ČESKÝ METROLOGICKÝ INSTITUT

Czech Metrology Institute

Okružní 31, 638 00 Brno

1. ------IND- 2018 0338 CZ- EN- ------ 20180803 --- --- PROJET

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

Spectrometric assemblies for analysing alpha, beta, gamma and neutron sources or fields—alpha and gamma radiation spectrometers 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 matter of this notified legislation is to lay down metrological and technical requirements for these measuring instruments. The legislation also lays down the tests to be used for type approval and verification.

(End of executive summary.)

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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 used 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 pursuant to § 46 APC on 4 April 2016, and, on the basis of supporting documents, issues the following:

I.

DRAFT GENERAL MEASURE

number: 0111-OOP-C077-16

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

'spectrometric assemblies for analysing alpha, beta, gamma and neutron sources or fields—alpha and gamma radiation spectrometers'

1 Basic definitions

For the purposes of this general measure, terms and definitions pursuant to VIM and VIML,[1)] as well as the terms and definitions stated below shall apply:

1.1
activity

the quotient of the expectation value of spontaneous nuclear transitions of an amount of a radionuclide in a particular energy state over a short time interval and this time interval

The unit of activity is the becquerel (Bq), where 1 Bq = 1 s^{-1}.

1.2
FWHM

full width at half maximum, characterises the instrument's resolution

1.3
peak-to-Compton ratio

the ratio of the maximum impulse count at the full absorption peak and the average height of the corresponding Compton continuum

This ratio is usually given for the 1 333 keV (^{60}Co) energy line. The corresponding Compton continuum is defined by the 1 040 keV to 1 096 keV interval.

1.4
nuclear radiation spectrometer

an instrument designed to measure radiation intensity distribution relative to its energy

1.5
variation coefficient *V*

the coefficient of standard deviation s and arithmetic mean $\bar{x}$ of a set of n measurements $x_i$given by the equation:

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

2 Metrological requirements

2.1 Reference conditions and standard test conditions

The reference and ambient test conditions based on the relevant requirements of European standards are given in Table 1. Different conditions may be specified by the manufacturer.

Table 1 – Reference conditions and standard test conditions

Influence quantity	Reference conditions	Normal test conditions
Ambient temperature	20 °C	18 °C to 22 °C

[1)] 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 field of metrology', which is publicly accessible at www.unmz.cz.

Relative humidity	65 %	50 % to 75 %
Atmospheric pressure	101.3 kPa	86 kPa to 106 kPa
Supply voltage	nominal supply voltage U_N	$U_N \pm 1$ %
AC supply voltage frequency	nominal frequency	nominal frequency ± 0.5 %
AC supply voltage waveform	sinusoidal	sinusoidal with total harmonic distortion of less than 5 %
Background gamma radiation	air kerma rate 0.20 μGy·h^{-1}	air kerma rate of less than 0.25 μGy·h^{-1}
Electrostatic field	negligible	negligible
Exterior electromagnetic field	negligible	less than the lowest value causing disturbances
Exterior magnetic field	negligible	less than twice the Earth's magnetic field
Controls	set for normal operation	set for normal operation
Radionuclide contamination	negligible	negligible
Contamination by chemical products	negligible	negligible

2.2 Measuring range

The measuring range of the spectrometer (in terms of energy and rates) shall be specified by the manufacturer. The manufacturer shall also specify any peak position extension and shift for the maximum input rate of impulses.

2.3 System linearity

The deviations of measured and reference values within the range of the measured rates shall not exceed 10 %.

2.4 Instrument accuracy

The measured activity value of the reference source shall not differ by more than 10 % from the conventionally true value plus the uncertainty of the radioactive source (at the 95 % probability level).

2.5 Energy resolution

The measured FWHM value shall be better than or equal to the manufacturer's specifications.

2.6 Peak-to-Compton ratio

The measured peak-to-Compton ratio shall be better than or equal to the manufacturer's specifications.

