Czech Metrology Institute
Okružní 31, 638 00 Brno

1. ------IND- 2018 0342 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 - portable dosimetric gamma radiation and X-ray meters used for purposes of radiation protection – are placed on the market and put into use in the Czech Republic pursuant to Act No 505/1990 on metrology, as amended.

The purpose of this notified regulation is to lay down metrological and technical requirements for these measuring instruments. This regulation also stipulates tests for type approval and verification.

(End of executive summary)

Author: Tomáš Hendrych
Telephone: +420 545 555 414

PUBLIC DECREE

As the authority with substantive and territorial jurisdiction in the matter of laying down metrological and technical requirements for legally controlled measuring instruments and stipulating the testing methods for type approval and verification of legally controlled measuring instruments pursuant to § 14(1) of Act No 505/1990 on metrology, as amended (hereinafter referred to as the 'Metrology Act'), and in accordance with the provisions of § 172 et seq. of Act No 500/2004, the Administrative Procedure Code (hereinafter referred to as the 'APC'), the Czech Metrology Institute (hereinafter referred to as the 'CMI') commenced ex officio proceedings on 4 April 2017 pursuant to § 46 APC, and, on the basis of supporting documents, issues the following:

I.

DRAFT GENERAL MEASURE

number: 0111-OOP-C081-16

laying down the metrological and technical requirements for legally controlled measuring instruments, including testing methods for verification of the following legally controlled 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 - portable dosimetric gamma radiation and X-ray meters used for purposes of radiation protection'

1. Basic definitions

For the purposes of this general measure, terms and definitions pursuant to VIM and VIML[1] and the following shall apply:

1.1
spatial dose equivalent $H^*(10)$

a dose equivalent that would be created by a corresponding ordered, expanded and rectilinear field at a depth of 10 mm in the ICRU sphere at the radius opposite the direction of the array.

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

1.2
spatial dose equivalent input $\dot{H}^*(10)$

quotient dH *(10)/dt, where dH*(10) is the increment of the spatial dose equivalent in the time interval dt.

The spatial dose equivalent input unit is Sv/s (Sv/min; Sv/h).

1.3
directional dose equivalent $H'(0.07)$

a dose equivalent that would be created in a corresponding expanded and rectilinear field in an ICRU sphere at a depth of 0.07 mm on the radius of vector-specified field direction.

The directional dose equivalent unit is Sv.

1.4
directional dose equivalent input $\dot{H}'(0,07)$

quotient dH'(0.07)/dt, where dH'(0.07) is the increment of the directional dose equivalent in the time interval dt.

The directional dose equivalent input unit is Sv/s (Sv/min; Sv/h).

1.5
reference point of the measuring instrument

physical mark or marks on the external surface of the measuring instrument for placing the measuring instrument at the test point.

1.6
test point

the point where the reference value of the measured figure is determined and where the reference point of the measuring instrument is placed for testing purposes.

1.7
measuring instrument response

response for the reference value of the figure $H_{r,0}$ measured under specific conditions

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

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

where $G_{r,0}$ is the suitable figure of the measuring instrument.

1.8
reference response

the ratio given under reference conditions by the relationship:

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

where G is the figure of the measuring instrument and H is the reference value of the measurement figure for the reference conditions.

1.9
relative response

ratio of response R and reference response R_0:

$$R = \frac{G}{H} \quad (3)$$

where G is the figure of the measuring instrument and H is the reference value of the figure.

1.10
effective measuring range

range of measured values of the figure that meets the requirements of the standard.

1.11
lower limit of the effective measuring range H_0

lowest value of the dose equivalent or its input that applies to the effective measuring range.

1.12
variation coefficient v

rate of relative data dispersion determined as a percentage of the standard deviation to the arithmetic mean in per cent.

2 Metrological requirements

2.1 Categorisation of measuring instruments

The categorisation of measuring instruments is stated in Table 1.

