Czech Metrology Institute
Okružní 31, 638 00 Brno

1. ------IND- 2018 0340 CZ- EN- ------ 20180803 --- --- PROJET

Executive summary for the EC (not part of this legal regulation)

Non-spectrometric activity and dose measuring instruments used to check for compliance with radiation protection or nuclear safety limits and for the measurement of emergency portable surface contamination measuring instruments are placed on the market and put into use in the Czech Republic pursuant to Act No 505/1990 on metrology, as amended.

The subject of this notified regulation is to determine the metrological and technical requirements for these measuring instruments. The regulation also provides for tests for type approval and verification purposes.

(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 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 4.4.2016 pursuant to § 46 of the CAP, and, based on supporting documents, issues the following:

I.

DRAFT GENERAL MEASURE

number: 0111-OOP-C079-16

laying down the metrological and technical requirements for the specified measuring instruments, including the testing method verification of the specified instruments:

"Non-spectrometric activity and dose measuring instruments used to check for compliance with radiation protection or nuclear safety limits and for emergency measurements – portable measuring instruments for surface contamination"

1 Basic definitions

The terms and definitions pursuant to the VIM and VIML[1] as well as the following terms and definitions shall apply for the purposes of this General Measure:

1.1

non-spectrometric activity and dose measuring instruments used to check for compliance with radiation protection or nuclear safety limits and for the measurement of emergency

radiation meters and monitors designed for direct measurement or direct detection of surface contamination by radionuclides emitting alpha or beta radiation and determination of the relationship to established limits

1.2

alpha and alpha/beta surface contamination meter

a device containing one or more radiation detectors and associated devices or basic functional units designed to measure the alpha (or beta or alpha/beta) emission of the surface area responsible for the contamination of the measured surface

1.3

alpha and alpha/beta surface contamination monitor

an alpha (or beta or alpha/beta) activity meter equipped with means for providing a clear warning when the indicated area emission input per unit area exceeds a certain adjustable set value

1.4

area emission input (of a source)

the number of particles of a given type with energy above a given threshold that emanates from the source area or its window per unit of time

1.5

source efficiency

the ratio between the number of particles of a given type with energy above a given threshold that emanate from the front surface of the source or its window per unit of time (area emission input) and the number of particles of the same type produced or released in the source (for minor source) or its saturation layer (for a large source) per unit of time

1.6

high-efficiency source

a source that has an efficiency per particle with an energy greater than 5.9 keV including backscattered particles greater than 0.25 (this definition applies to beta sources with a maximum energy of > 150 keV)

1.6

small-area source

a source whose active surface area has a maximum linear dimension not exceeding 1 cm

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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.

1.8
response to area emission input (device efficiency)
in case of set requirements specified by the manufacturer (sensitive area of the detector, sensitive area of the source and distance between the source and the detector) – response to the area emission (efficiency) of the detector used in conjunction with the devices, the ratio of the number of detected particles (for example the number of pulses per unit of time corrected in the background) to the number of particles of the same type emitted by the radiation source at the same time interval (conventionally the value of the area emission input)

1.9
sensitive area of the detector
the detector area defined by the manufacturer where the efficiency per source with a small area is greater than 50% of the maximum efficiency

1.10
total equivalent thickness
the thickness usually expressed as the weight per unit of area, which particles (alpha or beta) emitted usually from the contaminated surface pass to achieve a sensitive volume of the detector

1.11
specification error
the difference between the indicated value of the variable ν and the conventionally right value of the variable ν_c at the measurement point; expressed as ($\nu - \nu_c$)

1.12
response
ratio of the indicated value of the monitor or meter and conventionally true value:

$$R = \frac{\nu}{\nu_c} \tag{1}$$

Where ν is the value of the quantity measured by the test apparatus or device and ν_c is the conventionally true value of this variable

1.13
relative specification error *I*
ratio of specification error of the measured variable and conventional true value of the variable; may be expressed as a percentage

$$I(\%) = \frac{\nu - \nu_c}{\nu_c} \times 100 \tag{2}$$

where ν is the indicated value of the variable, and ν_c is the conventionally true value of the variable at the point of measurement

