

If the measuring instrument is subjected to mechanical shocks during operation, the change in response caused by the shocks must be less than $\pm 0.7 H_0$ (the lower limit of effective measurement range). No mechanical damage may be caused and no information saved on the measuring instrument may be lost.

2.3.8 Resistance to vibrations

If the measuring instrument is subjected to vibrations during operation, the change in response caused by the vibrations must be less than $\pm 0.7 H_0$ (lower limit of effective measurement range). No mechanical damage may be caused and no information saved on the measuring instrument may be lost.

2.3.9 Resistance to falls during transport

A measuring instrument packaged for transport purposes must be resistant to falls. If the measuring instrument is subjected to falls during operation, the change in response caused by the falls must be less than $\pm 0.7 H_0$ (the lower limit of effective measurement range). In the event of a fall, no mechanical damage may be caused and the device must exhibit normal functioning upon being turned on.

2.3.10 Ambient temperature

Changes in the measuring instrument's response caused by a change in ambient temperature (stable temperature, thermal shock, and turning on at low temperatures) over a range of −10 °C to +40 °C may not exceed −13 % to +18 % of the measuring instrument's response under standard test conditions. In the case of measuring instruments intended solely for indoor use, this requirement applies over a temperature range of +5 °C to +40 °C. Such measuring instruments must for example be labelled as 'for indoor use only'.

2.3.11 Relative humidity

Changes in the measuring instrument's response caused by a change in ambient humidity over a range of 40 % to +90 % may not exceed a deviation from -9 % to +11 % in comparison with the measuring instrument's response under standard test conditions. In measuring instruments intended for outdoor use, the measuring instrument's protection rating must be at least IP 53.

2.3.12 Atmospheric pressure

Changes in the measuring instrument's response caused by a change in atmospheric pressure over a range of 86.0 kPa to +106.0 kPa may not exceed a deviation from -9 % to +11 % in comparison with the measuring instrument's response under standard test conditions.

2.3.13 Resistance to electromagnetic interference

The maximum change in response (temporary and permanent) caused by electromagnetic interference must not be greater than $\pm 0.7 H_0$ (lower limit of effective measurement range).

2.3.14 Power supply source test

The capacity of the primary batteries must be such that the maximum change in the measuring instrument's relative response is within −0.09 to +0.11 after 100 hours of uninterrupted use (at a equivalent dose rate from 0.01 mSv/h to 0.1 mSv/h). The measuring instrument must not indicate low battery capacity.

The measuring instrument must be able to produce an audio signal and display that the set threshold has been exceeded for at least 15 minutes immediately after new batteries have been inserted.

The capacity of the secondary batteries (rechargeable batteries) must be such that the maximum change in the measuring instrument's relative response is within -0.09 to +0.11 after 24 hours of uninterrupted use (at a equivalent dose rate from 0.01 mSv/h to 0.1 mSv/h).

The measuring instrument must be able to produce an audio signal and display that the set threshold has been exceeded for at least 15 minutes immediately after the batteries have been recharged.

3 Technical requirements

3.1 Unit indication

The measuring instrument must display a value in Sv or Sv/h.

3.2 Minimum measurement range

The minimum measurement range of a measuring instrument for personal equivalent dose rate must be from 1 μSv to 10 Sv. The minimum measurement range of a measuring instrument for personal dose equivalent must be from 1 μSv to 1 Sv.

3.3 Information on operating status

The measuring instrument must indicate operating conditions under which accuracy of the dose equivalent reading is not ensured, for example if the battery is depleted, a detector is malfunctioning, or if the equivalent dose rate has been exceeded.

3.4 Easy decontamination

The measuring instrument must be designed and built to allow easy decontamination.

3.5 Protection from unauthorised tampering

The measuring instrument must be built to prevent the operator from inadvertently changing any factor of the settings. Parts of the measuring instrument that are essential to its metrological properties must be designed so that they can be secured by a means that provides proof of any tampering. Regulation elements must either be inside the measuring instrument and inaccessible from outside without the use of tools, or must be clearly marked and fitted with a scale so that they can be precisely adjusted in accordance with the capacity of the measuring instrument's resolution, and then blocked so as to prevent any accidental change to the settings. It must impossible to change corrective factors and calibration coefficients saved digitally unless the operator enters a security code (or password) or changes the position of a blocked or inaccessible switch.

3.6 Safety

The measuring instrument must be safe in the sense of the basic principles of radiation safety with ionising radiation and the requirements of the relevant technical regulations under ordinary conditions of use for the intended purpose.

