

1. -----IND- 2018 0341 CZ- CS- ----- 20180803 --- --- PROJET

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

Installed measuring instruments, warning assemblies and monitors for dosimetric gamma radiation and X-rays with energies from 50 keV to 1.5 MeV 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)

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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 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:

#### T.

# DRAFT GENERAL MEASURE

number: 0111-OOP-C080-16

laying down the metrological and technical requirements for legally controlled measuring instruments, including testing methods for verification of the following legally controlled measuring instruments:

'installed measuring instruments, warning assemblies and monitors for dosimetric gamma radiation and X-rays with energies from 50 keV to 1.5 MeV'

#### 1. Basic definitions

For the purposes of this general measure, terms and definitions pursuant to VIM and VIML<sup>1</sup> and the following shall apply:

#### 1.1

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

a dose equivalent that would be produced in the corresponding aligned, expanded and oriented field at a depth of 10 mm in the ICRU sphere on the radius opposing the direction of the aligned field. The spatial dose equivalent unit is Sv (J/kg).

## 1.2

# spatial dose equivalent rate ${\it PF}^{*}(10)$

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

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

#### 1.3

#### kerma in the air Ka

quotient dE (sum of the initial kinetic energies of all charged particles released by uncharged ionising particles in the given air mass) and dm (this weight).

The kerma in the air unit is Gy (J/kg).

#### 1.4

#### kerma in the air rate Ka

quotient dKa/dt, where dKa is the increment of kerma in the air in the time interval dt.

The kerma in the air rate unit is Gy/s (Gy/min; Gy/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

$$R_0 = \frac{G_{r,0}}{H_{r,0}} \tag{1}$$

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

<sup>&</sup>lt;sup>1</sup> 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.

#### 1.8

## reference response

the ratio given under reference conditions by the relationship

$$R = \frac{G}{H} \tag{2}$$

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  $R_0$ :

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

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 Article 2.3

#### 1.11

# lower limit of the effective measuring range $H_0$

lowest value of the dose equivalent or its rate 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

#### 1.13

#### dose rate monitor

assembly that fulfils both the function of the dose rate monitor and the dose rate warning assemblies

# 2 Metrological requirements

## 2.1 Design and execution

The device can be designed as a simple assembly in which the detector is attached to the assembly or part of the assembly or is separate from the rest of the device. In this case, the detector may be up to 10 m from the electronic part (main amplifier) and the detector and main amplifier from the indication and warning subassembly may be up to 100 m or more.

The device must measure the dose rate of X and gamma radiation in the energy range of at least 80 keV to 1.5 MeV. A response to lower energy of up to 50 keV and higher energy of up to 7 MeV may be stated. The measuring range of the device must be at least three full decades of dose rate; many applications may require five or more decades. Manually switching ranges must be avoided.

The design of the device must take account of the practical use of the assemblies, it may be required to measure radiation fields coming from different angles relative to the location of the device. (Radiation from distributed sources routinely emanates from walls and steel structures. Sometimes the 'front' layout  $(2\pi)$  corresponds best to the requirements, in other cases the 'side' layout, where it is required to be closer to the  $4\pi$  geometry, but the 'rear' response requirements are lower).

Assemblies shall be designed to minimise as far as possible undesirable responses to electromagnetic and ionising radiation other than X and gamma radiation.

#### 2.2 Reference conditions and standard test conditions

The reference conditions and standard test conditions are listed in Table 1.

Table 1 – 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)
Reference source of gamma radiation	<sup>137</sup> Cs	<sup>137</sup> Cs
Stabilisation period	30 minutes	>30 minutes
Heat	20 °C	18 °C to 22 °C
Relative humidity	65 %	50 % to 75 %
Air pressure	101.3 kPa	70 kPa to 106 kPa

continued

Table 1 – continued

Influencing variable	Reference conditions (unless otherwise specified by the manufacturer)	Standard test conditions (unless otherwise specified by the manufacturer)
AC supply voltage	sinusoidal	sinusoidal with a total harmonic distortion of less than 5 %
Radiation background	0.1 μGy/h	lower than 0.25 µGy/h
Radiation impact angle	calibration direction provided by the manufacturer	Designated direction ±10°
External electromagnetic field	negligible	less than the smallest value causing interference
External magnetic field	negligible	less than twice the Earth's magnetic field value
Assembly position	to be specified by the manufacturer	specified orientation $\pm$ 10 $^{\circ}$
Assembly controls	settings for normal mode	settings for normal mode
Radioactive particle contamination	negligible	negligible

# 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  $\pm 30$  %.

#### 2.3.2 Statistical fluctuation of response

Under standard conditions, the variation coefficient must not exceed 20 % in the most sensitive measurement range and 10 % in all other ranges.

## 2.3.3 Energy dependence of response

The relative response of the measuring instrument in the reference direction of the radiation incident in the energy range from 80 keV to 1.5 MeV must lie within the range of -25 % to +40 % relative to the reference gamma radiation  $^{137}\text{Cs}$ .