2.7 Statistical fluctuations

In light of the statistical nature of the interaction of ionising radiation with matter, the measured values may fluctuate around the mean value. When measurements of the same reference source are repeated using identical measurement geometry, the variation coefficient shall not exceed 5 %.

2.8 Stability

After the measuring instrument has been in operation for at least one hour, the measurement results shall not change by more than 10 % of the measured value during the next 100 hours.

3 Technical requirements

3.1 Design

A nuclear radiation spectrometer usually consists of a detector, an amplifier, an analogue-to-digital converter, an evaluation unit and various input and output units.

The design of spectrometers shall take into account the operating conditions of their expected applications.

3.2 Electromagnetic compatibility

3.2.1 Resistance to electromagnetic disturbances

The operation of the measuring instrument shall not be affected by electromagnetic disturbances in the surrounding environment. It shall function normally after electromagnetic compatibility tests have been conducted.

3.2.2 Radiation of electromagnetic fields

During operation, the measuring instrument shall not emit electromagnetic fields that could adversely affect the operation of other systems.

3.3 Safety

The measuring instrument must be safe in the sense defined within the basic safety principles for ionising radiation equipment and the requirements of the relevant technical regulations under normal conditions of use for the intended purposes.

3.4 Software

Software that is critical for the metrological characteristics of the measuring instrument (legally relevant software) shall be identifiable in accordance with the WELMEC 7.2 guide, as amended[2]. The programme must be easily identifiable.

4 Labelling the measuring instrument

4.1 Markings on the measuring instrument

The following shall appear on the measuring instrument:

a) identification of the manufacturer;
b) identification of the type of measuring instrument;
c) serial number of the measuring instrument and its evaluation units;
d) type-approval mark.

All marks and inscriptions shall be easily visible under normal conditions, legible, durable, clear and irremovable.

4.2 Placement of the official mark

The placement of the official marks shall be specified in the type-approval certificate.

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[2] WELMEC 7.2, 2015: Software Guide (Measuring Instruments Directive 2014/32/EU)—available on-line at <www.welmec.org>

As far as practicable, the marks shall be placed on the front panel of the measuring instrument so that none of the provided information is obscured.

5 Type approval of the measuring instrument

5.1 In general

The process of type approval of the measuring instrument includes the following tests:

a) external inspection;
b) functional tests;
c) tests of resistance to environmental disturbances;
d) electromagnetic compatibility tests.

5.2 External inspection

The following shall be assessed during the external inspection:

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

5.3 Functional tests

5.3.1 Linearity

The linearity test shall be conducted using a set of standard reference sources on the activity of one radionuclide (identical geometry), which covers the range of rates within which the measuring instrument is normally used.

Any peak position shift and extension with increasing rates must not exceed the limits referred to in Article 2.2. The resulting measurement must fall within the limits referred to in Article 2.3.

5.3.2 Accuracy

The accuracy test shall be conducted across the entire energy range by measuring reference sources chosen with regard to the use of the equipment (radionuclide, geometry).

The result of the measured activity shall be within the limits referred to in Article 2.4.

5.3.3 Energy resolution

During the test, the FWHM on the chosen energy line of the spectrum shall be established.

662 keV (^{137}Cs) shall be used for gamma radiation spectrometers with a scintillation detector and 1 333 keV (^{60}Co) for spectrometers with a germanium semiconductor detector. The reference value for soft photon radiation spectrometers with a Si(Li) detector shall be equal to 5.9 keV (^{55}Fe).

The energy resolution of alpha radiation spectrometers with silicon semiconductor detectors shall be tested for energy of 5.155 MeV (^{239}Pu).

The measured FWHM value shall comply with the requirement referred to in Article 2.5.

5.3.4 Peak-to-Compton ratio

The test shall be conducted for germanium gamma radiation detectors (HPGe) for energy of 1 333 keV (^{60}Co).

The measured peak-to-Compton ratio shall comply with the requirement referred to in Article 2.6.

5.3.5 Repeatability of measurement—short-term stability

During the test, the activity of a single reference source shall be repeatedly established. At least 10 measurements shall be conducted in the same geometric configuration.