4 Measuring instrument markings

4.1 Markings on the measuring instrument

On measuring instruments that may be composed of two functionally separate parts, the following information must be specified on each part:

a) manufacturer identification;
b) type designation of the measuring instrument;
c) serial number of the measuring instrument itself;
d) type approval mark;
e) measured quantity and type of radiation;
f) effective measurement range.

The position of the reference point must be marked on the measuring instrument. The type and polarity of the batteries used must be marked on the measuring instrument. All inscriptions and marks must be legible, permanent, unambiguous, and indelible.

4.2 Official mark placement

The positioning of official marks on the measuring instrument and evaluation unit is specified in the type approval certificate.

If possible, the marks are to be positioned on the front panel of the display unit in such a manner that they do not conceal any of the information shown on the measuring instrument.

5 Type approval of the measuring instrument

5.1 General information

The type approval process for a measuring instrument includes the following tests:

a) an external inspection;
b) a test of response linearity and statistical fluctuation;
c) a test of energy and directional dependence of the response;
d) a measured quantity storage test;
e) a test of resistance to overload;
f) a response time test;
g) a test of the accuracy of indication that the set level has been exceeded;
h) a test of response to beta radiation;
i) a mechanical resistance test;
j) a test of resistance to climatic influences;
k) EMC tests;
l) a power supply test.

5.2 External inspection

The following is assessed during an external inspection:

a) whether the required technical documentation, including operating instructions, is complete;
b) whether the metrological and technical characteristics specified by the manufacturer in the documentation comply with the requirements under this regulation as referred to in Chapters 2, 3 and 4.1;
c) the completeness and condition of the measuring instrument's functional units according to prescribed technical documentation;
d) whether the measuring instrument's software version matches the version specified by the manufacturer.

5.3 Radiation tests

5.3.1 Test of response linearity and statistical fluctuation

The linearity test is conducted by irradiating the measuring instrument in a collimated beam of gamma or X radiation of reproducible geometry and field size. The measured value is compared with the reference value obtained for this quantity using a reference gauge. The test is conducted using various values of equivalent dose rate and dose equivalent at three test points within each decade of the measurement range (at 20 %, 40 % and 80 % of the decade).

The response fluctuation test is conducted at the same time as the linearity test. The coefficient of variation after repeated measurement is determined at all test points.

Deviations in the measured values from the reference value may not exceed the limits pursuant to Article 2.3.1.

The coefficient of variation of the dosimetric values may not exceed the limits pursuant to Article 2.3.2 by more than 1.5 times. The specific value of the permissible multiplier is determined according to the actual number of test points and the actual number of measurements.

5.3.2 Test of energy and directional dependence of the response

The energy dependence of response test is conducted by irradiating the measuring instrument in a collimated beam of X or gamma radiation with reproducible geometry and field size in the required

energy range and the required angle range. The measured value is compared with the value measured of a quantity determined for the reference conditions with a reference gauge.

Deviations in the measured values from the reference value may not exceed the limits pursuant to Article 2.3.2.

5.3.3 Storage of measured dose equivalent data

The measuring instrument is exposed to a dose equivalent value that will make the subsequent influence of the natural background negligible. Afterwards, the saved reading is read each hour for a period of 8 hours and compared with the original value.

In the next test, the measuring instrument is likewise exposed to a dose equivalent value that will make the influence of the natural background negligible. The batteries are then removed, and after 24 hours have passed are re-inserted into the measuring instrument. The stored data is compared to the original value.

Deviations in the measured values from the reference value may not exceed the limits pursuant to Article 2.3.3.

5.3.4 Test of resistance to overload

5.3.4.1 Test of resistance to dose equivalent overload

The test consists of irradiating the measuring instrument 10 times with a dose equivalent that is higher than the upper limit of the measurement range (though no higher than 10 Sv). When irradiating the measuring instrument in a collimated beam of gamma radiation with reproducible geometry and field size, the measuring instrument must display the maximum measurement range and indicate that it has been exceeded.

The measuring instrument's behaviour when overloaded must meet the requirements of Article 2.3.4.

5.3.4.2 Test of resistance to equivalent dose rate overload

The test consists of exposing the measuring instrument to an equivalent dose rate that is 10 times (max. 10 Sv/h) the upper limit of the measurement range. When irradiating the measuring instrument in a collimated beam of gamma radiation with reproducible geometry and field size, the measuring instrument must indicate an overload. When the radiation source is removed, the measuring instrument should return to normal measuring mode within 10 seconds.