Table 1 – Categorisation of measuring instruments

Main category	Symbol	Minimum required range of use	Energy range	For range of angles	For dose equivalent impact	For dose equivalent
$H^*(10)$ gamma radiation	**G**	**energy:** 80 keV to 1.5 MeV **angle:** -45 ° to +45 ° **dose equivalent impact:**	**m:** lower limit 60 keV **l:** lower limit 20 keV	**w:** -90 ° to +90 °	**a:** upper limit 10 Sv/h **e:** lower limit 0.03 µSv/h	**a:** upper limit 2 Sv **f:** lower limit 10 µSv

		3 ranges in total 10 µSv/h **dose equivalent:** 3 ranges in total 0.1 mSv	**h:** total 6 MeV			**k:** lower limit 0.1 µSv
*H**(10) X radiation	**X**	**energy:** 20 keV to 150 keV **angle:** -45 ° to +45 ° **dose equivalent impact:** 3 ranges in total 10 µSv/h **dose equivalent:** 3 ranges in total 0.1 mSv	**l:** lower limit 10 keV **h:** total 300 keV	**w:** -90 ° to +90 °	**a:** upper limit 10 Sv/h **e:** lower limit 0.03 µSv/h	**a:** upper limit 2 Sv **f:** lower limit 10 µSv **k:** lower limit 0.1 µSv

continued

Table 1 – continued

Main category	Symbol	Minimum required range of use	Energy range	For range of angles	For dose equivalent impact	For dose equivalent
H′(0.07) gamma and X radiation	**S**	**energy:** 20 keV to 150 keV **dose equivalent impact:** 3 ranges in total 10 µSv/h **dose equivalent:** 3 ranges in total 0.1 mSv	**h:** total 300 keV **u:** total 1.3 MeV		**a:** upper limit 10 Sv/h **e:** lower limit 0.5 µSv/h	**a:** upper limit 2 Sv **f:** lower limit 10 µSv

2.2 Reference conditions and standard test conditions

The reference conditions and standard test conditions are listed in Table 2.

Table 2 – Reference conditions and standard test conditions

Influencing variable	**Reference conditions** (unless otherwise specified by the manufacturer)	**Standard test conditions** (unless otherwise specified by the manufacturer)
Photon radiation energy for: 1 − H*(10) – spatial dose equivalent 2 − H′(0.07) – directional dose equivalent	gamma radiation: ^{137}Cs or N-100 N-80 or ^{241}Am	gamma radiation: ^{137}Cs or N-100 N-80 or ^{241}Am
Beta radiation energy 2 − H′(0.07) – directional dose equivalent	^{90}Sr/^{90}Y	^{90}Sr/^{90}Y

Dose equivalent H*(10) H′(0.07)	 100 µSv 100 µSv	 10 µSv to 1 mSv [a)] 10 µSv to 1 mSv [a)]
Dose equivalent impact H*(10) H′(0.07)	 10 µSv/h 100 µSv/h	 3 µSv/h to 100 µSv/h [a)] 10 µSv/h to 1 mSv/h [a)]
Stabilisation period	15 minutes	≥15 minutes
Heat	20 °C	17 °C to 27 °C [a)]
Relative humidity	65 %	25 % to 75 % [a)]
Air pressure	101.3 kPa	86.0 kPa to 106.6 kPa [a)]
Power voltage	Nominal power voltage	Nominal power voltage ±1 %
Radiation impact angle	calibration direction provided by the manufacturer	Designated direction ±5 °
External electromagnetic field	negligible	less than the smallest value that causes the fault
External magnetic induction	negligible	less than twice the Earth's magnetic field value

continued

Table 2 – continued

Influencing variable	**Reference conditions** (unless otherwise specified by the manufacturer)	**Standard test conditions** (unless otherwise specified by the manufacturer)
Orientation of measuring instrument or dose equivalent (impact) monitor	to be specified by the manufacturer	specified orientation ± 5 °
Control of measuring instrument or dose equivalent (impact) monitor	settings for normal mode	settings for normal mode
Radiation background	0.1 µSv/h or less if appropriate	less than 0.25 µSv/h
Radioactive particle contamination	negligible	negligible
[a)] The actual value is determined in the test		

2.3 Largest permissible error

2.3.1 Linearity of response

Under standard conditions, the relative response of the measuring instrument across the effective measuring range must not exceed −15 % to +22 %.

