

1. -----IND- 2018 0590 CZ- EN- ----- 20181217 --- --- PROJET

*'Measuring instruments used to monitor activity limits and concentration of emissions 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 emissions – measuring instruments for continuous monitoring of radioactive noble gases in gas emissions 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 significance for protection of the public interest 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 separate legislation.* This is therefore a similar purpose as that which is 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, identified by Act No 505/1990 on metrology.

The purpose of this notified legislation is to lay down metrological and technical requirements for these 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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## **PUBLIC NOTICE**

As the authority with substantive and territorial jurisdiction in the matter of laying down metrological and technical requirements for specified measuring instruments and stipulating the testing methods for type approval and verification of specified 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 26.2.2016 pursuant to § 46 of the CAP, and, based on supporting documents, issues the following:

### **I.**

## **DRAFT GENERAL MEASURE**

number: 0111-OOP-C076-16

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

**‘measuring instruments used to monitor activity limits and concentration of emissions 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 emissions – measuring instruments for continuous monitoring of radioactive noble gases in gas emissions from nuclear facilities’**

This legislation stipulates metrological and technical requirements for measuring instruments for continuous monitoring of radioactive noble gases in gas emissions from nuclear facilities.

## **1 Basic definitions**

For the purposes of this general measure, terms and definitions pursuant to VIM and VIML<sup>1</sup> as well as the terms and definitions stated below apply.

### **1.1 gas emission monitor**

an apparatus intended for continuous monitoring of radioactivity in gas emissions; individual parts of the apparatus may be connected into two separate pieces of equipment that may be connected or separated according to monitoring and operating requirements

### **1.2 noble gas monitor**

a device for continuous monitoring of radioactive noble gases in emissions released into the environment

### **1.3 radioactive noble gases**

radionuclides  $^{133}\text{Xe}$ ,  $^{135}\text{Xe}$ ,  $^{85}\text{Kr}$ ,  $^{41}\text{Ar}$

### **1.4 detection apparatus**

includes one or more radiation detectors and related functional units

### **1.5 control and evaluation apparatus**

contains 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

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

## 1.6 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:

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

## 1.7 detection limit $L_D$

the measured value of a quantity obtained by a measurement procedure for which the probability of an inaccurate statement on the absence of a component in material is  $\beta$ , where the probability of an inaccurate statement on its presence is  $\alpha$ .

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,  $\beta$ ). The error  $\beta$  will equal error  $\alpha$  (Type I error) in ambient measurement, when 5 % of ambient measurements exceed the measurement limit. Implicit values equal to 0.05 are recommended for  $\alpha$  and  $\beta$ .

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.

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

## 1.8 coverage factor

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

## 1.9 decision variable

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

## 1.10 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

## 1.11 effective measuring range

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

## 1.12 dynamic range

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

### 1.13 indication error

the difference between the indicated value of a quantity  $v$  and this quantity's conventionally true value  $v_c$  at the measurement point

$$\Delta v = v - v_c \quad (4)$$

### 1.14 relative basic error

the relative error of a specification  $e_i$  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:

$$e_i = \frac{v - v_c}{v_c} \quad (5)$$

where:  $v$ ..... the indicated value of the quantity:

$v_c$  ..... the quantity's conventional value at the measurement point.

### 1.15 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

### 1.16 monitor air circuit efficiency

the efficiency of the monitor's air circuit describes activity losses on the monitor's walls between the circuit intake and the capture medium; it is defined as the ration of the total activity available for sampling by the monitor and the total activity in the air at the monitor's intake

### 1.17 reference response

under standard test conditions is given by the following relationship:

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

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

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

### 1.18 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.

### 1.21 activity concentration

activity per unit volume of air or gas

## 1.22 units

this legislation uses the SI system of units; where appropriate, the following auxiliary units are used:

- for time: year (y), day (d), hour (h), minute (min);
- for energy: electron-volt (eV);
- for activity concentration: becquerel per cubic metre (Bq/m<sup>3</sup>)

## 2 Metrological requirements

### 2.1 Rated operating conditions

The 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 <sup>1)</sup>	101.3 kPa	86 kPa to 106 kPa
Power supply <sup>2)</sup>	nominal supply voltage $V_N$	$V_N \pm 1 \%$
AC supply voltage frequency <sup>2)</sup>	nominal frequency	nominal frequency $\pm 0.5 \%$
AC supply voltage waveform <sup>2)</sup>	sinusoidal	sinusoidal with a total harmonic distortion of less than 5 %
Ambient gamma radiation	kerma rate in air 0.20 $\mu\text{Gy/h}$	kerma rate in air $< 0.25 \mu\text{Gy/h}$
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
Sampling flow rate	set to nominal flow rate (stipulated by the manufacturer)	set to nominal flow rate $\pm 5 \%$
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
<sup>1)</sup> If the detection method is particularly sensitive to changes in air pressure, conditions are restricted to $\pm 5 \%$ of reference pressure. <sup>2)</sup> DC power can be used, in which case no frequency is specified.		