1.14
variation coefficient *V*
the ratio of the standard deviation *s* and the arithmetic mean of the $\bar{x}$ set of measurements $n\bar{x}$, given by the equation:

$$V = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \sqrt{\frac{1}{n-1} \sum_{i=1}^{n} (x_i - \bar{x})^2} \tag{3}$$

1.15
detection limit of the area emission input per unit of area
for a given radionuclide

$$DL = \frac{R_n}{S_{(nuclide)} A} \tag{4}$$

where $S_{(nuclide)}$ ..... is the response to the area emission input (see 1.4),
A ..... sensitive area of the detection device,
R_n ..... lower detection limit of pure pulse frequency

For the lower detection limit of the pulse frequency, the following equation applies to the preselected time and the known background pulse frequency:

$$R_n = (k_{1-\alpha} + k_{1-\beta}) \sqrt{R_o \left(\frac{1}{t_o} + \frac{1}{t_n} \right)} \tag{5}$$

where R_o ..... is the pure background pulse frequency,
t_o ..... background measurement time,
t_n ..... sample measurement time,
$k_{1-\alpha}$ ..... quantile of normal distribution for the probability of an error of the first type,
$k_{1-\beta}$ ..... quantile of normal distribution for the probability of an error of the second type,

1.16
detection device
a device containing at least one detector

1.17
evaluation device
a device showing the level of contamination detected

2 Metrological requirements

2.1 Working conditions

The working conditions of the measuring instrument are determined by the manufacturer. The measuring instrument must meet the metrological requirements within the specified working conditions.

2.2 Measurement range

The manufacturer must establish an effective measurement range for all scales of each measured variable. For devices with more than one scale for one variable, the effective measurement ranges of the scales must overlap.

For devices with linear scales, the effective measurement range must be between 10% and 100% of each scale range.

For devices with logarithmic scales, the effective measurement range must be from the third of the least significant decade to the full scale.

For devices with digital scales, the effective measurement range must be from the beginning of the second least significant digit to the full scale.

2.3 Maximum permissible error

The relative error of the measured value relative to the reference radiation under reference conditions for the area reference radionuclide must not exceed ± 25% over the full effective range.

2.4 Response of the measuring instrument

2.4.1 Response of the measuring instrument to the area emission input

Response to the area emission input must be within ± 25% of the value specified by the manufacturer.

2.4.2 Dependence of the response of the measuring instrument on the area emission input to the source position

The response of a device to a source with a small area located on the test surface varies according to the position of the source relative to the detector and the permeability of the grid.

No response may be less than half the maximum response found in the test.

2.4.3 Dependence of the response of the measuring instrument on the area emission input to the radiation energy

The requirement for the area emission input specified in Article 2.4.1 must also be fulfilled for the different beta energies distributed as follows:

- one energy of up to 0.2 MeV;
- one energy of between 0.2 MeV and 0.5 MeV;
- one energy greater than 0.5 MeV.

2.4.4 Relative basic error

Under rated conditions, the relative basic error for the associated reference radionuclide must not exceed the full effective measurement range by ± 25%.

2.5 Statistical fluctuation

In case of repeated measurements of the standard activity source by the same gauge while maintaining the same geometry, the variation coefficient must not exceed 0.2.

2.6 Response time

The response time must be such that, after a sudden change in the contamination measured, the indicated value is reached within a period of less than 7 seconds when the signal is increased and 10 seconds when the signal is reduced:

$$M_p + \frac{90}{100}\left(M_k - M_p\right) \tag{6}$$

where M_p ..... is the starting point,

M_k ..... final figure.

2.7 Overload

For activities greater than the maximum value of the measurement range, the device indicator deviation must swerve off the scale at its upper end and must remain there or indicate an overload. The device must return to its normal state once the overload has been rectified.

2.8 Start-up time

The indicated value must reach ± 25% of the final value after one minute after the device has been turned on and ± 20% after two minutes.