The measuring instrument's behaviour when overloaded must meet the requirements of Article 2.3.4.

5.3.5 Indication that the set level has been exceeded

5.3.5.1 Response time for equivalent dose rate measurement and alarm

The test of the accuracy of indication that the set level has been exceeded is conducted by irradiating the measuring instrument in a collimated beam of gamma radiation with reproducible geometry and field size at each of the measurement ranges of the effective measurement range.

The measuring instrument is exposed to a rise or drop in equivalent dose rate, and the time required for the measuring instrument's response to reach 90 % of the change in reference value of the equivalent dose rate is recorded.

The measuring instrument's response time may not exceed the limits pursuant to 2.3.5.1.

5.3.5.2 Accuracy of indication that the set dose equivalent level has been exceeded

The test of the accuracy of indication that the set level has been exceeded is conducted by irradiating the measuring instrument in a collimated beam of gamma radiation with reproducible geometry and

field size. The test is conducted at a test point near the upper limit of the effective measurement range and at a test point near the second-lowest order of magnitude of the effective measurement range.

The measuring instrument is exposed to an equivalent dose rate that does not result in indication that the dose equivalent has been exceeded for at least 100 seconds. Then the time at which the measuring instrument begins to indicate that the set level has been exceeded is recorded. The ratio of the set indication level set and the product of the irradiation time and the equivalent dose rate used must lie within $0.87(1 - U_{rel})$ to $1.18(1 - U_{rel})$, where U_{rel} is the expanded ($k = 2$) uncertainty of the conventional true dose equivalent value.

The measuring instrument's behaviour must meet the requirements of Article 2.3.5.2.

5.3.5.3 Accuracy of signalling that the set equivalent dose rate level has been exceeded

The test of the accuracy of indication that the set level has been exceeded is conducted by irradiating the measuring instrument in a collimated beam of gamma radiation with reproducible geometry and field size. The test is conducted at a test point near the upper limit of the effective measurement range and at a test point near the second-lowest order of magnitude of the effective measurement range.

The equivalent dose rate measuring instrument is exposed to $(1 - U_{rel} - 2 \cdot \nu_{max})$ times the set equivalent dose rate value for 15 minutes and the cumulative time is measured after which the measuring instrument indicates that the set level has been exceeded. This period of time may not be longer than 5 % of the total time.

The measuring instrument is then exposed to $(1 + U_{rel} + 2 \cdot \nu_{max})$ times the set equivalent dose rate value and the cumulative time is measured after which the measuring instrument signals that the set level has been exceeded. This period of time may not be shorter than 95 % of the total time.

The measuring instrument must meet the requirements of Article 2.3.5.3.

5.3.6 Response to beta radiation

In this test, the measuring instrument is exposed to beta radiation $^{90}Sr/^{90}Y$ in a direction of radiation incidence of 0°.

Deviations in the measured values from the reference value may not exceed the requirements pursuant to Article 2.3.6.

5.4 Tests of resistance to environmental influences

5.4.1 Mechanical resistance tests

5.4.1.1 Shocks

An inspection of the measuring instrument's physical condition is conducted and its data is recorded. While in measuring mode, the measuring instrument is subjected to 60 falls (10 from each side) onto a steel surface from a height of 10 cm. After the test, another inspection of the measuring instrument's physical condition is conducted and its data is recorded. Dose data saved before the test may not be lost.

The measured value may not exceed the permissible change limits pursuant to Article 2.3.7.

5.4.1.2 Vibrations

An inspection of the measuring instrument's physical condition is conducted and its data is recorded. While in measuring mode, the measuring instrument is exposed to vibration loading of 20 m/s^2 for 15 minutes in each direction for one frequency between 10 Hz to 21 Hz and 22 Hz to 33 Hz. The indicated value is read after each vibration interval (15 minutes). After the test, another inspection of the measuring instrument's physical condition is conducted.

The measured value may not exceed the permissible change limits pursuant to Article 2.3.8.

5.4.1.3 Drop test

The measuring instrument, switched off and packaged for transport, is subjected to 6 drops (one from each side) onto a concrete surface from a height of 1 m. After the test, an inspection of the measuring instrument's physical condition is conducted, the measuring instrument is turned on, and its data is recorded once it has reached operating status. Dose equivalent data saved before the test must not be lost.

The measured value must not exceed the permissible change limits pursuant to Article 2.3.9.