## 2.2 Measuring range

The measuring range of the noble gas monitor 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 than 15 % of the value specified by the manufacturer.

## 2.4 System linearity

Under standard test conditions, the relative error of a reading must be less than  $\pm 10\%$  over the entire effective measurement range. Uncertainty of sources of radiation is not included. When fixed sources are used, then  $\nu$  and  $\nu_c$  apply to sensitivity during relative error calculations.

## 2.5 Response of monitors without specification of radionuclides to other radioactive gases

The manufacturer must specify the response of the apparatus to radioactive gases other than reference radioactive sources. The range of gases of interest is stipulated by the manufacturer, and a representative selection must be made from these for testing. It must be demonstrated that the characteristics of the apparatus comply with specifications.

## 2.6 Response of monitors for specific radionuclides to other radioactive gases

The manufacturer must specify the response of the apparatus to radioactive gases other than those to be measured; this response must be less than 15 % of the response to a specific gas. The activity concentration of the gas must be sufficient to provide an indicated value that demonstrates that the apparatus meets requirements.

## 2.7 Response to ambient gamma radiation

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  $10 \mu\text{Gy/h}$  from  $^{137}\text{Cs}$ . The response to irradiation with gamma radiation at any orientation and any gamma radiation energy up to 1.3 MeV ( $^{60}\text{Co}$ ) must not exceed double the decision level value.

## 2.8 Overload

Unless agreed upon otherwise between 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.

## 2.9 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  $\pm 10\%$  of the value obtained under standard conditions during the first 30 minutes after being switched on.

## 2.10 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.

## 2.11 Detection and evaluation apparatus reading stability

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.

## 2.12 Influence of pressure changes in the measurement chamber

Pressure changes in the measurement chamber influence response for a given activity concentration of measured air or gas. The manufacturer will stipulate the compensation algorithm for these pressure changes.

## 2.13 External leak

This test is used to determine the size of an external leak, which characterises the leak-resistance of the measurement chamber.

## 2.14 Ambient temperature

The indicated value must remain within the limits specified in Table 2 for the temperature range specified by the manufacturer. For this type of apparatus, detection and sampling apparatus may operate under different climactic conditions than the evaluation apparatus. Part or all of the detection apparatus may operate at a higher temperature than specified in Table 2. In this case, the relevant test must be stipulated by the manufacturer.

**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 requirement is the ability to measure a defined the emission level characterised by activity concentration and overall emission flow rate.

## **3.2 Monitor types**

### **3.2.1 General**

The types of apparatus under consideration for monitoring gas emissions are radioactive aerosol monitors, noble gas monitors and monitors for identification of specific radionuclides.

### **3.2.2 Classification of noble gas emission monitors**

An apparatus can be classified according to the type of radiation detected:

- gamma;
- beta;
- specific radionuclides.

An apparatus can also be classified according to measurement method:

- direct measurement with the detector in the outlet flow or in its vicinity;
- continuous sampling of part of the flow from a monitoring point to a remote location.

## **3.3 Overall apparatus design**

Various monitor configurations are possible depending on the exact circumstances and requirements for the given installation. Regardless of these variants, the apparatus must meet the following requirements:

### **3.3.1 Direct-measurement apparatus**

If measurement is performed directly in the emission flow or in its vicinity, only the detector and the bare minimum of electrical components must operate in these conditions. Unless there are special circumstances, this type of apparatus must not contain detectors that are especially sensitive to changes in ambient conditions or that require frequent checking and adjustment.

The relevant control and evaluation apparatus must be installed in a regulated environment if possible in order to minimize influences on its characteristics and to provide easy access for operation and maintenance.

### **3.3.2 Indirect-measurement apparatus**

If representative emission samples are collected continuously to a remote location, the sampling and detection apparatus (except for the sampling nozzle and pipes) and the control and evaluation apparatus must be located in a regulated environment. If this is not practical (for example due to excessive sampling pipe length), the same restrictions as for the detection apparatus must be applied (in accordance with 3.3.1) to ensure quick response to any increase in activity level.

