ČESKÝ METROLOGICKÝ INSTITUT

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

'*Measuring instruments used to monitor activity limits and concentration of effluents from nuclear facilities, nuclear raw material mining or processing facilities, radioactive waste processing plants and from the processing or application of radioactive materials, and also used to determine environmental radiation exposure due to effluents – measuring instruments for continuous monitoring of radioactive gamma radioisotopes in liquid effluents from nuclear facilities*' – may be placed on the market and put into use in the Czech Republic as specified measuring instruments pursuant to Act No 505/1990 on metrology, as amended. Pursuant to this act, the specified measuring instruments are measuring instruments in the List of Specified Measuring Device Types (Decree No 345/2002) and specified (by the manufacturer/importer) for measurement with relevance in the protection of the public interests in the following areas: *consumer protection; contractual relations; stipulation of sanctions, fees, tariffs and duties; health protection; environmental protection; occupational safety or protection of other public interests protected by special legislation.* This therefore has a purpose similar to that used to identify stipulated products — non-automatic measuring and weighing instruments pursuant to Directives 2014/31/EU and 2014/32/EU. The requirements of this legislation do not apply to measuring instruments not placed on the market in the Czech Republic for the above purposes, defined by Act No 505/1990 on metrology.

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

(End of executive summary)

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P U B L I C N O T I C E

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 12 February 2016 pursuant to § 46 of the CAP, and, based on supporting documents, issues the following:

I.

D R A F T G E N E R A L M E A S U R E

number:0111-OOP-C075-16

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

‘measuring instruments used to monitor activity limits and concentration of effluents from nuclear facilities, nuclear raw material mining or processing facilities, radioactive waste processing plants and from the processing or application of radioactive materials, and also used to determine environmental radiation exposure due to effluents – measuring instruments for continuous monitoring of gamma radioisotopes in liquid effluents from nuclear facilities’

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 will apply.

1.1
liquid effluent monitor

a device for continuous monitoring of radioactive substances in liquid effluents from nuclear facilities

1.2
detection apparatus

includes one or more radiation detectors and related functional units

1.3
control and evaluation apparatus

comprises apparatus and functional units for measuring quantities related to ionising radiation (activity, activity concentration, etc.); the apparatus has functional units providing clear warnings that the measured quantity has exceeded a pre-set value

1.4
coefficient of variation

the ratio V of the standard deviation s to the arithmetic mean $\bar{x}$ of a set of n measurements x_i, given by the relationship:

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

1.5
detection limit L_D

the measured value of a quantity obtained by a measurement procedure for which the probability of an untrue claim concerning the absence of a component in the material is β, where the probability of an untrue claim concerning its presence is α

[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 accessible at www.unmz.cz.

For a sample with a true content value of L_D only 5 % of measurements will be erroneously declared as indistinguishable from the ambient environment (type II error, β). The error β will equal error α (type I error) in ambient measurement, when 5 % of ambient measurements exceed the measurement limit.Implicit values equal to 0.05 are recommended for α and β.

The detection limit L_D is determined as follows:

$$L_D = 1.645\sqrt{2u(B)} \quad (2)$$

where$B$ .... is the ambient value;

t is the ambient measurement time;

$u(B)$ is the ambient standard deviation.

$$u(B) = \sqrt{\frac{B}{t}} \quad (3)$$

1.6
expansion factor

a numerical coefficient (k) used as a multiplier of the combined standard uncertainty in order to obtain an expanded uncertainty

1.7
decision variable

a variable used to decide whether a given physical phenomenon is or is not present

1.8
decision level

a fixed decision variable value that can be used to help decide if a given physical phenomenon is present if the result of the current measurement of the physical phenomenon has been exceeded

1.9
effective meter measuring range

the range of values of the measured activity within which the properties of the part of the apparatus or system comply with specifications

1.10
dynamic range

the ratio of the signal at the maximum measurable value of a quantity and the signal at the decision level

1.11
indication error

the difference between the indicated value of a quantity ν and this quantity's conventionally true value ν_c at the measurement point

$$\Delta\nu = \nu - \nu_c \quad (4)$$

1.12
relative basic error

the relative error of a reading e_i of part of a device or a system with respect to the given quantity under specified reference radiation and under specified reference conditions, expressed as:

$$e_i = \frac{\nu - \nu_c}{\nu_c} \quad (5)$$

where: ν the indicated value of the quantity;

ν_c the quantity's conventional value at the measurement point.

1.13
response time

the time needed after a step change in the measured quantity for the change in the output signal to first achieve a given relative value, usually 90 % of the final value

1.14
reference response

under standard test conditions is given by the following relationship:

$$R_{ref} = \frac{A}{A_c} \quad (6)$$

where: A........... the value of the activity concentration indicated by the tested device or system;

A_c .... the conventional value of the activity concentration.

1.15
sensitivity

is the ratio of the value obtained through measurement and the conventional activity value

$$S = \frac{I - B}{A} \quad (7)$$

where: I........... the indicated value from measurement of a radioactive sample;

B.......... the indicated value from measurement without a radioactive sample;

A.......... the conventional activity value of the measured sample.