The calculated variation coefficient shall comply with the requirement referred to in Article 2.7.

5.3.6 Long-term stability

During the long-term stability test, activity values of the reference source shall be recorded after 1 hour, 10 hours and 100 hours from initiating the instrument without further adjustment.

The measured activity values (corrected for half-life) shall comply with the requirement referred to in Article 2.8.

5.4 Tests of resistance to environmental disturbances

5.4.1 Resistance to climatic influences

Measuring instruments designated to be used for field measurements shall be tested to the extent specified by the manufacturer.

5.5 Electromagnetic compatibility tests

Electromagnetic compatibility tests shall be conducted in accordance with the relevant standards to the extent so as to ensure that the requirements referred to in Articles 3.2.1 and 3.2.2 are complied with.

The subsequent resistance tests shall primarily concern measuring instruments connected to the power grid; only the tests referred to in Articles 5.5.1, 5.5.2 and 5.5.8 shall be relevant for battery-powered portable measuring instruments.

5.5.1 Immunity to electrostatic discharges

Immunity to electrostatic discharge shall be tested using a ±4 kV contact discharge and a ±8 kV air discharge.

After the test has been conducted, the measuring instrument shall operate as designed. In the subsequent accuracy test, the measured value shall not exceed the limits referred to in Article 2.4.

5.5.2 Immunity to radio frequency electromagnetic fields

Immunity to the effects of radio frequency electromagnetic fields shall be tested in the following frequency ranges:

- 80 MHz to 1 GHz—field intensity 3 V·m-1;
- 1.4 MHz to 2 GHz—field intensity 3 V·m-1 and
- 2 MHz to 2.7 GHz—field intensity 1 V·m-1.

The test field shall be amplitude-modulated to a depth of 80 %; the modulation signal shall have a sinusoidal waveform with a frequency of 1 kHz.

During the test, the measuring instrument shall operate as designed. In the subsequent accuracy test, the measured value shall not exceed the limits referred to in Article 2.4.

5.5.3 Immunity to short-term voltage dips

During the test of immunity to short-term voltage dips, the supply voltage shall be reduced to 70 % of the nominal voltage for a period of 25 cycles of AC voltage, to 40 % of the nominal voltage for a period of 10 cycles and to 0 % of the nominal voltage for a period of one cycle.

After the test has been conducted, the measuring instrument shall operate as designed. In the subsequent accuracy test, the measured value shall not exceed the limits referred to in Article 2.4.

5.5.4 Immunity to voltage interruptions

Immunity to short-term voltage interruptions shall be tested by applying a voltage dip to 0 % of the nominal supply voltage for a period of 250 cycles of AC voltage.

Temporary loss of function of the measuring instrument during the test is allowed provided that its operation is restored after the test is completed (either by itself or by operator's intervention). In the subsequent accuracy test, the measured value shall not exceed the limits referred to in Article 2.4.

5.5.5 Immunity to fast transitional events

Immunity to fast transitional event shall be tested using a signal consisting of impulses (a leading edge of 5 ns, length—for the 50 % level —shall be 50 ns) combined into groups (duration of 15 ms). The repetition rate in the group shall be 5 kHz.

The test signal voltage shall be chosen as follows:

- ±2 kV on the AC or DC supply voltage terminals,
- ±1 kV on the terminals for connecting I/O lines not directly connected to the mains,
- ±2 kV on the terminals for connecting I/O lines directly connected to the mains.

After the test has been conducted, the measuring instrument shall operate as designed. In the subsequent accuracy test, the measured value shall not exceed the limits referred to in Article 2.4.

5.5.6 Immunity to electrical surges

Immunity to electrical surges shall be tested using a surge of t_r/t_h = 1.2/50 (8/20) μs with a voltage of:

- ±2 kV asymmetric and ±1 kV symmetric on AC or DC mains inputs,
- ±1 kV asymmetric on inputs of I/O lines longer than 30 m not directly connected to the mains,
- ±2 kV asymmetric and ±1 kV symmetric on inputs of I/O lines directly connected to the mains.