2.9 Influence of the environment

2.9.1 Temperature stability

The difference between the measured values at the lower and upper limit values of the ambient operating temperature range may not be

- greater than ±15% for a temperature range from +10 °C to +35 °C for indoor use in buildings;
- greater than ±20% for a temperature range from -10 °C to +40 °C for outdoor use;

2.9.2 Sudden temperature changes

If the temperature changes suddenly within a period shorter than 5 minutes

- from a temperature of +20 °C to +35 °C or from a temperature of +20 ° C to +10 ° C for indoor use in buildings;
- from a temperature of +20 °C to +40 °C or from a temperature of +20 ° C to −10 ° C for outdoor use;

the measured values must not change more than twice the measured values at a temperature of 20 °C.

2.9.3 Activation at a low temperature

After exposure to the lowest set operating temperature for 4 hours while deactivated, the measuring instrument must operate as required in Article 2.9.1.

2.9.4 Relative air humidity

The relative air humidity range must be 40% to 85%.

The difference in the measured value at the bottom range of relative humidity of 40% and at relative humidity of the range of relative humidity of 85% must be less than ±7.5%.

3 Technical requirements

3.1 General

The radiation meters and monitors consist of two parts:

- a detector device (comprising a gas detector, a scintillation detector or a semiconductor detector, etc.), which can be either fixed or wired, or built into a single device;
- an evaluation device.

This regulation applies to:

- alpha surface contamination meters/monitors;
- beta surface contamination meters/monitors;
- alpha/beta surface contamination meters/monitors;

If the device was designed to perform combined functions, it must meet the requirements applicable to these different functions. If, on the other hand, it is intended to perform one function and is also capable of performing other functions, then it must meet the requirements for the first function and it is desirable that it meet the requirements for the other functions.

3.2 Detection device

The detection device must be designed in such a way that the sensing surface of the detector can be located in the case of alpha detectors closer than 5 mm and, in the case of beta detectors, closer than 10 mm to the measured surface.

If the sensitive surface of the detector is equipped with a grid, the manufacturer must give the nominal uncertainty caused by this grid. The thickness of this protective grid must be such that the shading effect is minimised for all input angles.

Both the total and the sensitive areas of the detector must be indicated.

If the detector requires a gas supply, the manufacturer must specify the required gas type and flow rate.

3.3 Response to other ionising radiation

The surface contamination measuring instrument must be designed to minimise the impact of other ionising radiation.

3.4 Device indication

In addition to the visual indication of the pulse frequency, an acoustic indication of the pulse frequency must be provided.

The calibration controls must be protected against unauthorised adjustment.

3.5 Display

The data displayed by the device must be expressed in pulses per unit of time, or it can be used in units of activity or activity per unit of area.

3.6 Mechanical shocks

Portable devices must be capable of withstanding a mechanical shock from all directions with a peak acceleration of 300 $m \cdot s^{-2}$ (~30 g) in the form of 18 ms, the shape of the impact being semi-sinus.

3.7 Electromagnetic compatibility

3.7.1 Resistance to electrical and electromagnetic interference

The measuring instrument must not be affected by electrical and electromagnetic interference from the environment. After testing the electromagnetic compatibility in the laboratory, the measuring instrument must have a normal function.

3.7.2 Electromagnetic field emissions

The measuring instrument must not radiate an electromagnetic field during operation which could adversely affect the operation of other systems.

3.8 Safety

The characteristics of the measuring instrument must meet the requirements of the basic safety principles and the requirements of the technical regulations that the measuring instrument is safe under the conditions of its ordinary intended use.

4 Marking of the measuring instrument

4.1 Markings on the measuring instrument

The following information must be displayed on the measuring instrument:

manufacturer identification;

designation of the type of measuring instrument;

serial number of the measuring instrument;

type approval mark;

information on the safety of the measuring instrument.

All labels and inscriptions must be legible, permanent, unambiguous and unchangeable by ordinary means.

4.2 Location of the official mark

The location of the official marks must be stated in the type approval certificate.