1.16
activity concentration

activity per unit volume of the measured liquid

1.17
units of measurement

where appropriate, the following auxiliary units are used:

- for time: year (r), day (d), hour (h), minute (min.);
- for energy: electron-volt (eV);
- for activity concentration: Becquerel per cubic metre (Bq/m^3)

1.18
kerma

is defined as the sum of the initial kinetic energies of all the charged particles liberated by uncharged ionising radiation in a sample of matter, divided by the mass of the sample. The unit is the gray (Gy). The kerma is used in the area of measurement of indirectly ionising radiation; it characterises energy transferred by indirectly ionising radiation (photons, neutrons) upon initial collision with charged particles (electrons, protons)

1.19
kerma rate

the kerma increase per time interval; the unit is $Gy \cdot s^{-1}$

2 Metrological requirements

2.1 Stipulated operating conditions

A liquid monitor must comply with metrological requirements over the operating temperature and relative humidity range specified by the manufacturer.

2.1.1 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 variables	Reference conditions	Standard test conditions
Ambient temperature	20 °C	18 °C to 22 °C
Relative humidity	65 %	50 % to 75 %
Air pressure [1)]	101.3 kPa	86 kPa to 106 kPa
Power supply [2)]	nominal supply voltage V_N	V_N ±1 %
AC supply voltage frequency [2)]	nominal frequency	nominal frequency ±0.5 %
AC supply voltage waveform [2)]	sinusoidal	sinusoidal with a total harmonic distortion of less than 5 %
Ambient gamma radiation	kerma rate in air 0.20 μGy/h	kerma rate in air <0.25 μGy/h
Electrostatic field	negligible	negligible
External electromagnetic field	negligible	less than the smallest value causing interference
External magnetic field	negligible	less than twice the Earth's magnetic field value
Control elements	configured for routine operation	configured for routine operation
Radionuclide contamination	negligible	negligible
Radon daughters (222 and 220)	negligible	negligible
Contamination by chemical products	negligible	negligible

1) When the detection method is especially sensitive to air pressure changes, conditions are restricted to ±5 % of reference pressure.

2) DC power can be used, in which case no frequency is specified.

2.2 Measuring range

The monitor's measuring range is stipulated by the manufacturer.

2.3 Instrument accuracy

The manufacturer must stipulate the ratio between a reading on the measuring instrument and the activity of a reference source when the instrument is operating under standard test conditions and is configured according to the manufacturer's instructions. The reference response uncertainty must be specified. The reference response must not differ by more that 10 % of the value specified by the manufacturer.

2.4 System linearity

Under standard test conditions, the relative error of a reading must be less that ±10 % over the entire effective measurement range. Uncertainty of sources of radiation is not included. When fixed sources are used, then ν and ν_c apply to sensitivity during relative error calculations (part 1.12).

2.5 Response to other radionuclides

The manufacturer must specify the response to appropriate radionuclides present in the liquid sample.

2.6 Response to ambient gamma radiation

Because there is usually a relationship between the response to ambient gamma radiation and the decision level, and both parameters depend on the given operational use, the response to gamma radiation as well as the decision level must be agreed upon by the manufacturer and the user. The manufacturer must stipulate the decision level and the maximum reading when a detector with protection from ambient gamma radiation is irradiated in the position specified by the manufacturer with a step change in the kerma rate in air from the reference ambient air kerma rate to 10 μGy/h from ^{137}Cs. The response to irradiation with gamma radiation at any orientation and any gamma radiation energy up to 1.3 MeV (^{60}Co) must not exceed double the decision level value.

2.7 Overload

Unless agreed upon otherwise by the manufacturer and user, the device must indicate a reading past the upper end of the scale or indicate overload if it is irradiated by a source with activity concentration 10 times that of the upper limit of the measurement range, and once the source of overload is eliminated, must operate normally.

2.8 Detection and evaluation device start-up time

When irradiated with a source of radiation, the apparatus must indicate a value that will not differ by more than ±10 % of the value obtained under standard conditions during the first 30 minutes after being switched on.

2.9 Statistical fluctuations

Given the statistical nature of radiation, read values may fluctuate around a central value. The activity value coefficient of variation caused by statistical fluctuations must be less than 10 % for readings past the first decade of the effective measurement range.

2.10 Stability of values indicated on detection and evaluation device

The value indicated for a given source of radiation after 30 minutes of operation must not change by more than 10 % over the subsequent 100 hours.

2.11 Flow rate stability

The purpose of this test is to determine the nominal sampling flow rate or sampling stability under standard test conditions with a pressure drop caused only by the liquid circuit and retention apparatus. The manufacturer must specify a nominal flow rate for the type of retention apparatus used. After the standard start-up period of the sampling apparatus (30 minutes) the indicated sampling flow rate value must not differ by more than ±10 % of the conventional flow rate value, and the sampling flow rate must not change by more than 10 % during the subsequent 100 hours.

2.12 Influence of supply voltage on flow rate

The flow rate must not change by more than 5 % when the supply voltage fluctuates between +10 % and –12 % of the nominal supply voltage.