## **3.4 Sampling and detection apparatus**

### **3.4.1 Sampling and intake pipes**

The following characteristics must be considered and agreed upon:

- the influence of flow rate and pressure on measurement;
- transport delay to the detector (flow rate, pipe diameter, etc.).

### **3.4.2 Intake part**

The sampling circuit intake must have a suitable intake part in order to eliminate all particles, and, if necessary, iodine. In order to preserve the specified characteristics of the apparatus, this part must not capture or temporarily hold back noble gases and reduce flow rate.



The apparatus must also have suitable shielding to protect individuals and limit influence on the detection apparatus from radiation from radionuclides accumulated on these parts during the sampling period. This part must be accessible and its activity must be monitored.

It is necessary to note that iodine isotopes decay into noble gases. This is why if iodine filters are used at the intake of the monitor circuit, an analysis must be performed to demonstrate that iodine captured on the filter does not cause erroneous noble gas release estimates.

### **3.4.3 Sampling chamber**

When a measuring chamber or gas chamber providing the given volume of gas for measurement using a submerged or nearby detector is used as part of the sampling and detection apparatus, the following requirements have to be met:

- The sampling chamber must be of flow-through type. It can contain an absorption medium or compression apparatus.
- The volume of the sampling chamber and the operating pressure must be specified.
- The detector must be separated from the measured gas or air by a protective window or partition.
- It must be easy to remove the detector from the chamber for purposes of repair or replacement. The detector must be attached in such a way that in all cases it can be returned to the appropriate geometric position and this position can be maintained.
- If an absorption medium is used to increase gas monitor response for a given radioactive gas activity concentration, the sorbent type and its characteristics must be specified for various measured gases.

### **3.4.4 Radiation detector**

Any type of detector can be used that is suitable for the required measurement. The manufacturer must specify the detector type and all relevant characteristics, above all the response at operating geometry for activities of gases that are to be measured, and for activities of interfering radionuclides.

#### Beta radiation detector

The manufacturer must specify the dimensions of the detector and detection characteristics, for example effective area and thickness of all protective barriers etc.

#### Gamma radiation detector

These devices measure gamma radiation directly, and must generate an alarm if required. Ambient radiation must be taken into account for this monitor type.

#### Detector of specific gamma radionuclides

This detector combines gamma radiation measurement and spectroscopic radiation analysis. The manufacturer must specify the detector's resolution and efficiency as a function of energy.

## **3.5 Measurement and indication characteristics**

### **3.5.1 Effective measurement range**

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

### **3.5.2 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  $\mu\text{Gy/h}$ ) and activity concentrations in air (of radon and its daughters).

### 3.5.3 Display

The indicated value must correspond to the true value of emission activity concentration. This activity concentration is usually given in Bq/m<sup>3</sup> for the reference radionuclide or selected radionuclides from a mixture if a monitor that can distinguish radionuclides is used.

## 3.6 Reliability

The start-up time of the entire apparatus must be less than 30 minutes.

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

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

## 3.7 Alarms

### 3.7.1 Alarm types

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

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

- a) An alarm indicating loss of detector signal must be provided.
- b) An alarm indicating loss of sampling in the circuit must be provided.
- c) An alarm indicating faults in electronic system circuitry must be provided.
- d) Alarms must indicate the sources of defects and must have an automatic diagnostic system.
- e) There must be a separate indication for each fault.

## 3.8 Means of indication

Aside from visual indication of the measured value, the following must be indicated:

- power is on;
- the air fan (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 air 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.

It must be possible to check apparatus calibration at two representative points within the measuring range.

These checks must be performed using one or more (as needed) suitable sources of radiation. Measurement linearity can be checked electrically.

### **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 Control and evaluation apparatus**

Control and evaluation apparatus comprises primarily the following parts:

- electrical control and power supply;
- electronic measuring apparatus;
- measurement display;
- warning signal and alarm units.

The apparatus can be connected to a central radiation situation display panel. In this case it must be possible to install it in electronic frames of standardised dimensions.

### **3.12 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. 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 weighing 15 kg or less, unless specified otherwise by the manufacturer.

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.