After the test has been conducted, the measuring instrument shall operate as designed. In the subsequent accuracy test, the measured value shall not exceed the limits referred to in Article 2.4.

5.5.7 Immunity to disturbances induced by high-frequency fields of power lines

Immunity to disturbances from power lines shall be tested in the 150 kHz to 80 MHz frequency range. Voltage of 3 V shall be supplied to the terminals for connecting to AC or DC mains and to the terminals of I/O lines.

During the test, the measuring instrument shall operate as designed. In the subsequent accuracy test, the measured value shall not exceed the limits referred to in Article 2.4.

5.5.8 Radiated electromagnetic disturbance

During the test, emissions of high-frequency power line disturbances in the 150 kHz to 30 MHz frequency range and radiated disturbances in the 30 MHz to 1 GHz frequency range shall be measured. The relevant limits are given in Tables 2, 3 and 4. Stricter limit values shall apply to frequencies corresponding to frequency band boundaries.

Table 2 – Limits for disturbances emitted on the mains input terminals

Frequency range (MHz)	Disturbance limit values dB (µV)	
	quasi-peak	average
0.15 to 0.50	79	66
0.50 to 30	73	60

Table 3 – Limits for disturbances emitted on I/O lines

Frequency range (MHz)	Disturbance limit values dB (µV)	
	quasi-peak	average
0.15 to 5	97 to 89	84 to 76
5 to 30	89	76

Table 4 – Limits for disturbances from radiation at a measuring distance of 10 m

Frequency range (MHz)	Disturbance limit values dB (µV/m)
	quasi-peak
30 to 230	40
230 to 1 000	47

6 Initial verification

6.1 In general

Initial verification shall include the following tests:

a) visual inspection;
b) accuracy test of the instrument.

6.2 Visual inspection

The purpose of the visual inspection shall be to assess:

a) compliance of the measuring instrument with the approved type;
b) completeness of the measuring instrument according to the type-approval certificate;
c) functionality and intactness of individual components of the measuring instrument;
d) conformity of the SW version with the version approved in the context of type approval.

6.3 Functional tests

6.3.1 Linearity

The test of linearity of the measuring instrument shall be conducted in accordance with Article 5.3.1.

6.3.2 Accuracy

The test of accuracy of the measuring instrument shall be conducted in accordance with Article 5.3.2.

7 Subsequent verification

Subsequent verification shall be conducted using a procedure identical to that for 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 their incorrect measurement, the procedure in Chapter 7 shall be followed. The maximum permissible error shall be 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 stemming from this general measure, the CMI shall notify 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 shall be considered, to the extent and under the conditions laid down in the general measure, as compliance with those requirements laid down in this measure to which these standards or parts thereof apply.

Conformity with the 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 has issued this general measure laying down metrological and technical requirements for legally controlled measuring instruments and tests for the type approval and verification of these legally controlled measuring instruments—'spectrometric assemblies for analysing alpha, beta, gamma and neutron sources or fields—alpha and gamma radiation spectrometers' in accordance with § 14(1)(j) of the Metrology Act to implement § 6(2), § 9(1) and (9) and § 11a(3) of the Metrology Act.

Implementing Decree No 345/2002 specifying measuring instruments for mandatory verification and measuring instruments subject to type approval, as amended, classifies this type of measuring instruments under items 8.1, 8.6, 8.8 and 8.10 in the annex entitled 'List of the types 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.

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

In accordance with § 172(l) APC, in conjunction with § 39(l) APC, the CMI has stipulated a time limit for comments of 30 days as of the date of posting 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 § 172(4) APC, the comments shall be submitted in writing.

With regard to § 174(l) APC, in conjunction with § 37(l) APC, it must be clearly stated who is making the comments, which general measure the comments concern, how the draft contradicts legislation or how the general measure is inaccurate and must contain a 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 general measure shall be posted for 15 days.

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RNDr. Pavel Klenovský

Director-General

Person responsible for accuracy: Mgr. Tomáš Hendrych

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