2.13 Influence of supply voltage frequency

The flow rate must not change by more than 10 % when the supply voltage frequency changes from 47 Hz to 51 Hz.

2.14 Ambient temperature

The indicated value must remain within the limits specified in Table 2 for the temperature range specified by the manufacturer. It must be noted that for this type of apparatus, detection and sampling equipment may operate under different climactic conditions from the evaluation apparatus. Part or all of the detection apparatus may operate at a higher temperature than specified in Table 2.

Table 2 — Ambient temperature

Ambient temperature	Deviations under standard conditions
+10 °C to +35 °C (midpoint:+22 °C)	±10 %
–10 °C to +40 °C (midpoint:+15 °C)	±20 %
−25 °C to +50 °C (midpoint:+12 °C)	±50 %

2.15 Relative humidity

Deviations caused by relative humidity up to 90 % at 35 °C must be less than 10 %.

3 Technical requirements

3.1 General requirements

The main purpose of the apparatus for monitoring radioactive effluences is to provide information on whether effluents from all facilities comply with stipulated effluent limits.

This apparatus may also provide data on the proceedings of any processes being performed. Even though this is usually a secondary purpose, under certain circumstances it is possible to anticipate situations where the detection of activities significantly below permitted levels can provide early warning of incorrect plant operation.

Regardless of whether the purpose of effluent monitoring is to comply with requirements specified by a responsible authority or whether its main purpose is to provide the user with monitoring information, the most frequent requirement is the ability to measure a defined effluent level characterised by activity concentration and overall effluent flow rate.

This ability is influenced by a number of factors including detector type and characteristics, monitor operating mode, distribution of activity throughout the entire effluent flow, and sampling system efficiency (where only part and not all of the flow is measured).

When taking into account various factors, it is evidently possible to optimise the detailed design of the monitor during the final phase of plant design, but in the beginning there is often insufficient data concerning monitoring requirements and how the entire system of effluents should be arranged in order to permit effective monitoring with the required degree of sensitivity. For this reason, in order to achieve maximum efficacy, it is recommended that the required properties of the monitoring apparatus and the plant design be influenced already during the initial design phase of the plant in order to comply with monitoring requirements.

3.2 Classification of liquid monitors

Monitors can be classified according to their gamma radiation detection method as follows:

- total gamma activity monitors;
- gamma monitors discerning radionuclides emitting gamma radiation.

Monitors can also be classified according to operating method:

- with direct measurement using a detector placed in the effluent flow or in its vicinity;
- continuous sampling at the monitoring site, for example in a sampling chamber.

3.3 Activity collection

When it is impossible to directly measure effluent flow or take a representative sample due to low activity concentration of the effluent flow, various activity collection methods may be considered prior to measurement. The most frequent such procedure is concentration of activity using a suitable sampling medium. While this method is generally not possible for true continuous measurement, it can be used for quasi-continuous measurement, where activity is concentrated for a certain amount of time prior to measurement and where the concentration/measurement cycle repeats regularly. In apparatus designed in this manner, collection must occur proportionally to the overall volume of liquid released.

3.4 Measurement and indication characteristics

3.4.1 Effective measurement range

The effective measurement range must be appropriate to the given application.

3.4.2 Measurement characteristics

The manufacturer must specify the decision level, detection limit and effective measurement range of the apparatus. These characteristics must be provided for specified radionuclides, taking into account the reference ambient gamma radiation level (0.2 μGy/h) and activity concentrations in the liquid (of radon and its daughters).

3.4.3 Display

The indicated value should be the true activity concentration of the effluent. This activity concentration is usually given in Bq/m^3 for reference radionuclide ^{137}Cs, or in the case of monitors that can discern individual radionuclides, a set of radionuclides defined by the manufacturer.

3.5 Reliability

All apparatus must be designed to be as reliable as possible with a minimum of undetected faults.

The manufacturer must provide documentation concerning the expected MTBF of critical components such as air pumps, detectors, flow rate meters, etc.

The manufacturer must specify the periodicity of regular maintenance and must fully describe all maintenance procedures. Maintenance requirements should be minimised.

Warnings concerning faults must be available, indicating the system has a fault such as a power supply outage or a component failure.

3.6 Sampling and detection apparatus

3.6.1 Sampling and discharge pipes

When designing sampling apparatus, the following characteristics must be considered:

- the internal diameter and length of pipes, the number and radius of bends;
- the surface characteristics of internal pipe walls;
- joins, prevention of particle trapping;
- the properties of the structural material, minimisation of corrosion and erosion.

If it is likely that the effluent contains suspended particles, the design should minimise particle trapping.

3.6.2 Intake filter or retention apparatus

If appropriate, a filter or other absorbent medium may be situated in a holder at the intake of the sampling apparatus in order to eliminate certain substances. A filter may simply be used to protect the activity monitor's measurement chamber from substances dissolved in the liquid, and in this case the operating personnel of the monitored building must be instructed that the measurement of this monitor is not representative of effluents from the given building. Parts of the measuring system may be an apparatus intended for the separation of the measurement of undissolved particles.