### 3.13 Apparatus noise levels

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

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

### 3.14 Electromagnetic interference

Measuring instruments must not be influenced by ambient electrical and electromagnetic interference, and must comply with the requirements of relevant separate legislation<sup>2</sup>. The change in the response of the measuring instrument must not exceed 1 % during the interference test. All necessary measures to minimise electromagnetic interference must be implemented, both received and emitted by the apparatus.

- Severity level 3 is used for resistance.
- Severity level A is used for emission.

### 3.15 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.

### 3.16 Tamper protection

The parts of the measuring instrument essential to its metrological characteristics must be designed to be secured in such a way as to provide proof of any unauthorised interference.

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 according to the resolution of the measuring instrument and then locked in order for the settings not to be changed accidentally. Correction factors and calibration coefficients stored

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<sup>2</sup> Government Regulation No 117/2016 on product conformity assessment from the perspective of electromagnetic compatibility when being placed on the market

digitally may not be changed unless the operator enters the security code (or password) or changes the position of the blocked or inaccessible switch.

### **3.17 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) measuring instrument type;
- c) the serial number of the 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 data on the measuring instrument.

## **5 Type approval of measuring instruments**

### **5.1 In general**

The measuring instrument type approval process includes the following tests:

- a) external inspection;
- b) apparatus accuracy;
- c) system linearity;
- d) response to radioactive gases;
- e) response to ambient gamma radiation;
- f) overload;
- g) detection and evaluation apparatus start-up time;
- h) statistical fluctuations;
- i) detection and evaluation apparatus reading stability;
- j) influence of pressure changes in the measurement chamber;
- k) external leak;
- l) influence of ambient temperature;
- m) influence of relative humidity

- n) 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 this regulation's requirements specified in Chapters 2 and 3 and Article 4.1(a), (b) and (c);
- 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. Depending on the monitor's purpose, the tests are performed in one of two ways:

1. air or gas marked with a known activity concentration passes through the apparatus at a constant flow rate for a sufficient amount of time to achieve measurement equilibrium, and the equilibrium value is recorded;
2. the detector is submerged into a sufficiently large volume of gas with known activity concentration that is equivalent to the volume in the detector's actual operating position, and the reading under equilibrium conditions is recorded.

$R_{\text{ref}}$  is then 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 ( $\epsilon_{\text{sa}}$ ) of each source is better than 10 % ( $k = 2$ ) and the relative conventional activity value ( $\epsilon_{\text{sr}}$ ) between sources of the given test set is better than 5 % ( $k = 2$ ). Test sources must be linked to approved reference standards.

Tests can be performed in two ways:

- with gaseous or solid sources of radiation; or
- 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 of monitors for specific radionuclides to other radioactive gases

The test is performed in the same way as described in 5.3.1.

The results must comply with criteria pursuant to Article 2.5.

#### 5.3.4 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 specified by the manufacturer. 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  $\mu\text{Gy/h}$  from  $^{137}\text{Cs}$ . The response to irradiation with gamma radiation at any orientation and any gamma radiation energy up to 1.3 MeV ( $^{60}\text{Co}$ ) 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  $^{137}\text{Cs}$  source 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  $10 \mu\text{Gy/h} \pm 10 \%$ . 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 specified by the manufacturer. If the evaluation apparatus can be programmed with a compensation factor for gamma radiation, this factor must not be changed during this 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 specified by the manufacturer, including a  $^{60}\text{Co}$  source. If the evaluation apparatus can be programmed with a compensation factor for gamma radiation, this factor must not be changed during this test. Readings on the evaluation apparatus must not exceed double the value specified by the manufacturer for  $^{137}\text{Cs}$ .

The measured value must not exceed the permitted change limits specified in Article 2.7.

#### 5.3.5 Overload test

Unless otherwise specified by the manufacturer, 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.

- a) 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) Detection apparatus is exposed to a source of radiation with activity 10 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 specified by the manufacturer, usually less than one hour, the detection apparatus is irradiated under the same conditions as in a). The readings must not differ by more than 10 % of the original value.

#### 5.3.6 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  $\pm 10 \%$  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, a sufficient number of readings is taken in accordance with Chapter 5.3.7, and the mean value is used as the 'final value' of the 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: If activity is very low, less than 10 times the decision level, it may occur during the start-up period that the apparatus will not provide the required indicated value. This is due to statistical deviations at low measured impulse frequencies.

### **5.3.7 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 2.10.

### **5.3.8 Detection and evaluation apparatus reading stability**

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 2.11.