# 2.3.4 Directional dependence of response

Directional dependence of the measuring instrument in the 80 keV to 1.5 MeV energy range must fulfil the following criteria:

for 661.6 keV:  $0^{\circ}$ ,  $\pm 15^{\circ}$ ,  $\pm 30^{\circ}$ ,  $\pm 45^{\circ}$ ,  $\pm 60^{\circ}$  maximum deviation  $\pm 20^{\circ}$ % for 83 keV:  $0^{\circ}$ ,  $\pm 15^{\circ}$ ,  $\pm 30^{\circ}$ ,  $\pm 45^{\circ}$ ,  $\pm 60^{\circ}$  must be defined by the manufacturer for 59.5/60 keV:  $0^{\circ}$ ,  $\pm 15^{\circ}$ ,  $\pm 30^{\circ}$ ,  $\pm 45^{\circ}$ ,  $\pm 60^{\circ}$  maximum deviation  $\pm 30^{\circ}$ % (where applicable)

# 2.3.5 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 rate, which may cause an incorrect measuring instrument readout, the measuring instrument must indicate that it is unable to provide the correct data.

After overloading, the measured value must not differ by more than  $\pm$  10 % from the value measured before this test.

# 2.3.6 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 rate, the measuring instrument reading of the dose equivalent rate  $(I_i + 0.9 (I_f - I_i))$  is reached, where  $I_i$  is the initial figure of the dose equivalent rate and  $I_f$  is the final figure of the dose equivalent rate. The required response time limits for the measuring instrument are shown in Table 2.

Dose equivalent rate (PDE)	Period of response (s)
<60 μGy/h (μSv/h)	<60
60 μGy/h (μSv/h) - 1 mGy/h (mSv/h)	$(60 - \frac{PDE - 60 \mu Gy / h(\mu Sv / h)}{940 \mu Gy / h(\mu Sv / h)} \times 50)$
>1 mGy/h (mSv/h)	<10

Table 2 – Requirements for the measuring instrument response time

#### 2.3.7 Time constant and alert stability

Under standard conditions, the measuring instrument must not be exposed to 0.9 times the set value and must indicate if this value has been exceeded. A measuring instrument exposed to twice the set value must indicate that this value has been exceeded immediately.

If the meter has multiple alarm levels, the above requirements apply to each alarm level.

#### 2.3.8 Response to beta radiation

The measuring instrument must have as little sensitivity to beta radiation as possible. The value of the dose equivalent rate specified must be less than 10 % of the value of the dose equivalent rate to which the measuring instrument is exposed.

#### 2.3.9 Resistance to mechanical shock

If the measuring instrument is subject to mechanical impacts during operation, the response-induced shock response is less than  $\pm$  15 % compared to the measuring instrument's response before the test. No alarms may be activated or functional changes made.

# 2.3.10 Ambient temperature

Changes in the measuring instrument's response caused by changing the ambient temperature in the range from -25 °C to +40 °C must not exceed  $\pm$  15 % of the measuring instrument's response under standard test conditions. Changes in the measuring instrument's response caused by changing the ambient temperature in the range from +40 °C to +55 °C must not exceed  $\pm$  25 % 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 +10 °C to +50 °C. Such measuring instrument must be marked, for example, with the text 'indoor use only'.

#### 2.3.11 Relative humidity

Changes in the measuring instrument's response caused by changing the ambient humidity in the range from 40 % to 93 % must not exceed  $\pm$  15 % of the measuring instrument's response under standard test conditions

#### 2.3.12 Radiation interference

Emission limits for electromagnetic radiation must be less than 30 dB (for the emission frequency range from 30 MHz to 230 MHz) and less than 37 dB (for the emission frequency range from 230 MHz to 1 000 MHz).

#### 2.3.13 Resistance to electromagnetic interference

The maximum change in response (transient and permanent) induced by electromagnetic interference must not exceed  $\pm$  15 %.

# 3 Technical requirements

#### 3.1 Unit indication

The measuring instrument must display the value in Sv (Sv/h) or in Gy (Gy/h).

## 3.2 Minimum measuring range

The minimum effective measuring range of the measuring instrument must cover at least three digital places. In some cases, up to five or more measurement ranges may be required.

# 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 rate being exceeded.

#### 3.4 Alarms

The measuring instrument must be designed and constructed to signal that the selected alarm has been exceeded.

#### 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:

- a) Manufacturer identification;
- b) Designation of the type of measuring instrument;
- c) Serial number of the measuring instrument itself and the assessment unit;
- d) Type approval mark;
- e) Measured quantity and type of radiation;
- f) 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) Test of exceeding the set level (response and alarm stabilisation periods);
- g) Stabilisation period test;
- h) Test of response to beta radiation;
- i) Mechanical resistance test;
- j) Tests of resistance to climatic influences;
- k) EMC tests.

# 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 (SW) 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 decade of the measuring range (at 25 %, 50 % and 75 % of the decade).

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.