3.6.3 Sampling chamber

Where the sampling and detection apparatus includes a measurement chamber and where this chamber provides a volume of liquid for measurement using a submerged detector or a detector situated near the liquid, the following requirements apply:

3.6.3.1 The sampling chamber must be a flow-through type, designed so that the volume of liquid flow-through remains constant.

3.6.3.2 The volume of the sampling chamber and the pressure must be specified.

3.6.3.3 The sampling chamber must be designed to minimise possible contamination. Access to all elements of the sampling chamber during decontamination must be provided.

3.6.4 Ionising radiation detector

Any type of detector suitable for the required measurement according to the manufacturer's specifications may be used. The manufacturer stipulates the detector type and all relevant parameters, especially the response at a defined geometry to the activity of measured radionuclides and other interfering activities. Regardless of the detector type used, the manufacturer will stipulate the response as a function of the gamma radiation energy, and if the detector is intended for spectroscopic measurement, also its resolution capacity as a function of energy.

3.6.5 Ease of decontamination

If possible, the detector must be protected from the measured liquid by a protective window of appropriate thickness.

If possible, it must be possible to quickly dismount the detector for repairs or replacement. A defined detector position must be ensured so that the detector can always be mounted while preserving the required geometry. The detection apparatus must be designed and built to minimise contamination and facilitate easy decontamination.

3.6.6 Checking and calibration

The detection apparatus must be designed to easily situate the checking and calibration sources of radiation in a defined geometry near the detector.

3.7 Alarms

3.7.1 Alarm types

Alarms and indication elements must be appropriate to the purpose of the apparatus and must be specified by the manufacturer.

High-level alarms and fault alarms must provide separate local visual indication on the monitor, and must also have two sets of output contacts (which may be common for all fault alarms) for external warning purposes. Audible alarms may also be provided.

All alarm functions must have means of testing alarm functionality. In the case of a configurable alarm, it must be possible to perform a check within the configuration range with indication of the current operating alarm point.

Alarm circuits must operate in a mode where alarm conditions are maintained until they are specifically reset using a reset button, or in a mode where they automatically reset when the alarm state disappears.

3.7.2 High-level alarms

Configurable high-level alarms covering the entire effective measurement range must be provided.

3.7.3 Fault alarms

The following alarms must be provided:

- indicating detector signal loss;
- indicating loss of sampling in the circuit;
- indicating faults in the electronic system circuitry.

Alarms must indicate the source of defects and must have an automatic diagnostic system.

There must be a separate indication for each fault.

3.8 Means of indication

Aside from visual indication of the measured value, the apparatus must indicate that:

- power is on;
- the pump (if present) is on;
- the high-voltage power supply for the detector (if present) is on;
- the flow or level in the detector coolant tank (if present).

If liquid flows through the apparatus, suitable flow measurement indication must be provided.

Outputs allowing remote indication of measurement and alarms must be provided.

3.9 Means for operating checks

Means must be provided for the user to provide periodic checks to ensure satisfactory apparatus operation, including calibration and verification of measurement linearity. These means must be installed in a manner that allows checks to be performed from the control and evaluation unit. These checks must be performed using one or more (as needed) suitable sources of radiation.

3.10 Means for configuration and maintenance

All electronic devices must have a sufficient number of easily accessible test points to facilitate configuration and defect localisation. All special maintenance tools and the appropriate maintenance manual must be provided. All apparatus must be designed to facilitate easy repair and maintenance.

The display must provide information on automatic diagnostic elements.

3.11 Ambient shielding or compensation apparatus

This apparatus or procedures are used to reduce the influence of the ambient environment on measurement. They involve the following types:

- shielding apparatus;
- electronic apparatus;
- software methods.

These types may be incorporated into the overall system design as needed.

Shielding must provide identical radiation attenuation in all directions from the detector's sensitive volume, taking into account the structural materials used in the detection apparatus and the detector's angular response. The shielding thickness must be stipulated taking into account the detector's detection efficiency.

If it is not possible to easily remove the apparatus from the shielding, the shielding must be easy to disassemble, and thus must comprise overlapping building-block elements.

If electronic methods employing auxiliary detectors are used to reduce the influence of the ambient gamma radiation, these detectors must be selected and situated to achieve the best possible compensation, taking into account the gamma energy range and radiation direction.

3.12 Apparatus noise levels

Apparatus noise is primarily due to the sampling and detection apparatus, and especially from the operation of the pipe system and resultant vibrations.

The manufacturer must select components and design the apparatus to minimise noise in line with the type of environment for which the apparatus is intended.

3.13 Electromagnetic interference

Measuring instruments must not be influenced by ambient electrical and electromagnetic interference, and must comply with the requirements of relevant special legislation[2)]. During the interference influence test, the change in the measuring instrument's response must not exceed 1 %. All necessary measures to minimise electromagnetic interference must be implemented, both that received and emitted by the apparatus.

Severity level 3 is used for resistance.

[2)] Government Regulation No 117/2016 on product conformity assessment from the perspective of electromagnetic compatibility when being placed on the market.

Severity level A is used for emission.

3.14 Power

The apparatus must be designed to operate on single-phase AC power in one of the following categories according to:

- Series I:230 V AC;
- series II:100 V AC;
- series III:120 V or 240 V AC;
- series IV:24 V DC.