### **5.3.9 Influence of pressure changes in the measurement chamber**

The purpose of this test is to test the method used to compensate for pressure changes in the measurement chamber. Changes causing a pressure drop or increase in the measurement chamber can lead to an incorrect measured value for gas or air activity concentration under standard conditions. Pressure change values must be stipulated by the manufacturer.

For this test, the monitor must be equipped with a pressure meter in the measurement chamber. A calibrated pressure sensor (differential manometer, etc.) is inserted into the closed circuit with the measurement chamber at a point specified by the manufacturer so that the pressure change in the measurement chamber is measured. Nominal activity concentration at nominal pressure in the measurement chamber is measured. The pressure in the measurement chamber is then changed while the activity of the reference radionuclide is kept constant, until a pressure change of +10% above nominal pressure is achieved under standard test conditions, unless specified otherwise by the manufacturer. The conventionally true value of the activity concentration is measured under these conditions.

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

### **5.3.10 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 measurement chamber and the second in the direction of flow past the measurement chamber. A series of ten consecutive measurements performed at suitable time intervals. The mean values of flow rates measured in before and after must not differ by more than 5 % during a standard sampling period. If needed, corrections for air pressure differences are performed.

#### **5.3.11 Ambient temperature**

For this type of apparatus, detection and sampling apparatus may operate under different climactic conditions than 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  $\pm 10\%$  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.

#### **5.3.12 Relative humidity**

For this type of apparatus, detection and sampling apparatus may operate under different climactic conditions than 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  $\pm 10\%$  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**

EMC tests are performed using an aerosol monitor connected according to the manufacturer's specifications. These tests must demonstrate that the aerosol monitor complies with the requirements of relevant separate legislation<sup>2)</sup>.

#### **5.5.1 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 3000 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 transients disturbances is tested with the apparatus switched on. A test voltage of  $\pm 0.5$  kV,  $\pm 1$  kV and  $\pm 2$  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  $\pm 0.5$  kV,  $\pm 1$  kV and  $\pm 2$  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 10 % 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 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 seconds 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( $\mu$ V)	
	Quasi-maximum	Medium
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 ( $\mu$ V)		Current limits dB ( $\mu$ A)	
	Quasi-maximum	Medium	Quasi-maximum	Medium
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 the 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 rangeMHz	Quasi-peak limitsdB ( $\mu$ V/m)
30 to 230	40
230 to 1000	47
NOTE: Lower limits apply to band edge frequencies.	

## 6 Initial verification

### 6.1 General

During initial verification, the following tests are performed:

- visual inspection;
- apparatus accuracy;
- system linearity;
- response to ambient gamma radiation;
- overload;
- statistical fluctuations;
- detection and evaluation apparatus reading stability;
- external leak.

## **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 System 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 5.3.4.

### **6.3.4 Overload test**

The test is performed in accordance with Article 5.3.5.

### **6.3.5 Statistical fluctuation test**

The test is performed in accordance with Article 5.3.7.

### **6.3.6 Test of long-term stability of detection and evaluation apparatus readings**

The test is performed in accordance with Article 5.3.8.

### **6.3.7 External leak test**

The test is performed in accordance with Article 5.3.10.

## **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) detection and evaluation apparatus reading stability;
- f) external leak.

### **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 System 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 5.3.5.

**7.3.4 Test of long-term stability of detection and evaluation apparatus readings**

The test is performed in accordance with Article 5.3.8.

**7.3.5 External leak influence test**

The test is performed in accordance with Article 5.3.10.

**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 1.25 times the maximum permissible errors pursuant to Chapter 7.

**9 Notified standards**

For the purposes of specifying the metrological and technical requirements for measuring instruments and specifying the testing methods for their type approval and verification arising from this general measure, the CMI shall notify Czech technical standards, other technical standards or technical documents of international or foreign organisations, or other technical documents containing more detailed technical requirements (hereinafter referred to as 'notified standards'). The CMI 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](http://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.****GR O U N D S**

In accordance with § 14(1)(j) of the Metrology Act implementing § 6(2), § 9(1) and (9), and § 11a(3) of the Metrology Act, this general measure, 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 limits and concentration of emissions 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 emissions – measuring instruments for continuous monitoring of radioactive noble gases in gas emissions 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 (General Measure) 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(1) APC, in conjunction with § 39(1) 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.

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RNDr. Pavel Klenovský  
Director-General

Person responsible for accuracy: Mgr. Tomáš Hendrych

Posted on: 17.10.2018

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

Removed on:

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