5.4.2 Tests of resistance to climatic influences

5.4.2.1 Test of ambient temperature influence

Stable temperature:

The test is conducting while irradiating the measuring instrument with the dosimetric quantity at a constant rate. The measured values of the quantity determined as the arithmetic mean of at least ten measurements at the maximum and minimum of the required temperature range are compared to the reference value of the measured quantity determined at standard temperature. The measuring instrument must be subjected to individual temperatures for at least 4 hours; the measuring instrument's reading is recorded during the last 30 minutes of this period.

Temperature shock:

The test is conducting while irradiating the measuring instrument with the dosimetric quantity at a constant rate at standard temperature after stabilising the temperature for at least 60 minutes. The temperature is changed to the required values as quickly as possible and the measuring instrument's response is read every 15 minutes for a period of 2 hours. The values obtained are compared to the reference value of the measured quantity determined at standard temperature.

Switching the measuring instrument on at low temperature:

The switched-off measuring instrument is placed in a climate chamber that is set to the minimum value of the required temperature range. The measuring instrument is left in the chamber for a period of 4 hours. After that, the measuring instrument is turned on and its behaviour is observed.

The measured values must not exceed the permissible change limits pursuant to Article 2.3.10.

5.4.2.2 Humidity influence test

The test is conducting while irradiating the measuring instrument with the dosimetric quantity at a constant rate. The measured values of the quantity determined as the arithmetical mean of at least ten measurements at a relative humidity within 40 % to 90 % at a temperature of +35 °C are compared to the reference value of the measured quantity determined under standard conditions. The time measuring instrument must be subjected to individual moisture values for at least 24 hours; the measuring instrument's reading is recorded during the last 30 minutes of this period.

The measured value may not exceed the permissible change limits pursuant to Article 2.3.11.

5.4.2.3 Test of atmospheric pressure influence

The test is conducting while irradiating the measuring instrument with the dosimetric quantity at a constant rate. The measured values of the quantity determined as the arithmetical mean of at least ten measurements at pressure values of 86 kPa and 106.6 kPa are compared to the reference value of the measured quantity determined at the reference atmospheric pressure of 101.3 kPa.

The measured value may not exceed the permissible change limits pursuant to Article 2.3.12.

5.4.3 Electromagnetic compatibility (EMC) tests

5.4.3.1 Immunity to electrostatic discharge

Immunity to electrostatic discharge is tested with the measuring instrument switched on in its most sensitive measurement range via contact discharge of 4 kV or air discharge of 8 kV (in the case of measuring instruments with insulated surfaces). Discharges are applied to various external parts of the measuring instrument with which the operator may come into contact when using the measuring instrument. The total number of discharges is 10/hour.

In this test, the measured value may not exceed the limits specified in Article 2.3.13.

5.4.3.2 Immunity to a high-frequency electromagnetic field

Immunity to a high-frequency electromagnetic field is tested with the measuring instrument switched on in its most sensitive range in the frequency range of 80 MHz to 2.7 GHz at a test field amplitude of 30 V/m.

In this test, the measured value may not exceed the limits specified in Article 2.3.13.

5.4.3.3 Immunity to disturbances caused by rapid transients

Immunity to disturbances caused by rapid transients is tested at a voltage of ±2 kV. The total number of transients is 10/hour.

In this test, the measured value may not exceed the limits specified in Article 2.3.13.

5.4.3.4 Immunity to disturbances caused by overvoltage

Immunity to disturbances caused by overvoltage is tested at a voltage of ±1 kV or ±2 kV. The total number of disturbances is 10/hour.

In this test, the measured value may not exceed the limits specified in Article 2.3.13.

5.4.3.5 Immunity to interference caused by induced high-frequency fields

Immunity to interference caused by induced high-frequency fields is tested with the measuring instrument switched on in its most sensitive range in the frequency range of 150 kHz to 80 MHz at a voltage of 10 V. This test is only carried out on measuring instruments that have at least one conductor cable (e.g. for conducting a signal).

In this test, the measured value may not exceed the limits specified in Article 2.3.13.

5.4.3.6 Immunity to a 50 Hz/60 Hz magnetic field

Resistance to a magnetic field is tested with the device switched on in its most sensitive range at a frequency of 50 Hz or 60 Hz and a field intensity of 30 A/m. The test is conducted with the measuring instrument exposed to the magnetic field in two positions (0 ° and 90 °).

In this test, the measured value may not exceed the limits specified in Article 2.3.13.