The apparatus may be designed to operate on a low-voltage source of backup power in case of a power outage. In these cases it is desirable that the apparatus does not malfunction due to the power supply switch or that no alarm is triggered, but this switch must be indicated.

Air-fan motors may use three-phase power.

3.15 Tamper protection

The parts of the measuring instrument essential to its metrological properties must be designed to be secured in such a way as to provide proof of any unauthorised interference. If the response of the measuring instrument can be adjusted to correct for long-term changes in response, correct for the effect of temperature and pressure on response, or through application of a corrective factor, then the measuring instrument must be designed to rule out accidental changes to any factors configured by its operator. Control switches and potentiometers 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 in accordance with the resolution capacity of the measuring instrument and then locked in order for the settings not to be changed accidentally. Correction factors and calibration coefficients stored digitally must be impossible to change unless the operator enters a security code (or password) or changes the position of a blocked or inaccessible switch.

3.16 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) the serial number of the measuring instrument's detector(s) and evaluation unit, pumps, flow meter;
d) type-approval mark;
e) ionising radiation meter safety information.

All labels and inscriptions must be legible, durable, unambiguous and impossible to remove using common means.

4.2 Official mark placement

The placement of official marks on the detection part and the evaluation 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 information on the measuring instrument.

5 Type approval of measuring instruments

5.1 General

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

a) External inspection;
b) instrument accuracy;
c) system linearity;
d) response to ambient gamma radiation;
e) overload;
f) detection and evaluation apparatus start-up time;
g) statistical fluctuation;
h) stability of values indicated on detection and evaluation apparatus;
i) stability of flow rate or of the value of the quantity that characterises the concentration part of the cycle for measuring instruments operating in quasi-continuous concentration/measurement mode;
j) influence of supply voltage on flow rate;
k) influence of supply voltage frequency;
l) external leak;
m) influence of ambient temperature;
n) influence of relative humidity;
o) electromagnetic compatibility.

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 Instrument accuracy

The apparatus operates under standard test conditions and is configured according to the manufacturer's instructions without the presence of reference radiation. The ambient value is recorded. The apparatus is then irradiated with an appropriate reference source with sufficient activity to provide values at approximately the midpoint of the scale or decade above the lowest scale or decade. The indicated value is recorded and R_{ref} is calculated.

The measured value must not exceed the permitted change limits specified in Article 2.3.

5.3.2 System linearity

The test is performed using a set of sources with the same radionuclide and geometric characteristics. Standard preparation of test sources used in required tests must be such that the uncertainty in the absolute conventional activity value (ε_{sa}) of each source is better than 10 % ($k = 2$) and the relative conventional activity value (ε_{sr}) between sources of the given test set is better than 5 % ($k = 2$). Test sources must be linked to approved reference standards.

Tests must be performed in one of two ways:

- with liquid or solid sources of radiation;
- through the application of an electrical signal.

Type-approval tests are performed at one point on each scale for instruments with a linear scale, and on each decade of the effective measurement range for instruments with a digital or logarithmic display at approximately 25 % of the most sensitive range or decade, at 50 % of the maximum of central ranges or decades, and 75 % of the maximum value. At least three of these tests must be performed using a radioactive source, with two being at limit values. When electrical signals are used, they must be used for all ranges or decades (in addition to radionuclide sources).

The measured value must not exceed the permitted change limits specified in Article 2.4.

5.3.3 Response to ambient gamma radiation

Because there is usually a relationship between the response to ambient gamma radiation and the decision level, and both parameters depend on the given operational use, the response to gamma radiation as well as the decision level must be agreed upon by the manufacturer and the user. The manufacturer must stipulate the decision level and the maximum reading when a detector with protection from ambient gamma radiation is irradiated in the position specified by the manufacturer with a step change in the kerma rate in air from the reference ambient air kerma rate to 10 μGy/h from ^{137}Cs. The response to irradiation with gamma radiation at any orientation and any gamma radiation energy up to 1.3 MeV (^{60}Co) must not exceed double the decision level value.

The apparatus must operate under standard test conditions without the presence of a radioactive source, and the indicated ambient value is determined. The ^{137}Cs is then situated relative to the detector so that the distance between the source and detector is at least 2 metres, and the conventional kerma rate in air at the detector location, if the detector was not present, would be 10 μGy/h ± 10 %. The detector's reference orientation relative to the source must comply with the manufacturer's specifications. Once irradiation has started, values are recorded at one-minute intervals until the values shown by the apparatus have reached a steady state. Once a steady state has been achieved, at least 10 readings are performed. The decision level is calculated based on the last readings. This decision level must comply with the manufacturer's specifications. The maximum reading of the evaluation apparatus must not exceed the value specified by the manufacturer. The detector is then irradiated at several source-detector geometries according to the manufacturer's specifications. If the evaluation apparatus can be programmed with a compensation factor for gamma radiation, this factor must not be changed during the test. Readings on the evaluation apparatus in all directions must not exceed double the value specified by the manufacturer for the reference direction.