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

5 Measuring instrument type approval

5.1 General

The measuring instrument type approval process includes the following tests:

a) External inspection;
b) Response to the area emission input;
c) Dependence of the response on the area emission input to the source position
d) Relative basic error (linearity);
e) Dependence of the response on the area emission input to the radiation energy;
f) Statistical fluctuation;
g) Response time;
h) Overload;
i) Start-up time;
j) Influence of the environment;
k) EMC 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 and 3;
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 Area emission input response test

The area emission input response test is performed with a standard source with an area which covers the entire sensitive area of the detector. If such a source is unavailable, a reference gauge with an area smaller than the detector area must be used. In this case, the measurements must be taken at different points in succession so that the detector area is covered. The true value of the area emission of the standard source must be known with an error of less than ±10%.

When testing the response to the area emission input, the result of the measurement must meet the requirements of Article 2.4.1.

5.3.2 Test of the dependence of the response on the area emission input to the source position

The test is performed using a source with a small area. The sensitive surface of the detector must be divided into nearly the same areas as the dimensions as closely as possible to (25 × 25) mm. If this dimension cannot be fulfilled, the dimensions are chosen so that each area is the same. The radiation source is placed in the centre of each region and the response is measured.

The measurement results must fulfil the requirements of Article 2.4.2.

5.3.3 Relative basic error (linearity) test

For the test, a set of sources of activity of one radionuclide over the known activity and the same geometry must be used to cover the measurement range of the device. For each measurement, the ratio of the expected value and measured value is calculated.

The calculated deviations must meet the requirements of Article 2.4.4.

5.3.4 Test of the dependence of the response on the area emission input to the radiation energy

The test must be carried out in accordance with Article 5.3.2 with at least three beta sources of energy having the maximum energy distributed as follows:

- one energy of up to 0.2 MeV
- one energy of between 0.2 MeV and 0.5 MeV
- one energy up to 0.5 MeV

The measurement results must fulfil the requirements of Article 2.4.1.

5.3.5 Statistical fluctuation test

The device is irradiated with a radiation source that gives an indication between one third and one half of the device's measurement range. At least 20 readings are performed.

The calculated variation coefficient must fulfil the requirement in Article 2.5.

5.3.6 Response time test

Measurements are made for both increasing and decreasing the pulse frequency data.

In a test with an increasing pulse frequency, the measuring instrument is subject to a higher pulse frequency and M_k is recorded. The measuring instrument is then subjected to a pulse frequency, which should be at least ten times lower. Once the data have stabilised, M_p is will be recorded. The change in frequency M_k must then be made as quickly as possible and the time taken to reach the value of the given relation specified Article 2.6 must be measured.

The decreasing pulse rate test is performed in the same manner with the values M_p and M_k interchanged.

5.3.8 Overload test

The test is performed by exposing the measuring instrument for 1 minute of activity at least 10 times higher than that corresponding to the full scale on each sub-range. It must return to its normal state within 5 minutes after the activity has stopped.

5.3.9 Start-up time

The test is carried out on a measuring instrument which has been switched off for at least 4 hours. The device is then irradiated with a suitable radiation source. After switching the instrument on, the value is read out every 5 s in the range from 20 s to 120 s. 15 minutes after activation, at least 10 readings are made and the mean value is used as the "final value".

The difference between the "final value" and the values subtracted in 60 s and 120 s must be in accordance with Article 2.8.

5.3.10 Influence of the environment

These tests are carried out in an air conditioning chamber.

a) Temperature stability

The temperature is maintained at both extreme limits for at least 4 hours and measurements are made during the last 30 minutes of this interval.

The measured values must comply with the requirements of Article 2.9.1.

b) Temperature shock

Allow the device to stabilise at +20 °C for at least 40 minutes. It is then placed in an ambient temperature of + 40 °C (or +35 °C). Measurements are made after 5 minutes and then every 15 minutes for 2 hours. Let the temperature drop to +20 °C for 4 hours and then place the device in a -10 °C (+10 °C) temperature environment. The measurement is also performed at higher temperatures.

The measured values must comply with the requirements of Article 2.9.2.

c) Activation at a low temperature

The device is placed in an environment with a temperature of -10 °C (+10 °C) for 4 hours and then activated.

The device must work as in Section 2.9.1.

d) Relative air humidity

The test of this influencing variable is only required if it is assumed that its influence is significant.

The test is carried out as in Section a) with the temperature maintained at +35 °C.

The measured values must comply with the requirements of Article 2.9.4.

5.4 Electromagnetic compatibility test

EMC tests are performed with the device connected according to the manufacturer's specifications.

5.4.1 Resistance to electrostatic discharge

The resistance to electrostatic discharge is tested on the device with the supplied radioactive source with a 6 kV contact discharge and an 8 kV air discharge. Discharges are applied to conductive surfaces.

The maximum incorrect value indication caused by the electrostatic discharge must be less than 10% of the indicated specification.

5.4.2 Resistance to high-frequency electromagnetic fields

The resistance to radiated radio frequency fields must be tested with the radio frequency source supplied in the frequency range from 80 MHz to 1,000 MHz, field strength 10 V/m. Amplitude modulation 80% AM/1 kHz sin.

The maximum incorrect value indication must be less than 10% of the indicated specification.

3.7.3 Emission (electromagnetic) radiation

The radiation is measured using a narrow bandwidth in a shielded chamber, the antenna is located 1 metre from the device. The wave bandwidths for each frequency are listed in Table 1.

Table 1 – Waveband widths

Frequency (Hz)	**Bandwidth** (Hz)
1 k to 50 k	100
50 k to 500 k	400
500 k to 1 M	2 k
1 M to 10 M	10 k
10 M to 1 G	50 k

The frequency and the indicated emission level when the device is switched off (background) and switched on.

Radiation must be less than 0.1 V/m throughout the frequency range.

6 Initial verification

6.1 General

The following tests are performed during initial verification:

a) Visual inspection,
b) Response to the area emission input,
c) Relative basic error (linearity),
d) Dependence of the response on the area emission input to the radiation energy.

6.2 Visual inspection

A visual inspection of the portable surface contamination measuring instruments is conducted to assess the following:

a) conformity of the portable surface contamination measuring instruments with an approved type;
b) completeness of the portable surface contamination measuring instruments according to the type approval certificate;
c) whether the individual parts of the portable surface contamination measuring instruments are damaged and whether they are functioning;

6.3 Functional tests

6.3.1 Area emission input response test

The area emission input response test must be carried out in the same way as for type approval pursuant to Article 5.3.1.

6.3.2 Relative basic error (linearity) test

The relative basic error test must be carried out in the same way as for type approval pursuant to Article 5.3.3.

6.3.3 Test of the dependence of the response on the area emission input to the radiation energy

The test of the dependence of the response on the area emission input to the radiation energy must be carried out in the same way as for type approval pursuant to Article 5.3.4.

7 Follow-up verification

Follow-up verification is carried out in the same way as the initial verification in chapter 6.

8 Testing of the measuring instrument

When testing the measuring instruments pursuant to § 11a Metrology Act, proceed according to chapter 7 at the request of the person who may be affected by an incorrect measurement. The maximum permissible errors are double the maximum permissible errors in 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 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 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.

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 general measure, 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 and dose measuring instruments

used to check for compliance with radiation protection or nuclear safety limits and for the measurement of emergency portable surface contamination measuring instrument".

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 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.

I N S T R U C T I O N S

In accordance with the provisions of § 172 (1) CAP in conjunction with the provision of § 39 (1) CAP, the ČMI sets a deadline for making comments of 30 days from the date of posting on the official board. Comments submitted after this deadline will be disregarded.

The persons concerned are hereby invited to comment on this general draft measure. With regard to the provisions of § 172 (4) CAP, comments are submitted in writing.

In accordance with the provisions of § 174(l) CAP in conjunction with § 37(l) CAP, it must be clear who is making the comments, which general measure they address, how it contradicts legislation or how the general measure 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 general measure shall be posted for 15 days.

...…….....

RNDr. Pavel Klenovský

Managing Director

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: .....