5.4.3.7 Immunity to drops in voltage and brief interruptions

Resistance to drops in voltage and brief interruptions is tested at 500 ms (30 % drop), 200 ms (60 % drop) and 5000 ms (100 % drop), at least 10/hour.

In this test, the measured value may not exceed the limits specified in Article 2.3.13.

5.4.4 Power supply test

Battery capacity is tested with the measuring instrument switched on, with new batteries or fully charged rechargeable batteries, exposed to a equivalent dose rate between 10 µSv/h and 100 µSv/h. The measuring instrument is then left in uninterrupted operation for a period of 100 hours (primary battery) or 24 hours (rechargeable batteries).

The measuring instrument’s behaviour must meet the requirements specified in Article 2.3.14.

6 Initial verification

6.1 General information

The following tests are conducted during initial verification:

a) visual inspection;
b) device response linearity test;

6.2 Visual inspection

The purpose of the visual inspection of the measuring instrument is to check that:

a) the measuring instrument conforms with the approved type;
b) the measuring instrument is complete according to the type approval certificate;
c) individual parts of the measuring instrument are not damaged and are functional;
d) the software version matches the version approved during type approval.

6.3 Function tests

6.3.1 Device response linearity test

The device response linearity test is conducted pursuant to Article 5.3.1.

7 Follow-up verification

The follow-up verification is conducted by way of the same procedure as the initial verification pursuant to Chapter 6.

8 Measuring instrument examination

When examining measuring instruments pursuant to § 11a of the Metrology Act at the request of a person who may be affected by an incorrect measuring instrument, proceed according to Chapter 7. Two times the maximum permitted errors pursuant to Chapter 7 will be applied as the maximum permitted errors.

9 Notified standards

For the purposes of specifying the metrological and technical requirements for measuring instruments and specifying the testing methods for their type approval and verification arising from this General Measure, the CMI will provide notification of the Czech technical standards, other technical standards or technical documents of international or foreign organisations, or other technical documents containing more detailed technical requirements (hereinafter referred to as ‘notified standards’). The CMI will publish a list of these notified standards attached to the relevant measures, together with the measure of a general nature, in a manner accessible to the public (on www.cmi.cz).

Compliance with notified standards or parts thereof is considered, to the extent and under the conditions stipulated by a measure of a general nature, to be compliance with the requirements stipulated by this measure to which these standards or parts thereof apply.

Compliance with notified standards is one way of demonstrating compliance with the requirements. These requirements may also be met by using another technical solution guaranteeing an equivalent or higher level of protection of legitimate interests.

II.

G R O U N D S

The CMI issues, pursuant to § 14(1)(j) of the Metrology Act, for the implementation § 6(2), § 9(1) and (9) as well as § 11a(3) of the Metrology Act, this measure of a general nature, stipulating metrological and technical requirements for specified measuring instruments and test methods during type approval and verification of these specified measuring instruments – 'non-spectrometric activity meters and dosimeters used to monitor compliance with limits in the area of radiation protection or nuclear safety and for emergency measurement - electronic personal dosimeters for measuring gamma radiation and X-rays'.

Decree No 345/2002 laying down measurement instruments for mandatory validation and measurement instruments subject to type approval, as amended, classifies the measuring instruments under Items 8.5, 8.7, and 8.8 in the Annex to the Second List of Specified Measurement Instruments of the specified type as measurement instruments subject to type approval and mandatory validation.

This legislation (Measure of a General Nature) will be notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

III.

L E G A L I N S T R U C T I O N S

In accordance with § 172(l) APC, in conjunction with § 39(l) APC, the CMI has stipulated a time limit for comments of 30 days as of the date of posting on the official notice board. Comments submitted after this time limit will not be considered.

The persons concerned are hereby invited to comment on this draft General Measure. In light of the provisions of § 172(4) of the APC, the comments are submitted in written form.

In accordance with the provisions of § 174(l) APC in conjunction with § 37(l) APC, it must be clear who is making the comments, which measure of a general nature they address, how it contradicts legislation or how the measure of a general nature is inaccurate, and the signature of the person making the comment must be included.

The supporting documents for this draft Measure of a General Nature may be consulted at the Czech Metrological Institute, Department of Legal Metrology, Okružní 31, 638 00 Brno, upon appointment by telephone.

This measure of a general nature will be posted for 15 days.

...…….....

RNDr. Pavel Klenovský

Director-General

Person responsible for accuracy: Mgr. Tomáš Hendrych

Posted on:

Signature of the authorised person confirming posting: .....

Removed on:

Signature of the authorised person confirming removal: .....