The above test is repeated for the reference source-detector direction using alternative sources of gamma radiation as agreed upon by the manufacturer and user, including a 60-Co source. If the evaluation apparatus can be programmed with a compensation factor for gamma radiation, this factor must not be changed during the test. Readings on the evaluation apparatus must not exceed double the value specified by the manufacturer for ^{137}Cs.

The measured value must not exceed the permitted change limits specified in Article 2.6.

5.3.4 Overload test

The measuring instrument must indicate a value past the upper end of the scale, or indicate overload. If it is irradiated by a source with activity (or surface emission rate) up to ten times the maximum of the measurement range, once the overload has ceased, it must function normally.

a) The detection apparatus is exposed to a source of radiation with activity that provides a reading at approximately 50 % of the first decade of the measurement range, and the reading is recorded.
b) The detection apparatus is exposed to a source of radiation with activity ten times the maximum measurable value. Irradiation is maintained for at least 10 minutes, and the instrument is checked to ensure that it permanently indicates a reading past the upper end of the scale.
c) The source of radiation is removed and after a period of time agreed upon by the manufacturer and user, usually less than one hour, the detection apparatus is irradiated under the same conditions as in a). The readings must not differ by more that 10 % of the original value.

5.3.5 Detection and evaluation apparatus start-up time

When irradiated with a source of radiation, the apparatus must indicate a value that will not differ by more than ±10 % of the value obtained under standard conditions during the first 30 minutes after being switched on.

Prior to this test, the apparatus must be disconnected from power for at least one hour. A source of radiation is used that provides a reading at approximately one third to one half of the range maximum. The detection and evaluation apparatus is switched on. Readings are recorded every five minutes for one hour. Ten hours after the apparatus was switched on, at least 10 readings are taken at appropriate intervals to obtain independent values. The mean value is used as the 'final value' of readings. A graph of the indicated activity value over time is drawn, and if needed a correction is made for half-life. The difference between the 'final value' and the value read from the graph for 30 minutes must lie between specified limits.

NOTE When activity is very low, less than 10 times the decision level, it may occur that during the start-up period the apparatus will not provide the required indicated value. This is due to statistical deviations at low measured impulse frequencies.

5.3.6 Statistical fluctuations

Given the statistical nature of radiation, read values may fluctuate around a central value. The activity value coefficient of variation caused by statistical fluctuations must be less than 10 % for readings past the first decade of the effective measurement range.

A radioactive source that provides an indicated value between 10 and 20 times the decision level is used. At least 10 readings are taken at appropriate intervals to obtain independent values. The mean value and coefficient of variation are calculated from all readings. The coefficient of variation must be within the required limits.

The measured value must not exceed the permitted change limits specified in Article 2.9.

5.3.7 Stability of values indicated on detection and evaluation apparatus

The reading indicated for a given source of radiation after 30 minutes of operation must not change by more than 10 % over the subsequent 100 hours.

A radioactive source that provides an indicated value between 10 and 20 times the decision level is used. A sufficient number of readings are performed after 30 minutes, then additional readings after 10 hours and 100 hours without any changes to apparatus settings or conditions. The mean reading values for all times must be between the specified limits.

If needed, readings must be corrected for half-life.

The measured value must not exceed the permitted change limits specified in Article 2.10.

5.3.8 Flow rate stability

The purpose of this test is to determine the nominal sampling flow rate and sampling stability under standard test conditions with a pressure drop caused only by the liquid circuit and an intake or sampling filter (clean filter). The manufacturer must specify a nominal flow rate for the type of filter used. After the standard start-up period of the sampling apparatus (30 minutes) the indicated sampling flow rate value must not differ by more than ±10 % of the conventional flow rate value, and the sampling flow rate must not change by more than 10 % during the subsequent 100 hours.

This test is performed using distilled water to prevent any changes to the pressure drop of the collection apparatus during the test. For this test, a flow meter calibrated under measurement conditions with an uncertainty better than 3 % ($k = 2$) is installed at the intake of the liquid circuit. The apparatus is turned on and flow rate is measured after 30 minutes, 5 hours, 20 hours and 100 hours of operation.Readings must comply with requirements.

The measured value must not exceed the permitted change limits specified in Article 2.11.

5.3.9 Influence of supply voltage on flow rate

Supply voltage is varied between +10 % and –12 % of the nominal supply voltage.

This test is performed using dustless air to prevent any changes to the pressure drop of the collection apparatus during the test. For this reason, a HEPA filter with a very low pressure drop is placed in front of the air circuit. For this test, a flow meter calibrated under measurement conditions with an uncertainty better than 3 % ($k = 2$) is installed at the intake of the air circuit. The apparatus is turned on and flow rate is measured and recorded at stable voltage. Then the supply voltage is varied over a defined range of 88 % Vn to 110 % Vn and the flow rate is simultaneously measured.

The measured value must not exceed the permitted change limits specified in Article 2.12.

5.3.10 Influence of power frequency

Power frequency is varied from 47 Hz to 51 Hz.