2.3.2 Statistical fluctuation of response

Under standard conditions, the variation coefficient throughout the measuring range must not exceed:

for $H = H_0$ 15 %
for $H_0 < H < 11\ H_0$ $(16 - H/H_0)$ %
for $H \geq 11\ H_0$ 5 %

2.3.3 Energy and direction dependence of response

The relative response of the measuring instrument caused by the angle of incidence of radiation in the range of angles from 0 ° to ± 45 ° (relative to the reference radiation direction) and in the energy range:

10 to 250 keV (for H′(0,07) and X radiation), or
30 to 150 keV (for H*(10) and X radiation), or
80 keV to 1.5 MeV (for H*(10) and X radiation and gamma)

must be in the range from −29 % to +67 %.

2.3.4 Overloading

The measuring instrument must indicate overloading when the upper limit of the measuring range is exceeded. This requirement applies to all measuring ranges.

If a dose equivalent measuring instrument is exposed to a sufficiently high dose equivalent impact, which may cause an incorrect measuring instrument readout, the measuring instrument must indicate that it is unable to provide the correct data.

2.3.5 Period of response

The period of response is understood to be the period after which, in the event of a sudden increase or drop in the dose equivalent impact, the measuring instrument reading of the dose equivalent impact [I_i + 0,9 (I_f - I_i)] is reached, where I_i is the initial figure of the dose equivalent impact and I_f is the final figure of the dose equivalent impact. The required response time limits for the measuring instrument are shown in Table 3.

Table 3 – Requirements for the measuring instrument response time

Dose equivalent impact	**Period of response**(s)
1 μSv/h to 10 mSv/h	<10
>10 mSv/h	<2

If the dose equivalent of the measuring instrument is exposed to the dose equivalent impact, it must indicate a 91 % to 111 % increase in the dose equivalent within 10 seconds.

2.3.6 Signalling of exceeding the set level

Under standard conditions, the measuring instrument must not be exposed to 0.8 times the set value and must indicate if this value has been exceeded. A measuring instrument exposed to 1.2 times the set value must indicate that this value has been exceeded.

If the measuring instrument is equipped with multiple detectors, the requirements apply to each detector.

2.3.7 Resistance to mechanical shock

If the measuring instrument is subject to mechanical impacts during operation, the response-induced shock response is less than ±0.7 H_o (lower limit of the effective measuring range). There must be no mechanical damage and the information stored in the measuring instrument must not be lost.

2.3.8 Resistance to falls during transport

The measuring instrument packed for transport must be crash-proof. During a fall, there must be no mechanical damage to the measuring instrument and it must function normally when activated.

2.3.9 Ambient temperature

Changes in the measuring instrument's response caused by changing the ambient temperature in the range from −10 °C to +40 °C must not exceed −13 % to +18 % of the measuring instrument's response under standard test conditions. For measuring instruments intended for indoor use only, this requirement is valid in the temperature range from +5 ° C to +40 ° C. Such measuring instruments must be marked, for example, with the text ‘indoor use only’.

2.3.10 Relative humidity

Changes in the measuring instrument's response caused by changing the ambient humidity in the range of up to 85 % must not exceed -9 % to +11 % of the measuring instrument's response under standard test conditions.

2.3.11 Atmospheric pressure

Changes in the measuring instrument's response caused by changing the atmospheric pressure in the range from 70.0 kPa to 106.0 kPa must not exceed -9 % to +11 % of the measuring instrument's response under standard test conditions.

2.3.12 Shielding

For measuring instruments intended for outdoor environments, the shielding of the measuring instrument must be at least IP 53.

2.3.13 Resistance to electromagnetic interference

The maximum change in response (transient and permanent) induced by electromagnetic interference must not exceed ± 0.7 H_o (lower limit of the effective measuring range).

2.3.14 Power supply test

Portable measuring instruments of the dose equivalent (impact) must have battery power. The capacity of the batteries must be such that for a maximum of 40 hours of alternating use (i.e. 8 hours of continuous use followed by 16 hours deactivated for 5 consecutive days) the maximum readings of the measuring instrument are within ± 5 % and the other functions remain within the limit specifications.

3 Technical requirements

3.1 Unit indication

The measuring instrument of the dose equivalent or its impact must display a value in Sv or Sv/h.

3.2 Minimum measuring range

The minimum effective measuring range of the measuring instrument of the dose equivalent impact must cover at least three digital places and include 10 μSv/h (in the case of $H^*(10)$) or 0.1 mSv/h (in the case of quantity $H'(0.07)$). The minimum effective measuring range of the measuring instrument of the dose equivalent must cover at least three digit places and include 0.1 mSv.

3.3 Operating status information

The measuring instrument must indicate operating conditions for which the accuracy of the dose equivalent figure is not guaranteed, such as a dead battery, a detector failure or the dose equivalent impact being exceeded.

3.4 Easy decontamination

The measuring instrument must be designed to enable easy decontamination.

3.5 Protection against unauthorised tampering

The measuring instrument must be designed to prevent unintentional changes to any factor of the operation settings. The parts of the measuring instrument essential to its metrological characteristics must be designed to be secured in such a way as to provide proof of any unauthorised interference. The control elements must either be inside the measuring instrument and inaccessible from the outside without using tools, or be clearly marked and fitted with a scale so that they can be precisely adjusted according to the resolution of the measuring instrument and then locked in order for the settings not to be changed accidentally. Correction factors and calibration coefficients stored digitally may not be changed unless the operator enters the security code (or password) or changes the position of the blocked or inaccessible switch.

3.6 Safety

The measuring instrument must be safe in accordance with the basic principles of safety of ionising radiation installations and the requirements of relevant technical regulations under the conditions of normal use for the intended purposes.

4 Measuring instrument markings

4.1 Markings on the measuring instrument

The following information must be provided on each part of the measuring instrument, which may consist of two functionally separate parts:

Manufacturer identification;

Designation of the type of measuring instrument;

Serial number of the measuring instrument itself and assessment of the measuring unit;

Type approval mark;

Measured quantity and type of radiation;

Effective measuring range.

The position of the reference point must be indicated on the measuring instrument. The type and polarity of the batteries used must be indicated on the measuring instrument. All labels and inscriptions must be legible, durable, unambiguous and unalterable.

4.2 Placement of the official mark

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

Where possible, marks are to be placed on the front panel of the display unit so that they do not cover any of the data on the measuring instrument.

5 Type approval of the measuring instrument

5.1 General

The measuring instrument type approval process includes the following tests:

a) External inspection;
b) Linearity test and statistical fluctuation of response;
c) Energy and direction dependence of response test;
d) Overload resistance test;

e) Response time test;
f) Accuracy test for set level exceedance signalling;
g) Stabilisation period test;
h) Mechanical resistance test;
i) Tests of resistance to climatic influences;
j) EMC tests;
k) Power supply test.

5.2 External inspection

The external inspection assesses

a) the completeness of the prescribed technical documentation, including the operating instructions;
b) the conformity of the metrological and technical characteristics specified by the manufacturer in the documentation with the requirements of this regulation set out in chapters 2, 3 and 4.1;
c) the completeness and status of the functional units of the measuring instrument according to the prescribed technical documentation;
d) the software version of the measuring instrument with the version specified by the manufacturer.

5.3 Functional tests

5.3.1 Linearity test and statistical fluctuation of response

The linearity test is performed by irradiating the measuring instrument in a collimated gamma or X beam with reproducible geometry and field size. The measured value, determined as the arithmetic mean of at least ten statistically independent measurements, is compared with the reference value of the measured value determined by the standard. The test is performed at three test points for each decile of the measuring range (at 20 %, 40 % and 80 % of the decile).

The deviations of the measured values from the reference value must not exceed the limits in Article 2.3.1.

The test of the statistical fluctuation of the response is carried out simultaneously with the linearity test. A variation coefficient is established at all test points.

The variation coefficient must not exceed the limits specified in Article 2.3.2 more than 1.5 times. (The specific value of the admissible multiple is determined by the actual number of test points and the actual number of measurements.)

5.3.2 Energy and direction dependence of response test

The energy dependence response test is performed by irradiating the measuring instrument in the collimated X and gamma beam with reproducible geometry and a field size in the required energy range and the required range of angles. The measured value, determined as the arithmetic mean of at least ten measurements, is compared with the value of the measured value determined by the standard for reference values.

The measured value must not exceed the limits specified in Articles 2.3.3.

5.3.3 Overload resistance test

The overload resistance test consists of subjecting the measuring instrument to a dose equivalent (impact) value that is a multiple of the upper limit of the measuring range (a specific value for the multiplication is determined by the actual upper limit of the measuring range of the measuring instrument). When the measuring instrument is irradiated in a collimated gamma beam with reproducible geometry and field size, the measuring instrument must indicate an overload. After

removing the radiation source, the measuring instrument should return to the normal measurement mode within 5 minutes or display a warning that this is not possible.

The overload measuring instrument must comply with the requirements of Article 2.3.4.

5.3.4 Response time test

The response time of the measuring instrument test is performed by irradiating the measuring instrument in a collimated gamma beam with reproducible geometry and field size. The measuring instrument of the dose equivalent is exposed to different dose impact values for 10 seconds and then the measuring instrument readings are compared with the reference value of the dose equivalent.

The figure shown on the measuring instrument must not exceed the limits specified in Article 2.3.5.

The dose equivalent measuring instrument is exposed to varying rates of increase or decrease in the dose equivalent impact, recording the time at which the measuring instrument response reaches 90 % of the change in the reference value of the dose equivalent impact.

The response time of the measuring instrument must not exceed the limits specified in Article 2.3.5.

5.3.5 Accuracy test for set level exceedance signalling

The accuracy test for set level exceedance signalling is performed by irradiating the measuring instrument in a collimated gamma beam with reproducible geometry and field size. The test must be performed at the test point near the upper limit of the effective measuring range and at the test point near the second lowest digit of the effective measuring range.

The dose equivalent measuring instrument is exposed to such a dose equivalent impact that signalling does not occur for at least 100 seconds, and the time when the measuring instrument starts to signal the exceeded level is measured. The ratio of the set signalling level to the product of the irradiation time and the dose impact used must lie within a range from 0.8 $(1 - U_{rel})$ to 1.2 $(1 - U_{rel})$, where U_{rel} is the common ($k = 2$) uncertainty of the conventionally true value of the dose equivalent

The measuring instrument of the dose equivalent is exposed (0.8 - U_{rel}) times the set value of the dose equivalent impact over a period of 10 minutes, and the total time over which the measuring instrument signals the exceedance of the set level is measured. This period must not be any longer than 10 minutes. The measuring instrument is further exposed to (1.2 - U_{rel}) times the set value of the dose equivalent impact and the total time over which the measuring instrument signals the exceedance of the set level is measured. This period must not be any shorter than 9 minutes.

5.3.6 Stabilisation period test

The test is performed by irradiating the measuring instrument in a collimated gamma beam with reproducible geometry and field size. When the measuring instrument is activated, the value of the measuring instrument is recorded for 6 minutes (reading every 15 seconds). 30 minutes after the measuring instrument is activated, the final measured value is determined from a sufficient number measuring instrument readings.

The stabilisation period is defined as the time from which the deviation of the measuring instrument readings from the final measured value is less than 5 %. The stabilisation period is compared with the manufacturer's data.

5.4 Tests of resistance to environmental influences

5.4.1 Mechanical resistance test

5.4.1.1 Shocks

An inspection of the physical condition is carried out and a reading is taken from the measuring instrument. The measuring instrument in measuring mode is exposed to 60 falls (10 on each side) from

a height of 10 cm on the steel surface. After the test, the physical condition is again inspected and a reading is taken from the measuring instrument.

The measured value must not exceed the permitted change limits specified in Article 2.3.7. There must also be no mechanical damage and the information stored in the measuring instrument must not be lost.

5.4.1.1 Fall test

The deactivated measuring instrument packed for transport is exposed to 6 falls (one on each side) from a height of 1 m on a concrete surface. After the test, the physical condition is inspected, the measuring instrument is activated and the data from the measuring instrument is read after the operating mode has been reached.

There must be no mechanical damage and the information stored in the measuring instrument must not be lost. The meter must be fully operational after the test.

5.4.2 Tests of resistance to climatic influences

5.4.2.1 Ambient temperature impact test

The test is carried out by irradiating the measuring instrument with a constant input of the dosimetric quantity. The measured values of the quantity determined as the arithmetic mean of a minimum of ten measurements at the maximum and minimum temperatures of the desired temperature range are compared with the reference value of the measured value determined at the standard temperature. The exposure time of the measuring instrument at individual temperatures must be at least 4 hours, the measuring instrument readings are recorded over the course of the last 30 minutes.

The measured value must not exceed the permitted change limits specified in Article 2.3.9.

5.4.2.2 Humidity impact test

The test is carried out by irradiating the measuring instrument with a constant input of the dosimetric quantity. The measured values of the quantity determined as the arithmetic mean of a minimum of ten measurements at a relative humidity of up to 85 % at +35 ° C are compared with the reference value of the measured quantity determined under standard conditions. The exposure time of the measuring instrument to individual humidity values must be at least 4 hours, the measuring instrument readings are recorded over the course of the last 30 minutes.

The measured value must not exceed the permitted change limits specified in Article 2.3.10.

5.4.2.3 Atmospheric pressure impact test

The test is carried out by irradiating the measuring instrument with a constant input of the dosimetric quantity. The measured values of the quantity determined as the arithmetic mean of at least ten measurements at pressure values of 70 kPa and 106 kPa are compared to the reference value of the measured quantity determined at a reference atmospheric pressure of 101.3 kPa.

The measured value must not exceed the permitted change limits specified in Article 2.3.11.

5.4.3 Electromagnetic compatibility (EMC) test

5.4.3.1 Resistance to electrostatic discharge

Resistance to electrostatic discharge is tested on the measuring instrument in the most sensitive measurement range with a contact discharge of 4 kV or an air discharge of 8 kV (for measuring instruments with insulated surfaces). The discharges are applied to the various external parts of the measuring instrument that can be touched by the operator when using the measuring instrument. The total number of discharges is at least 10/hour.

In this test, the measured value must not exceed the limits given in Article 2.3.13.

5.4.3.2 Resistance to a high-frequency electromagnetic field

Resistance to a high-frequency electromagnetic field must be tested on the measuring instrument at the most sensitive range in the 80 MHz to 2 GHz frequency ranges at a test field amplitude intensity of 10 V/m. The measuring instrument is exposed to a dose equivalent impact of seven times the lower limit of the effective measuring range.

In this test, the measured value must not exceed the limits given in Article 2.3.13.

5.4.3.3 Resistance to radiated electromagnetic field by mobile phones and wireless networks

Resistance to a radiated high-frequency electromagnetic field must be tested on the measuring instrument at the most sensitive range in the presence of an electromagnetic field emitted by mobile phones and wireless networks in the 800 MHz to 960 MHz and 1.4 GHz to 2.7 GHz frequency ranges at an amplitude of test field strength of 30 V/m.

In this test, the measured value must not exceed the limits given in Article 2.3.13.

5.4.3.4 Resistance to induced interference by high-frequency fields

Resistance to induced interference by high-frequency fields is tested on the measuring instrument at the most sensitive range in the 150 kHz to 80 MHz frequency range at 10 V. This test is only performed on measuring instruments with at least one conductive cable (e.g. for signal conduction).

In this test, the measured value must not exceed the limits given in Article 2.3.13.

5.4.3.5 Resistance to a magnetic field of 50 Hz/60 Hz

Magnetic field resistance is tested on the measuring instrument at its most sensitive range of 50 Hz or 60 Hz at a field strength of 30 A/m. The test is performed with the magnetic field measuring instrument in two positions (0 ° and 90 °).

In this test, the measured value must not exceed the limits given in Article 2.3.13.

5.4.4 Power supply test

The battery capacity is tested on a measuring instrument with new batteries or fully charged batteries when activated at a dose equivalent between 10 μSv/h and 1 mSv/h. The measuring instrument is kept in activated mode for 8 consecutive hours and in deactivated mode for around 16 consecutive hours.

The measuring instrument data at the end of the test must not differ by more than 5 % from the measuring instrument data at the start of the test and the measuring instrument must not indicate low battery capacity.

6 Initial verification

6.1 General

During initial verification, the following tests are performed:

a) Visual inspection;
b) linearity response test of the instrument;

6.2 Visual inspection

During visual inspection of the measuring instrument, the following is assessed:

a) compliance of the measuring instrument with the approved type;
b) completeness of the measuring instrument according to the type approval certificate;

c) whether the individual parts of the measuring instrument are damaged and whether they are functioning;
d) the software version with the version approved during type approval.

6.3 Functional tests

6.3.1 Linearity response time test of the device

The linearity response test of the device is carried out in accordance with Article 5.3.1.

7 Subsequent verification

Subsequent verification is carried out in the same way as the initial verification in chapter 6.

8 Examination of the measuring instrument

When examining measuring instruments pursuant to § 11a of the Metrology Act at the request of a person who may be affected by an incorrect measurement, please proceed according to Chapter 7. The maximum permissible error used is double the maximum permissible errors pursuant to Chapter 7.

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 shall notify 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 shall publish a list of these notified standards attached to the relevant measures, together with the general measure, 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 general measure, 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.

SUBSTANTIATION

The CMI issues, pursuant to § 14(1)(j) of the Metrology Act, towards the implementation of § 6(2), § 9(1), § 9(9) and § 11a(3) of the Metrology Act, this general measure, laying down metrological and technical requirements for the specified measuring instruments and test methods for the type approval and verification of the 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 - portable dosimetric gamma radiation and X-ray meters used for purposes of radiation protection'.

Implementing Decree No 345/2002 specifying measuring instruments for mandatory verification and measuring instruments subject to type approval, as amended, classifies the measuring instruments under

items 8.7, 8.8 and 8.11 in the annex entitled ‘List of legally controlled measuring instruments’ as measuring instruments subject to type approval and mandatory verification.

This legislation (general measure) 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.

INFORMATION

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 the draft 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. With regard to the provisions of § 172(4) APC, comments are to be submitted in writing.

Pursuant to the provisions of § 174(1) APC, in conjunction with the provisions of § 37(1) APC, it must be clearly stated who is submitting the comments, which general measure the comments concern, how the draft contradicts legislation or how the general measure is inaccurate. The comments must also contain the signature of the person making the comments.

The supporting documents for this draft general measure may be consulted at the Czech Metrology Institute, Legal Metrology Department, Okružní 31, 638 00 Brno, after making arrangements by telephone.

This draft general measure shall be posted for 15 days.

...…….....

Pavel Klenovský

Director-General

Person responsible for accuracy: Tomáš Hendrych

Posted on:

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

Removed on:

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