## 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 (83 keV, 100 keV, 118 keV, 164 keV, 208 keV, 662 keV and 1 250 keV) and the required range of angles (0 °,  $\pm$  15 °,  $\pm$  30 °,  $\pm$  45 °,  $\pm$  60 °). 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. (energy dependence) and 2.3.4 (directional dependence).

# **5.3.3** Overload resistance test

The overload resistance test consists of subjecting the measuring instrument to a dose equivalent (rate) value that is 10 times the upper limit of the measuring range. 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 10 minutes or display a warning that this is not possible.

The overload measuring instrument must comply with the requirements of Article 2.3.5.

#### **5.3.4** Response time test

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

The response time of the measuring instrument must not exceed the limits specified in Article 2.3.6.

## 5.3.5 Time constant and alert stability

The time constant and alert stability test is performed by irradiating the measuring instrument in a collimated gamma beam with reproducible geometry and field size. The test is performed at one test point of the dose equivalent rate.

The measuring instrument of the dose equivalent is exposed to 0.9 times the set dose equivalent rate signalling level. The measuring instrument must not signal the exceedance of the set signalling level for 1 minute.

The measuring instrument of the dose equivalent is exposed to double the set dose equivalent rate signalling level. The measuring instrument must immediately signal the exceedance of the set signalling level for 1 minute.

The same test is performed again after 24 hours.

#### 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 30 minutes (reading every 30 seconds). 30 minutes after the measuring instrument is activated, the final measured value is determined from 10 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 10 %. The stabilisation period is compared with the manufacturer's data.

#### **5.3.7** Response to beta radiation

In this test, the measuring instrument is exposed to beta  $^{90}Sr/^{90}Y$  radiation in the 0 ° radiation direction. The measured value must not exceed the requirements of Article 2.3.8.

## 5.4 Tests of the dosimeter's 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 18 shocks (3 on each side) of 1 J of energy. After the test, the physical condition is again inspected and the measuring instrument read.

The measured value must not exceed the permitted change limits specified in Article 2.3.9. No alarms may be activated or functional changes made.

#### **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 dosimetric rate. The measured values of the quantity determined as the arithmetic mean 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 16 hours, the measuring instrument readings are recorded every 60 minutes.

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

# 5.4.2.2 <u>Humidity impact test</u>

The test is carried out by irradiating the measuring instrument with a constant dosimetric rate. The measured values of the quantity determined as the arithmetic mean at a relative humidity of up to 93 % at +35 °C are compared with the reference value of the measured quantity determined under standard conditions. The exposure time of the measuring instrument at individual humidities must be at least 24 hours, the measuring instrument readings are to be recorded every 2 minutes.

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 Radiation interference

The radiation interference must be tested on the measuring instrument at the most sensitive measuring range in the frequency range of 30 MHz to 230 MHz and 230 MHz to 1 000 MHz with a 50 kHz bandwidth.

In this test, the measured value must not exceed the limits given in Article 2.3.12.

# 5.4.3.2 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 dosimeter that can be touched by the operator when using the measuring instrument. The total number of discharges is at least 5.

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

## 5.4.3.3 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 1~GHz and 1.4~GHz to 2.5~GHz frequency ranges at a test field amplitude intensity of 10~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 disturbances caused by rapid transients

Resistance to disturbances caused by rapid transients is tested at a voltage of  $\pm 2$  kV.

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

#### 5.4.3.5 Resistance to disturbances caused by overvoltage

Resistance to disturbances caused by overvoltage is tested at  $\pm 1$  kV or  $\pm 2$  kV.

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

# 5.4.3.6 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.

#### 5.4.3.7 Resistance to circular waves

Resistance to induced interference must be tested on the measuring instrument at the most sensitive range at a frequency of 1 MHz + 10 %, a main voltage between 50 Hz and 400 Hz and an unsynchronised network frequency.

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

## 5.4.3.8 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  $^{\circ}$  and 90  $^{\circ}$ ).

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

#### 5.4.3.9 Resistance to a drop in voltage and a short interruption

Resistance to a drop in voltage and a short interruption is tested at 500 ms (30 % decrease), 200 ms (60 % decrease) and 5 000 ms (100 % decrease), at least 10 times per hour.

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

# 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 dosimeter, 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 SW 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 measuring instrument is performed according to Article 5.3.1, while only one dose value of the dose equivalent rate is tested in each measuring range, at 50 % to 75 % of each decade.

# 7 Subsequent verification

Subsequent verification is carried out in the same way as the initial verification in 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 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 <a href="https://www.cmi.cz">www.cmi.cz</a>).

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.

# **GROUNDS**

The CMI issues, pursuant to  $\S$  14(1)(j) of the Metrology Act, towards the implementation of  $\S$  6(2),  $\S$  9(1),  $\S$  9(9) and  $\S$  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 - 'installed measuring instruments, warning assemblies and monitors for dosimetric gamma radiation and X-rays with energies from 50 keV to 1.5 MeV'.

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.

## **INSTRUCTIONS**

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 general draft 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:	