During this test, the sampling and detection apparatus is connected to a power supply with nominal voltage and frequency that changes from 47 Hz to 51 Hz (alternative values are 57 Hz to 61 Hz). This test is performed using dustless air to prevent any changes to the pressure drop of the collection apparatus during the test. For this reason, a HEPA filter with a very low pressure drop is placed in front of the air circuit. For this test, a flow meter calibrated under measurement conditions with an uncertainty better than 3 % ($k = 2$) is installed at the intake of the air circuit. The flow rate is recorded at nominal frequency and at the specified frequency limits.

The measured value must not exceed the permitted change limits specified in Article 2.13.

5.3.11 External leak

This test is used to determine the size of an external leak.

The size of the leak is measured using two volume meters or flow rate meters; they must be mutually calibrated to an accuracy greater than 1 %. One meter is situated before the apparatus and the second in the direction of flow past the apparatus. A series of 10 consecutive measurements is performed at suitable time intervals. The mean values of flow rates measured before and after must not differ by more than 5 % during a normal sampling period.

5.3.12 Ambient temperature

It must be noted that for this type of apparatus, detection and sampling equipment may operate under different climactic conditions from the evaluation apparatus. Part or all of the detection apparatus may operate at a higher temperature.

The detection apparatus is irradiated using a suitable test source in a manner that provides a known nominal reading value under standard test conditions. This test is usually performed in a climate chamber. It is usually not necessary to regulate humidity in the chamber if the apparatus is not especially sensitive to humidity changes. Temperature is maintained at both limit values of the agreed upon temperature range for at least 24 hours. During the last 30 minutes of this interval, the indicated value is read, which must be within appropriate limits. The indicated value is also read at the midpoint of the temperature range shown in Table 2. If the reading at this median temperature is not within ±10 % of the monitor's reading at the reference temperature, the manufacturer must specify the difference at this point.

The measured value must not exceed the permitted change limits specified in Article 2.14.

5.3.13 Relative humidity

It must be noted that for this type of apparatus, detection and sampling equipment may operate under different climactic conditions from the evaluation apparatus. Part or all of the detection apparatus may operate at a higher relative humidity.

The detection apparatus is irradiated using a suitable test source in a manner that provides a known nominal reading value under standard test conditions. The test may be performed at one temperature, 35 °C, and relative humidity of 90 %; the permitted reading deviation of ±10 % of the value is in addition to the permitted deviation caused by temperature alone.

The measured value must not exceed the permitted change limits specified in Article 2.15.

5.4 Electromagnetic compatibility tests

Electromagnetic compatibility tests are performed with the monitor connected according to the manufacturer's specifications. These tests must demonstrate that the monitor complies with the requirements of relevant special legislation[2)].

5.4.1 Immunity to electrostatic discharge

Immunity to electromagnetic discharge is tested with the apparatus switched on, using a contact discharge of 6 kV and an air discharge of 8 kV. Discharges are applied to conductive surfaces and connecting plates.

After this test, a subsequent apparatus accuracy test must not result in a measured deviation that exceeds limits specified in Article 2.3.

5.4.2 Immunity to high-frequency electromagnetic fields

Immunity to a radiated high-frequency field is tested with the apparatus switched on, over a frequency range of 80 MHz to 3 000 MHz, with field intensity of 10 V/m. Amplitude modulation 80 % AM/1 kHz sine.

After this test, a subsequent apparatus accuracy test must not result in a measured deviation that exceeds limits specified in Article 2.3.

5.4.3 Immunity to transients

Immunity to repeated electrical transient disturbances is tested with the apparatus switched on. A test voltage of ±0.5 kV, ±1 kV and ±2 kV is applied via a coupling circuit to power, earth and signal inputs/outputs.

After this test, a subsequent apparatus accuracy test must not result in a measured deviation that exceeds limits specified in Article 2.3.

5.4.4 Immunity to surges

Immunity to surges is tested by applying a test voltage of ±0.5 kV, ±1 kV and ±2 kV between power conductors.

After this test, a subsequent apparatus accuracy test must not result in a measured deviation that exceeds limits specified in Article 2.3.

5.4.5 Immunity to conducted disturbances induced by radio-frequency fields

Immunity to conducted disturbances induced by radio-frequency fields are tested with the apparatus switched on over a frequency range of 150 kHz to 80 MHz. Amplitude modulation 80 % AM/1 kHz, voltage 10 V.

After this test, a subsequent apparatus accuracy test must not result in a measured deviation that exceeds limits specified in Article 2.3.

5.4.6 Immunity to interference due to a damped wave

Immunity to interference due to a damped wave is tested with the apparatus switched on, by applying damped waves to the monitor's power, signal and control inputs/outputs. The test level is defined as the voltage of the first peak (maximum or minimum) of the test waveform, and is non-symmetrical 2 kV, symmetrical 1 kV for a slow damped 100 kHz and 1 MHz wave, and for a fast 3 MHz, 10 MHz or 30 MHz damped wave is 2 kV non-symmetrical.

After this test, a subsequent apparatus accuracy test must not result in a measured deviation that exceeds limits specified in Article 2.3.

5.4.7 Immunity to supply voltage dips, short interruptions and voltage variations

Immunity to supply voltage dips, short interruptions and voltage variations is tested with the apparatus switched on, by applying a voltage dip to 0 % V_t for 10 ms.

After this test, a subsequent apparatus accuracy test must not result in a measured deviation that exceeds limits specified in Article 2.3.

5.4.8 Measurement of power line disturbances

The tested monitor must comply with disturbance limits specified in Tables 3 and 4. The test is performed with the apparatus switched on by measuring power line disturbances on the monitor's power, signal and control inputs/outputs. If the reading on the measuring receiver fluctuates near limits, the reading must be monitored for at least 15 s at each measurement frequency. The maximum value is recorded, except for random, brief extreme values, which are ignored.

Table 3 contains voltage disturbance limits for power terminals.

Table 3 — Limits for power line disturbances on power terminals

Frequency range (MHz)	**dB limits**(μV)	
	Quasi-maximum	Median
0.15 to 0.50	79	66
0.50 to 30	73	60
NOTE Lower limits apply to band edge frequencies.		

Table 4 contains voltage disturbance limits for signal inputs/outputs.

Table 4 — Limits for power line disturbances on signal inputs/outputs

Frequency range (MHz)	**Voltage limits dB** (µV)		**Current limits dB** (µA)	
	Quasi-maximum	Median	Quasi-maximum	Median
0.15 to 0.50	97 to 87	84 to 74	53 to 43	40 to 30
0.50 to 30	87	74	43	30
NOTE Lower limits apply to band edge frequencies.				

5.4.9 Measurement of EM interference (radiated high-frequency interference)

The tested monitor must comply with interference limits specified in Table 5.The test is performed with the apparatus switched on by measuring EM radiation at 10 metres. If the reading on the measuring receiver fluctuates near limits, the reading must be monitored for at least 15 seconds at each measurement frequency. The maximum value is recorded, except for random, brief extreme values, which are ignored.

Table 5 — Radiated EM interference limits when measured at 10 m

Frequency range (MHz)	**Quasi-peak limits** dB (µV/m)
30 to 230	40
230 to 1 000	47
NOTE Lower limits apply to band edge frequencies.	

6 Initial verification

6.1 General

During initial verification, the following tests are performed:

a) a visual inspection;
b) apparatus accuracy;
c) system linearity;
d) response to ambient gamma radiation;
e) overload;
f) statistical fluctuations;
g) stability of values indicated on detection and evaluation apparatus;
h) flow rate stability;
i) influence of ambient temperature.

6.2 Visual inspection

The inspection is performed in accordance with Article 5.2.

6.3 Functional tests

6.3.1 Apparatus accuracy test

The test is performed in accordance with Article 5.3.1.

6.3.2 Apparatus linearity test

The test is performed in accordance with Article 5.3.2.

6.3.3 Test of response to ambient gamma radiation

The test is performed in accordance with Article 5.3.3.

6.3.4 Overload test

The test is performed in accordance with Article 5.3.4.

6.3.5 Statistical fluctuation test

The test is performed in accordance with Article 5.3.6.

6.3.6 Long-term stability test

The test is performed in accordance with Article 5.3.7.

6.3.7 Long-term flow rate stability test

The test is performed in accordance with Article 5.3.8.

6.3.8 Ambient temperature influence test

The test is performed in accordance with Articles 5.3.12 and 5.3.13.

7 Subsequent verification

7.1 General

During subsequent verification, the following tests are performed:

a) a visual inspection;
b) apparatus accuracy;
c) system linearity;
d) overload;
e) stability of values indicated on detection and evaluation apparatus.

7.2 Visual inspection

The inspection is performed in accordance with Article 5.2.

7.3 Functional tests

7.3.1 Apparatus accuracy test

The test is performed in accordance with Article 5.3.1.

7.3.2 Apparatus linearity test

The test is performed in accordance with Article 5.3.2.

7.3.3 Overload test

The test is performed in accordance with Article 5.3.4.

7.3.4 Long-term stability test

The test is performed in accordance with Article 5.3.7.

8 Measuring instrument check

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 will 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 will 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, toward the implementation of § 6(2), § 9(1) and (9), and § 11a(3) of the Metrology Act, this measure of a general nature, stipulating metrological and technical requirements for the specified measuring instruments and test methods for the type approval and verification of the specified measuring instruments — 'Measuring instruments used to monitor activity and concentration of effluents from nuclear facilities, from nuclear raw material mining or processing facilities, from the processing or application of radioactive materials, and from radioactive waste processing plants, and to determine environmental radiation exposure due to effluents — measuring instruments for continuous monitoring of radioactive gamma radioisotopes in liquid effluents from nuclear facilities'.

Decree No 345/2002 specifying measuring instruments for mandatory verification and measuring instruments subject to type approval, as amended, classifies the measuring instruments under item 8.1 in the Annex entitled 'List of specified measuring instruments' as measuring instruments subject to type approval and mandatory verification.

This legislation (Measure of a General Nature) was 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 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.

RNDr.Pavel Klenovský m.p.

Director-General

Person responsible for accuracy:Mgr.Tomáš Hendrych

Posted on:17 October 2018

Signature of the authorised person confirming posting:Tomáš Hendrych m.p.

Removed on:

Signature of the authorised person confirming removal: