FINAL REGULATORY IMPACT ASSESSMENT REPORT

1. REASON FOR SUBMISSION AND OBJECTIVES

1.1 Name

Draft Decree amending Decree of the Ministry of Industry and Trade No. 345/2002 laying down measuring instruments subject to mandatory verification and measuring instruments subject to type approval, as amended.

1.2 Definition of the issue

The current Decree No 345/2002, as amended (hereinafter 'Decree No 345/2002'), is implementing legislation for selected sections of Act No 505/1990 on metrology, as amended (hereinafter the 'Metrology Act'). The Decree is submitted on the basis of the 'Plan for the Preparation of Decrees of Central Government Authorities for 2023'.

The basic objective of the draft is to amend Decree No. 345/2002, thereby responding to the current needs of practice and the requirements of central government in the area of determining the types and use of specified measuring instruments, and to eliminate obsolete terminology. The draft amendment to the Decree leads to a partial extension and modification of the current scope of regulation in the field of legal metrology on the one hand, and the abolition of regulation for certain types of measuring instruments on the other. By regulation is meant the determination of measuring instruments subject to mandatory verification and measuring instruments subject to type approval.

The proposal does not make any substantial changes to the legal regulation of legal metrology, the changes do not affect EU metrology legislation or the international obligations of the Czech Republic. The Decree does not create technical barriers to trade, it only clarifies some issues in the placing of measuring instruments on the domestic market and their operation.

The regulatory impact assessment for the draft decree concerns only substantive changes for existing items of types of measuring instruments and for newly introduced types of measuring instruments, the regulation of which has a new immediate impact on public authorities, corporations and sole traders, and indirectly also on private individuals.

The impact assessment is divided into areas and types of measuring instruments that correspond to the draft annex to the Decree.

1.3 Description of the existing provisions

The current version of Decree No 345/2002 meets the requirements of the Metrology Act The principles governing the decree are long-standing and proven in practice. The responsibility for the uniformity and accuracy of measurements and measuring instruments is imposed on the users of measuring instruments by the Metrology Act. Decree No 345/2002 stipulates the types of measuring instruments subject to mandatory verification and type approval if they are placed on the market intended for measurements with significance specified in the Metrology Act [§ 3(3)].

Currently, in terms of number of units, the majority of the specified measuring instruments, i.e. about 80%, are placed on the market under the conformity assessment procedure pursuant to Act No. 90/2016 on conformity assessment of specified products when they are supplied to the market, as amended, and related (listed below) government regulations. These are measuring instruments specified in particular by Directive 2014/32/EU of the European Parliament and of the Council on the making available on the market of measuring instruments (transposed by Government Regulation No 120/2016) and Directive 2014/31/EU of the European Parliament and of the Council on the making available on the market of non-automatic weighing instruments (transposed by Government Regulation No 121/2016). Only a fraction of the newly marketed measuring instruments accounts for the voluntary EC type-approval system and EC initial verification under the European old approach Directives (Framework Directive 2009/34/EC of the European Parliament and of the Council, laying down common provisions for measuring instruments and methods of metrological control). The EC type-approval and EC initial verification system under the old approach directives will end in 2025. The remaining part of measuring instruments, i.e. about 20%, is marketed according to 'national legislation', i.e. according to the Metrology Act, where the technical and metrological requirements for specified measuring instruments and the determination of their testing methods during type approval are laid down in measures of a general nature (hereinafter 'MGN'), which are issued by the Czech Metrology Institute under the Metrology Act. In order to ensure the correctness of the measuring instruments in operation, which is secured by subsequent verification, the MGN also provide for verification tests. Subsequent verification tests apply to all specified measuring instruments used in the Czech Republic (regardless of how they were placed on the market).

1.4 Identification of stakeholders

- users of specified measuring instruments;
- manufacturers and their authorised representatives, distributors and sellers of specified measuring instruments;
- entities carrying out type-approval and verification of specified measuring instruments;
- state administration authorities.

1.5 Description of the objectives

The aim of the new Decree is to amend the current Decree No 345/2002. The basic objective is to ensure uniformity and accuracy of measurements and measuring instruments in the regulated area, i.e. when the measuring instruments are used in the public interest (with the meaning defined in the Metrology Act), in the current economic and social conditions. At the same time, the draft Decree concerns the updating of the generic list of specified measuring instruments in relation to European Directives (Directive 2014/31/EU of the European

Parliament and of the Council and Directive 2014/32/EU of the European Parliament and of the Council).

The amendment to the Decree introduces some new items in the list of specified measuring instruments (types of measuring instruments listed in the annex to the Decree), and for some types of measuring instruments it regulates the period of validity of the verification in the context of empirical research into the stability of metrological properties. On the other hand, the types of measuring instruments for which the reasons for regulation no longer exist will be deleted from the list of specified measuring instruments. The Decree shall also specify the cases where it is necessary to issue a verification certificate.

Last but not least, the Decree specifies the types of measuring instruments for which it will be possible, on the basis of a positive result of the statistical sample test, to extend the period of validity of the verification, the types of measuring instruments for which the validity of the verification will be conditional upon the performance of a shortened test and the types of measuring instruments that are not type-approved.

In connection with the proposed changes, there will be a structural change in the annex to the Decree, i.e. group and terminological adjustment of items, which also represents the renumbering of items compared to the current Decree No 345/2002.

1.6 Risk assessment

Without the adoption of the draft amendment, the current regulation of the use of specified measuring instruments for measurements with significance for the public interest would no longer fully meet the current needs of practice and obsolete requirements would not be eliminated.

2. PROPOSED SOLUTION OPTIONS

2.1 Option 1 (status quo) – Maintaining the current version of Decree No 345/2002

The current decree is an implementing legislation to Act No 505/1990 on metrology that no longer fully meets the economic and social needs of the state.

2.2 Option 2 — Amendment to Decree No 345/2002

This option responds to the current needs in the field of the use specified of specified measuring instruments in measurements of public interest as defined by the Metrology Act. This option is in line with the reasons for the draft amendment to Decree No 345/2002.

The proposed amendments concern the following types of measuring instruments:

1. New items in the type list of specified measuring instruments

Item	Name.	Verification validity period
1.2.2	Multi-dimensional measuring instruments	2 years
1.3.3	Precision Class A volumetric cylinders used for volume checks	unlimited

1.3.5	Transport tanks (cisterns) for liquids	
	b) transport tanks with automatic level gauges	2 years
2.1.1	Measuring instruments measuring water flow quantity	
	c) measuring instruments measuring water flow quantity – water meters with the exception of measuring instruments referred to in points (a) and (b)	5 years
2.2.1	Measuring instruments and measuring systems for gas flow rate and quantity and elements thereof	
	f) thermal mass gas meters	2 years
4.1.5	Temperature measuring instruments used on stationary tanks for conversion to reference conditions	
	a) temperature sensors	4 years
	b) temperature sensors with transducer	2 years
5.1.4	Measuring instruments and measuring systems for charging stations	4 years
8.1.6	Oscillating laboratory density meters with ability to temper the measured sample or with automatic temperature correction	1 year
8.3.2	Measuring systems for determining the energy value of energy gases and their mixtures	1 year
8.3.3	Analysers for the chemical composition of energy gases and their mixtures	1 year
9.6	Measuring instruments for pulse frequency, activity and dosimetric quantitative variables used for early detection of deviations from normal operation in order to prevent the occurrence or development of a radiological emergency	2 years

2. Items subject to a change in the period of validity of the verification or a change in the specification

1.1.1	Material measures of length	5 years
2.1.1	Measuring instruments measuring water flow quantity	
	a) measuring instruments measuring the flow quantity of cold drinking water and hot water	
	— mechanical water meters	5 years
	b) meters measuring the flow quantity of cold drinking water and hot water	
	— static water meters	8 years
2.2.2	Meters and measuring assemblies for compressed gas for the propulsion of motor vehicles	1 year
4.1.1	Electronic contact-type medical thermometers	2 years
4.1.2	Thermal energy meters and elements thereof	
	a) compact thermal energy meters	5 years
	b) flow sensors and flow meters	5 years

	c) temperature sensors	5 years
	f) evaluation units of combined thermal energy meters	5 years
4.1.3	Thermometers for checking temperatures laid down by food and food legislation used by inspection authorities	2 years
4.1.4	Thermometers for checking ambient and hot water temperature with 0.1 °C or better scale division used by inspection authorities	
	a) glass	unlimited
5.1.1	Induction electricity meters for alternating current	
	b) for measuring electrical energy in conjunction with measuring transformers	5 years
5.1.2	Static electricity meters for alternating current	
	b) for measuring electrical energy in conjunction with measuring transformers	5 years

3. Items subject to a change in the type-approval obligation

8.4.1 Butyrometers

4. Items deleted from the existing generic list of specified measuring instrument types

1.1.2 Measuring tapes
1.1.4 Taxi meters
1.2.1 Machines for measuring the area of leather
1.3.1 Metal measuring containers
1.3.4 Sedimentation (Westergren) pipettes
1.3.5 a) transport barrels with the exception of barrels referred to in point (b)
1.3.6 c) concrete and masonry storage tanks
4.1.1 Induction electricity meter manufactured up to 31 December 1989
a) for measuring electrical energy in direct connection
b) for measuring electrical energy in conjunction with measuring transformers
5.1.1 Optical radiometers for the 400 nm to 2800 nm spectral range and radiation measurements in the range 10^{-3} W.m^{-2} to 10^{-2} W.m^{-2}
7.2.1 Prism refractometers with refractive index measurement error $\leq \pm 2.10^{-4}$
7.2.2 Prism refractometers with refractive index measurement error $\leq \pm 5.10^{-5}$

Note: These items are numbered pursuant to Decree No 345/2002

5. Items that are subject to a change of name, division or content

1.1.2	Measuring containers	unlimited
1.3.1	Automatic level gauges of stationary tank measuring systems	
	a) automatic level gauges without automatic checking of metrological parameters	2 years

1.3.2	Volumetric flasks, burettes, precision class A pipettes, AS used for volume checks	5 years
1.3.5	Transport tanks (cisterns) for liquids	
	a) transport tanks with one or more volume marks	4 years
1.3.6	Stationary storage tanks used as volume gauges	
	b) wooden non-transport barrels	5 years
	c) non-transport barrels of other materials	10 years
	d) tanks excluding concrete and masonry storage tanks	10 years
2.2.1	Measuring instruments and measuring systems for gas flow rate and flow quantity and their elements	
	b) Coriolis mass gas meters	5 years
	c) turbine gas meters	5 years
	d) rotary gas meters	5 years
	e) ultrasound gas meters	5 years
	g) compact and combined gas quantity calculators	5 years
	iii. temperature sensor with transducer	2 years
	iv. pressure transducer	2 years
	j) static pressure transducers	2 years
	k) differential pressure transducers	1 year
	m) temperature sensors with transducer	2 years
	n) density and relative density measuring instruments	1 year
3.1.2	Non-automatic scales	
	c) scales for determining axle or wheel loads on rolling stock	3 years
	d) scales for static inspection weighing of vehicles	1 year
3.1.3	Automatic scales	
	e) continuous summing scales	2 years
	f) gravimetric filling scales	2 years
	g) catch-weighing scales	2 years
	h) discontinuous summing scales	2 years
3.3.1	Eye tonometers	
	a) contact mechanical	1 year
	b) contactless and contact electronic	2 years
4.1.2	Thermal energy meters and elements thereof	
	b) flow sensors and flow meters	4 years
	e) pressure transducers	2 years
7.1.1	Measuring instruments and measuring systems for measuring sound as a Class 1 and 2 sound meter or analyser	2 years
9.1	Activity quantitative variables measuring instruments[11] for aerosols, gases and liquids released in the workplace	2 years
9.2	Activity quantitative variables measuring instruments used to check the content of radionuclides in solid substances, items and in equipment released in the workplace	2 years

9.3	Activity quantitative variables measuring instruments used to determine the content of radionuclides in the environment	2 years
9.4	Measuring instruments for activity and dosimetric quantitative variables[12] used to check compliance with the criteria set out in the limits and conditions of a nuclear installation	2 years
9.5	Measuring instruments for activity and dosimetric quantitative variables used to check compliance with the criteria set out in the limits and conditions for handling nuclear waste	2 years
9.7	Measuring instruments for activity and dosimetric quantitative variables designed to monitor the radiation situation during and after a radiological emergency	2 years
9.8	Measuring instruments for activity and dosimetric quantitative variables used to determine personal doses, including personal doses from a radiation emergency	1 year
9.10	Measuring instruments for dosimetric quantitative variables used to determine diagnostic and therapeutic doses applied in medical irradiation	2 years
9.11	Volumetric activity meters for natural radionuclides in the air, equivalent volume activity of radon[13] and dosimetric quantitative variables used for the purposes of preventing the penetration of radon into buildings and for protection against exposure from natural radionuclides in buildings and workplaces with the possibility of increased exposure from a natural source of radiation and with possible increased irradiation from radon	2 years
9.12	Measuring instruments for activity quantitative variables used to check the content of natural radionuclides in building materials and drinking water	2 years
9.13	Measuring instruments for activity quantitative variables used to check the content of radionuclides in food and dosimetric quantity meters used for routine and validation measurements in food irradiation	2 years
9.14	Measuring instruments for pulse frequency, activity and dosimetric quantitative variables used to prevent and detect unauthorised activity associated with fissile and other radioactive substances	2 years
9.15	Measuring instruments for pulse frequency, activity and dosimetric quantitative variables used for the detection and identification of a radionuclide source in the search for an orphan source by operators of a scrap metal smelting, collection and processing facilities and operators of waste incineration plants and co-incineration plants	2 years
9.16	Activity spectrometers used to check radionuclide content in metallurgical products and radiopharmaceuticals	2 years

Note:

[11] Activity quantitative variables are defined by ČSN EN ISO 80000-10:2013.

[12] Dosimetric quantitative variables are defined by ČSN EN ISO 80000-10:2013 and ICRU Report No. 51.

[13] The equivalent volume activity of radon is defined by ICRU Report No. 88.

A detailed overview of the proposed amendments is set out in the Annex.

3. ASSESSMENT OF COSTS AND BENEFITS

3.1 Option 1 (status quo)

Benefits

None identified.

Costs

The current costs of 'national' type approval and initial verification in the range of measuring instruments listed in the type list of Decree No 345/2002 will not change for domestic manufacturers.

3.2 Option 2

Benefits

The adoption of the proposed legislation will make the necessary adjustments with regard to the alignment (terminological) with the European legal order as well as with the law of the Czech Republic and with regard to requirements based on the needs of state authorities in connection with the protection of public interests (e.g. consumer protection, protection of the public interest in the determination of fees and taxes, environmental protection, etc.). Most of the items in the type list of specified measuring instruments are retained in the proposed amendment within the wording of the existing Decree.

Users of specified measuring instruments for which the validation period is extended shall experience a decrease in the periodic cost of verification of the specified instrument for the duration of its use.

Costs

In the case of measuring instruments of a type that is newly included in the Annex to the Decree and for which the resulting obligation of type-approval and verification before placing on the market arises, the manufacturer shall incur a one-off cost of type-approval of the specified measuring instrument.

In the case of the use of a specified measuring instrument, this is the cost to the user of the specified measuring instrument which incurs the periodic cost of verifying the fixed meter during its use.

The amount of these costs is described below for each new item in the type list of specified measuring instruments.

I. New entries in the type list of specified measuring instruments

1. Multi-dimensional measuring instruments (item 1.2.2)

This is a type of measuring instrument that is made available on the market by (harmonised) conformity assessment procedures (pursuant to Act No 90/2016) and to which the technical requirements specified in Decree No 120/2016 are applied. (Annex 11 to Government Regulation No 120/2016 — Measuring instruments for measuring dimensions). These are the requirements of Directive 2014/32/EU of the European Parliament and of the Council on the making available on the market of measuring instruments (MID). These are therefore specified products placed on the market (EU) for measurement with importance to the public interest. From the group of measuring instruments for measuring dimensions, in the current regulation there are measuring instruments for measuring length and measuring instruments for measuring area. However, measuring instruments for multidimensional measurements (used to determine the circumferential dimension/length, height, width/lowest rectangular parallel beam containing the measured object) are also used in recent years for measurements in contractual relationships, i.e. with the meaning defined in § 3(3) of the Metrology Act, which is analogous to that stated in the MID. The regulation will apply to units or a few dozen meters used mainly in logistics services. The proposed period of validity of the verification is 2 years. The costs of verification (excluding transport and carriage costs for reference artefacts) are estimated at thousands of CZK (up to approximately CZK 5,000), depending on the measuring ranges and the design of the multi-dimensional measuring instrument. Verification will be carried out by the CMI.

2. Precision Class A volumetric cylinders used for volume checks (item 1.3.3)

This is an item that allows the use of graduated cylinders of accuracy class 'A' for state-defined purposes (checking contractual obligations, consumer protection) pursuant to the Metrology Act and other legislation.

Grounds for inclusion of these measuring instruments under metrological regulation is the legal requirement laid down by Act No 634/1992 on consumer protection – in particular § 3(1)(a) and (d) and § 15(1), from which it follows that the seller is obliged to sell the products in the correct weight and extent, … and must enable the consumer to check these data. At the same time, measuring instruments used by inspection bodies for inspection of sellers must comply with the requirements laid down in another regulation, the one governing the field of metrology (the Metrology Act). The users of these measuring instruments are therefore, for example, the operators of restaurant establishments selling beverages by the glass and inspection authorities (for example, the Czech Trade Inspection Authority, the State Agricultural and Food Inspection Authority), which inspect these operators within the scope of their competence. On the basis of the observations and objections of the entities impacted by the measurements, it is desirable that the accuracy of these measuring instruments to be declared by official verification as a guarantee of the reliability of the measurement.

The methodology for checking the volume of draught and poured beverages, elaborated as part of the metrology development program in 2015, refers directly to graduated cylinders of accuracy class 'A', which were for these purposes up to now only calibrated. Accuracy class 'A' allows identification of the measuring cylinder (by marking during production) and guarantees the required measurement accuracy and thus checking. In terms of ease of use and at the same time low price, the use of graduated cylinders to check volume is more efficient and faster than the use of scales.

The period of validity of the verification (unlimited) is identical to very similar types of measuring instruments (burettes, pipettes, etc.) that have long been included in the type list of specified measuring instruments.

Modernisation of the legislation with regards to the introduction of measuring cylinders of accuracy class 'A' on the type list of specified measuring instruments will make it possible to prevent the consequences of non-conforming states of these measuring instruments in operation to the benefit of the parties to the obligations and leads, among other things, to the improvement of the metrological regulation in the area similarly addressed by other neighbouring EU Member States**.**

The regulation will affect an unspecified number of measuring instruments in operation. The proposed type list item shall define only measuring cylinders in precision class 'A' for state-specified purposes. In the Czech Republic there are currently two producers of these measuring instruments – Technosklo, s.r.o. and Kavalierglass, a.s. In addition to domestic producers, there are a number of importers of these measuring instruments from abroad. Measuring cylinders are manufactured according to ČSN EN ISO 4788 'Laboratory glass – graduated cylinders' and, as in the case of measuring flasks, are not subject to type approval, only initial verification. The initial verification process will be the manufacturers' responsibility. Since the period of validity of the verification is unlimited, no additional costs are expected to burden the users of these measuring instruments.

3. Transport tanks for liquids – transport tanks with automatic level gauges (item 1.3.5 b)

Under this legislation, transport tanks mean mobile tanks for liquids such as petroleum products, certain foodstuffs (beer or milk) situated on road or railway vehicles that are also built as measuring instruments for the volume of liquid transported (theoretically these may also be measuring instruments on ships). It is either a tank fitted with a structural element with a single volume mark (e.g. a viewport showing a mark related to the level of liquid in the tank, or an overflow device identifying a level corresponding to the relevant volume) or a tank that is equipped with multiple volume marks (a scale by which a specific level of liquid in the tank corresponds to a given volume) or a tank that is equipped with a level meter (an electronic measuring rod or an ultrasonic level sensor, where automatic level gauge means a type of level gauge with an operating mode that calculates the volume of liquid in the tank including the influence of inclination relative to the longitudinal and transverse axis).

In practice, these measuring instruments are currently used within the meaning pursuant to § 3(3) of the Metrology Act, i.e. as specified measuring instruments, in particular when measuring volume for the purposes of contractual relations in connection with the distribution of the aforementioned liquid goods. In the vast majority of cases, this involves measuring the volume of fuel when delivering fuel to petrol stations from refineries and measurement when distributing beer from breweries to larger customers.

This type of measuring instrument (in the case of a tank with a level gauge we can speak of a measuring system) is already included in metrological regulation (transport tanks for liquids), but an addition is proposed that takes into account use and practical experience with the stability of automatic level meters subjected to mobile operation (compared to automatic level gauges on stationary tanks).

The reason for adding the specification of the item to the type list of measuring instruments is to make it possible to distinguish the period of validity of the verification of measuring instruments (measuring systems) in an operationally 'more robust' (albeit less convenient) mechanical design from modern but more operationally sensitive measuring instruments with automatic level gauges.

The proposed period of validity of the verification corresponds to existing knowledge regarding the stability of these measuring instruments in normal operation, taking into account mobile operation and the opinions of manufacturers of level gauges. This is in accordance

with the period of validity established for stationary tanks with electronic level gauges (without automatic checking of metrological parameters) and in particular with measuring systems based on other measuring methods – items 1.3.11(i) and 1.3.12 of the Annex to existing Decree No 345/2002 and with the period of validity of the verification of these measuring instruments in Germany. Technical and metrological requirements are covered by OIML R 80 (2017). The qualified estimate of the number of such meters in operation is more than 200. The regulation does not significantly affect the type approval or initial verification of measuring instruments. The price for type approval is about CZK 40,000 and for verification about CZK 18,000 (price for verification of a five-chamber tank (cistern) with level gauge, which usually represents five separate measuring systems). The proposed period of validity of the verification is 2 years. Verification will be provided by the CMI.

4. Water flow quantity meters – water flow quantity meters – water meters other than those set out in points (a) and (b) (item 2.1.1 c)

The implementation of Directive 2014/32/EU of the European Parliament and of the Council on the making available on the market of measuring instruments into Czech legislation defined water meters made available on the market by means of conformity assessment, namely water meters intended for measuring cold drinking water and hot water.

The new standard for water meters (ČSN EN ISO 4064) terminologically introduces water meters for cold drinking water and hot water, i.e. water that is supplied to normal customers. The designation of the type of water meters in the draft amendment to the Decree therefore adheres to the term used in that standard.

At the same time as measuring the supply of cold drinking water and hot water, there is a need to measure the flow of dirty water, i.e. water that does not meet the above specification. This includes, for example, surface water, groundwater, waste, rainfall, irrigation, etc. Measurement of such waters is stipulated in legislation (e.g. Act No 274/2001 on water supply and sewerage systems or Decree No 328/2018 on the procedure for determining waste water pollution, carrying out readings of the amount of pollution and measuring the volume of discharged waste water into surface water) including the requirements for a meter if the volume of water flow is measured in a fully filled pipeline.

This is a regulation in the field of measurement of unclean water, which is not harmonised within the EU.

The proposal to include a new type of measuring instrument addresses the situation where the Czech legal order stipulates measurement of the flow rate of other than cold drinking water or hot water and where there is no precise specification of the corresponding type of measuring instruments (with different technical and metrological requirements) in metrological regulation. The introduction of a new item on the type list of specified measuring instruments should eliminate this disproportion. The proposed period of validity of the verification is 5 years.

The estimated number of metering instruments is in hundreds of units. The cost of type-approval and verification is comparable to the cost of testing water meters for cold drinking water and hot water. Verifications will be carried out by CMI and authorised metrology centres.

5. Measuring instruments and measuring systems for gas flow rate and flow quantity and their elements

- thermal mass gas meters (item 2.2.1 f)

This is a new item on the type list of specified measuring instruments, which can be used in contractual relationships similar to other measuring instruments and gas flow rate and quantity measurement systems set out in item 2.2.1. The reason for the proposal is to allow the use of gas meters with new design solutions, as in the future it can be assumed that their technical development will reach a level meeting the standard requirements for measurement reliability.

Gas meters are representative of a type of measuring instrument whose accuracy of measurement is of great social importance on a global scale and are therefore subject to harmonised metrological regulation when making them available on the market and putting them into service (see Directive 2014/32/EU or Government Regulation No 120/2016) and during their operation. For the same reasons, it is a type of measuring instrument undergoing intensive technical development, not only within the framework of established 'traditional' measurement principles, such as diaphragm gas meters or rotary and turbine gas meters, but also by introducing gas meters operating on other measurement principles, such as meters based on the thermal mass principle.

The aim of the proposed legislative amendment is therefore to allow the use of gas meters using all measuring principles as specified measuring instruments. Simultaneously, the aim is to bring the national legislation for the regulation of measuring instruments and measurement into line with the European legislation for the placing on the market of gas meters. In terms of placing on the market and putting into service, the said Measuring Instrument Directive explicitly applies only to meters intended for measuring, recording and indicating the flow quantity (volume or weight) of heating gas, but is not limited to specifically specified (and thus defined) measurement principles, unlike the current legislation of the Czech Republic. This may lead to regulatory inconsistencies in that a non-diaphragm gas meter with rotary pistons or speed-type (intended to measure the flow quantity of heating gas intended for use in housing, trade and light industry) was marketed for use in contractual relationships [see § 1(2) (b) of Government Regulation No 120/2016, as amended], i.e. as a specified product (pursuant to Act No 90/2016, as amended), but could not be used for measurements in contractual relationships in the Czech Republic because its type would not be included in the type list of measuring instruments.

Several EU type-examination certificates for thermal mass gas meters have recently been issued by notified bodies in the EU. This leads to a relevant consideration that the number of installations in the regulated area of metrology will increase in the coming years (tens to hundreds of installations over the next ten years). Given that contrary to expectations this principle was ultimately maintained in the overview of suitable types of flow meters and flow-through quantities of gas for the transport of natural gas, mentioned in the revised version of the internationally recognised normative document EN 1776 (in the Czech Republic ČSN EN 1776), we can legitimately expect an increased demand for potential users of these meters with the possibility of their use as a specified metering instrument in the coming years.

Due to the lack of tested and confirmed long-term stability of measuring instruments based on this principle not only in the Czech Republic but also abroad, a verification validity period of 2 years is proposed. The cost of verification is estimated at CZK 2-3,000 depending on the possibilities of using synergistic effects of the tests performed (similarly as in the case of the most widely used diaphragm gas meters). Verification will be provided by CMI and Authorised metrology centres (AMS).

6. Temperature gauges used on stationary tanks for conversion to reference conditions (item 4.1.5.)

a) temperature sensors

b) temperature sensors with transducer

Temperature sensors installed on stationary tanks intended to measure the temperature of a stored liquid are considered to be temperature sensors used in stationary tanks for conversion to reference conditions within the framework of national metrology legislation.

A new amendment is proposed, which takes into account the need for unambiguous identification of the temperature gauge used on (in) the tank for conversion to reference conditions, directly in the type list of specified meters. This change will result in full coverage of the measured physical quantitative variables for measuring systems on (in) tanks and full consideration of the methods used to measure the volume on stationary tanks.

At present, a qualified estimate can be made that the number of measuring instruments of these types, operated or operable as specified measuring instruments, is approximately 200 based on records of metrological activity kept by the CMI. No major consequences of the proposed regulation in relation to type-approval or verification processes are expected. The continuity of these measuring instruments is already ensured through calibration, and these are already regular type-approved temperature gauges. The number of types of temperature gauges is in the single digits.

The measuring instruments are not manufactured in the Czech Republic, and are imported from other countries. The cost of verification is estimated at approximately CZK 3,000-9,600 depending on the type and number of sensors. If the temperature sensors are also equipped with electronic transducers, the cost of type approval will also increase proportionally (EMC tests, SW tests, etc.), which can roughly double the cost.

Verification will be carried out by CMI and AMS.

7. Measuring instruments and measuring systems for charging stations (item 5.1.4)

This is a new entry in the type list of specified measuring instruments including measuring instruments and measuring systems used to measure electricity taken from the grid and supplied to vehicles (electric cars) within publicly accessible electricity networks – public charging stations. Although the billing regimes for electricity use may be different or even combined (with a flat fee for occupying a charging point, billing per time unit), charging for electricity use is considered an essential component and, from the point of view of the contractual relationship, it is a relationship in the public interest (similar to the sale of fuel at filling stations) – direct sale of electricity to consumers (see also Act No 311/2006 on fuels and filling stations and Act No 458/2000, the Energy Act). A measuring instrument used to indicate the quantity of energy consumed (when implementing a supplier-consumer contract) should be subject to national regulation in metrology. Recharging (and in particular fast-charging) stations a part of which are measuring instruments and/or measuring systems, are a key part of the charging infrastructure [see the Alternative Fuels Infrastructure Regulation (AFIR), which is part of the Fit for 55 package of the European Union]. The list of public charging stations in the Czech Republic is kept by the Ministry of Industry and Trade. According to this list, a total of 2,462 recharging points (1,739 AC – AC + 723 DC – DC) were put into operation as at 30 October 2022. As far as the types of measuring instruments/measuring systems are concerned, the number of types of metering systems that are expected to be subject to the type-approval of the meter is from single digits to a few dozen. In the case of stand-alone electricity meters (AC and DC), the use of conformity

assessment procedures (electricity meters complying with the requirements of Directive 2014/32/EU or Government Regulation No 120/2016) is foreseen. The cost of type-approval of a charging station can only be estimated (approximately CZK 300k to 400k), because the technical and metrological requirements for charging stations (EVCS, Electric Vehicle Charging Station) and the range of tests are not yet laid down in any applicable technical or normative document, but only in the OIML G 22:2022 guidance document, which is expected to be converted into OIML R document format (recognised EC normative document) within two years. In parallel with OIML activities, the EURAMET project LegalEVcharge (2021-2024) aims to create a practical framework for legal metrology for charging points (including the design of systems for laboratory and on-site verification of EVCS). This trend reflects the delayed effectiveness of introducing new types of measuring instruments, including this one, in the annex to the Decree. The verification costs will be quantified in relation to verification methods, which, taking into account the above mentioned OIML international document, will be specified in the upcoming legally binding regulation – measure of a general nature. The objective is to achieve such technical parameterisation of tests during the verification of meters and measuring systems of charging stations so that the cost of verification is on the order of thousands of CZK (from CZK 2,000 to CZK 4,000) depending on the technical parameters and design of the meters being verified. At present, in view of the dynamic technical and harmonisation developments in this area and related activities in the form of the creation of normative or technical documents, the price for verification cannot be defined more precisely.

In view of the fact that the nature of the verification of this type of measuring instrument is, in principle, very close to the verification of fuel pumps (covered by the CMI's regional inspectorates with territorial jurisdiction), involving direct sale to the public, which is accompanied by an increased public interest in demonstrating the correctness of measurements of the specified measuring instruments used, it is assumed the existing optimal CMI infrastructure will be used for verification.

8. Oscillating laboratory density meters with ability to temper the measured sample or with automatic temperature correction (item 8.1.6)

At present, item 7.1 of Decree No 345/2002 lists various types of laboratory glass density meters that are used as specified measuring instruments. The Czech manufacturer of glass density meters is Exatherm s.r.o. based in Železný Brod.

Glass density meters are gradually being replaced by a more modern alternative – oscillating density meters, confirmed by a gradual increase in the number of oscillating density meters currently being calibrated.

Oscillating density meters provide quick and easy measurement of density throughout their declared temperature range. In addition, more accurate oscillating density meters allow adjustment to the desired temperature with high accuracy. Most of the measurements are carried out at a temperature of 20 ^{o}C, in the case of petroleum products at a temperature of 15 ^{o}C. This eliminates the problem of self-tempering of the measuring solutions before and during the measurement if glass density meters are used.

Oscillating density meters provide a quick way of measuring density using a minimal sample quantity (approx. 2 ml per sample). In the case of glass density meters, measurements are carried out in a measuring cylinder and therefore at least 1000 ml of the measuring solution or sample is needed.

In addition to simplifying and accelerating density measurements, the accuracy of density measurement of liquids will be improved.

There are no statistical data available, but it can be estimated that an order of dozens to several hundred measuring instruments will be affected by the introduction of oscillating density meters in regulation. No manufacturer has been identified in the Czech Republic and the measuring instruments are imported from abroad (Anton Paar – Austria, Mettler Toledo – a Swiss-American company). The estimated cost of type approval is about CZK 300,000, for verification about CZK 10,000.

The proposed validity period of 1 year is based on typical data on the long-term stability of the metrological properties of the measuring instrument, which is reported by the manufacturer in the technical documentation, and experience in calibration of oscillating density meters.

The users of laboratory density meters are customs officers (checks of volume concentration of alcohol) and taxable entities (distillers, grower distillers), with the estimated number of meters being in the hundreds. Users of laboratory density meters are also personnel checking the density of petroleum products, with the estimated number of meters being in the dozens.

Verification will be provided by the CMI.

9. Measuring systems for determining the energy value of energy gases and their mixtures (item 8.3.2)

Measuring systems for determining energy values of energy gases and their mixtures are intended for determining the energy value (gross calorific value - GCV) of energy gases and their mixtures during their distribution in gas networks. While the quantity of gas (standard volume) is measured individually for each customer, the GCV is measured at several locations in larger areas of the gas network.

If gases, the GCV's of which differs only marginally are supplied to the gas network, general procedures may be used to determine the value of GCV in the gas network, such as attributing the volume-weighted average value of GCV measured at the input to the grid over a given billing period.

In networks with very different GCV (e.g. deviation of one or more GCV by more than 1%, from the volume-weighted average GCV in the grid), alternative procedures for the clear determination of GCV need to be used.

If, for technical or economic reasons, measures such as splitting the grid into separate sub-networks with only one input at a given time, an open network route and the measurement of GCV at all transmission or mixing points, or limiting the range of fluctuations in delivered calorific values is not possible to use, a dynamical GCV calculation from the GCVs at the gas network inputs is another technical option.

The dynamic calculation of GCV is based on the operation of the so-called reconstruction system, which is based on the geometry and topology of the network (pipe length, internal pipe diameters, roughness of pipes, position of valves, etc.), volume flow and gas quality data at the input points of the network and data on pressure and volume flow measurements at the outlet points of the network. The numerical solution of a systems of equations for each required point of a specific gas network is used to calculate the GCV of the gas and its variation over time. Since in practice it is not possible in most cases to determine the geometry of the pipeline network with sufficient precision, in particular the roughness of the pipeline, even small differences in the volume balance of the gas network cannot be avoided. For this reason, additional pressure or flow meters that are installed in the gas network are integrated into the mathematical-physical system description. Thanks to these metering instruments the improbable calculation results can be identified. It is also possible to correct

these differences by automatically adjusting the calculated pressures or volumes to those measured.

Due to the complexity of these systems (measuring systems for determining energy value of energy gases and their mixtures) regular comparison of the calculated gas quality values with the results of measurements of the reference measuring devices, which must be located at selected grid points, must be carried out in order to check for correct operation.

The system for determining the GCV of energy gases and their mixtures in the gas network can be very different in individual cases for different gas companies, due to differences in network topology, their operation and different data transmission and processing systems. The basic components of the system are as follows:

- measuring equipment for recording and storing qualitative gas parameters at inputs (process gas chromatographs, equipment for recording measured values)

- measuring equipment for recording and storing volumetric flow rates at inlet and outlet (volume meters, equipment for recording measured values)

- reference measuring points (calorimeters, PGC)

- other measuring equipment for recording supporting values (e.g. pressure measurement)

- network topology (pipe diameter, roughness, compressors and regulators, gate valves, geodetic height).

- equipment, programs and procedures for data transmission, data storage and programs for generating substitute values

- programs for gas flow reconstruction and determination of data on gas quality for each sampling point

- auxiliary programs for process documentation, visualisation of network topology and system control.

Data in measurement systems are usually stored temporarily and transmitted to a central system. For this purpose, known measuring recording devices can be used as well as remote control systems for system management. For data transmission and storage, there are certain requirements for GCV systems that ensure data protection. The protection of data transmission must be checked during the type-approval of such systems.

In addition the reconstruction software itself, the GCV system software also consists of programs for transmission, processing and storage of input and output data. As part of the approval procedure, the parts of the program that are subject to type-approval are determined, checked and described.

One of the main prerequisites for the deployment of a GCV measurement system for energy gases and their mixtures is the existence of a gas network model. The network model must correspond as closely as possible to the real gas network. The topology of the network is part of the type-approval and verification of the given system. It must be possible to display it at any time in a clear form (e.g. a network diagram). Changes in network topology must be documented in a traceable manner.

In determining GCV, the correct grid topology applicable at a given time must always be used, even in the case of repeated runs.

Due to the complexity and size of the systems for determining GCV, the Monte Carlo method is recommended to determine the measurement uncertainty. The advantage of the Monte Carlo method is primarily the ability to calculate uncertainties with a complicated distribution of input quantitative variables and the suitability of use when the model contains non-linearities or correlated quantities.

A measuring system for determining the energy value of energy gases and their mixtures is therefore a complex system in which the quantity of gas (volume), gas quality, gas pressure and gas temperature are all measured.

Type-approval of measuring systems for determining the GCV of energy gases and their mixtures will be performed by the CMI. The type-approval of the system will always be linked to the specific infrastructure (topology and technical solution) of the gas supply company that will use the system. Therefore, the cost of type-approval cannot be exhaustively determined. However, given the demanding nature and complexity of such systems, the cost of such systems cannot be estimated to be less than hundreds of thousands of CZK.

Verification of measuring systems will be carried out by the CMI. Based on the reconstruction runs, the measuring system being verified will be checked to determine whether it delivers values that correspond to sampling in the network within the defined maximum allowable errors. Measurement points shall be established taking into account technical and marginal conditions, giving priority to sites where fluctuations in gas quality can be expected. Information on such possible network sections may be part of the type-approval. Similarly to type approval, verification costs cannot be determined. However, given the demanding nature and complexity of such systems, the cost of such systems cannot be estimated to be less than tens of thousands of CZK.

In addition to periodic verification (5 years), measurement systems in the gas network will be periodically checked using 'short tests', which need to be passed for the verification of the whole system for determining the energy value of energy gas or its mixtures to be valid. Specified metrological check tools to demonstrate the correctness of the calculated values will be subjected to systems for completeness and admissibility even in cases where there is a change in the network topology or the conditions under which the type-approval of the measuring instrument/measuring system has been carried out.

10. Chemical composition analysers for energy gases and their mixtures (item 8.3.3)

This type of metering instrument is being increasingly used in the gas sector, as the gas industry is currently intensively preparing to measure the chemical composition of new mixtures of energy gases. For example, mining gases or degassing gases (in some sources these two terms are understood as synonyms, in some, including legal documents, as two types of gas), are gases (methane, etc.) that objectively always occur in mining during the preparation of deep mines for extraction or even immediately prior to extraction, from newly opened fields (the gas yield is reduced, including preventively on the face of long mining works by systematic degassing, even regardless of the presence of gases). Biogas is a raw gas produced by anaerobic fermentation of organic matter that contains about 50% to 70% methane, with the rest consisting of carbon dioxide, sulphur compounds, ammonia and other impurities. Biomethane is purified biogas, suitable for injection into gas networks, containing at least 95% methane. Biomethane is a CO_2-free biogas and has the lowest greenhouse gas emissions and the lowest life-cycle energy consumption compared to other conventional biofuels, especially when produced from waste biomass.

Decree No 166/2022 on reporting energy from supported sources and Decree No 108/2011 on the measurement of gas are relevant within the legislative framework.

In view of the strategic objectives of finding alternative energy sources, the distribution and utilisation of various gases with energy potential is generally foreseen.

Currently, in relation to the gas distribution system, it is possible to speak of natural gas, biomethane and degassing gas. The physical and chemical parameters of gas, currently specifically natural gas and biomethane (within the meaning of Decree No 108/2011, as

amended), must correspond to the limit parameters laid down in the Decree and must also be measured.

The analyser of the chemical composition of gases in this sense is a gas chromatograph. In the case of natural gas, the established term is *process gas chromatograph*, which means a gas chromatograph installed in the distribution system, regularly and continuously measuring the chemical parameters of natural gas automatically sampled from the system. However, in the case of measurements of the chemical composition of degassing gas and biomethane, a gas chromatograph cannot be recommended, as it is unnecessarily complex and expensive, and in operation is sensitive to gas purity, condensates and volatile chemical composition. In addition, a process gas chromatograph capable of measuring methane in the range starting at 40% is not capable of measuring methane concentrations in degassing gas below this minimum, though these concentrations occur in practice. It seems more appropriate to measure the chemical composition of degassing gas and biomethane using a *chemical composition analyser*, which compared to a process gas chromatograph has a simpler design, and hence is cheaper and less sensitive to the quality of operating conditions.

In the Czech Republic, several types of degassing gas analysers are being used to measure its quality, e.g. SICK S710 (which measures CO_2, CH_4, O_2). Degassing gas currently is not distributed together with natural gas (it does not fulfil qualitative parameters that are important to allow it to be introduced into the distribution system: methane content, moisture content, etc.), and is mostly used at the mining site and in its vicinity. It is distributed by separate piping systems (operations using degassing gas are specifically modified for the use of this fuel). In the case of these analysers for degassing gas, in the present and near future, applications in the area of use in local networks are therefore more likely, as its injection into the conventional gas network used for the distribution of primarily natural gas is not yet being considered.

In the case of biomethane, which is expected to be injected into the gas network (or already is), the process gas chromatographs normally used to determine the energy value of natural gas are currently being used to determine its quality, though with certain pitfalls. As opposed to degassing gas, biomethane can be co-distributed with natural gas after treatment. Biomethane chemical composition analysers can become a suitable alternative to process gas chromatographs, or replace them under certain circumstances and conditions, especially in local networks.

The proposed amendment reflects the social importance of measuring the parameters of energy gas during its supply and consumption.

The proposed change may have an impact on users who are already ensuring the correctness of these measuring instruments in calibration operations when using significantly longer recalibration intervals than recommended by the manufacturer. The verification price is assumed to be comparable to the calibration price.

Gas chemical composition analysers (as well as process gas chromatographs) belong among meters whose measurement principles, when required to maintain elemental qualitative parameters, do not allow to determine a metrological continuity period of more than 1 year. This data (the proposed validation period) corresponds to the recommendations of most manufacturers as well as to the experience that CMI has from the previous continuity processes (calibration and assessment) for degassing gas analysers.

The qualified estimate of the number of such meters in operation is dozens of units. At present, it is not possible to estimate the number of types of measuring instruments of this kind that could (qualitatively) be considered as 'suitable' for type approval and that are on the market or in operation in the Czech Republic.

The cost of type approval is estimated at about CZK 120,000, the cost of verification will be approximately CZK 10,000. Verification will be carried out by the CMI.

11. Pulse frequency, activity and dosimetric quantitative variables measuring instruments used for early detection of deviations from normal operation in order to prevent the occurrence or development of a radiological emergency (item 9.6)

This is an entry in the type list of specified measuring instruments, that logically relates to part 8.7 of the current Decree No 345/2002 (from which Group 8 items are restructured overall) and that relates to emergency measurements as it covers the emergence and development of deviations from normal operation that may lead to a radiological emergency.

The existing type of measuring instrument '8.7 … measuring instrument for emergency measurement' is supplemented and split into two specific items in the new draft decree, which include newly included measuring instruments for early detection of deviations from normal operating state as well as existing measuring instruments for monitoring the radiation situation during and after radiation emergencies, which are a different type of measuring instrument with different parameters and qualifications. The reason for the proposal to include the measuring instruments in question in the regulation are the amended IAEA safety standards and their reflection in the new Czech legislation. The documents also redefine the purpose of measurements. The effect of the regulation of these measuring instruments is to increase the safety of the operation of nuclear facilities and workplaces with radioactive emitters, where a radiological emergency may occur.

Newly introduced measuring instruments for early detection of emerging deviations from normal operating conditions are intended to enable operators to diagnose evolving deviations from normal operating conditions in accordance with IAEA safety standards, so that they can evaluate parameters and take corrective action at an early stage to ensure that a small failure does not develop into a serious equipment failure or accident.

The introduction of these measuring instruments among the types of specified measuring instruments is supported (justified) by Czech and international regulations and recommendations.

Act No 263/2016 of 14 July 2016 (hereinafter the 'Atomic Act'), as amended by Act No 183/2017, lays down in § 155(1)(a) the obligation to prepare for the detection of the occurrence of a radiological emergency as part of the preparedness to respond to a radiation emergency. Implementing Decree No 359/2016 of 17 October 2016 on details for ensuring the management of a radiological emergency lays down in Part Three (§ 5 to § 20) the requirements for preparedness to respond to a radiological emergency, including requirements for measured quantitative variables and measuring instruments. This concerns, in particular, § 6(4), which imposes requirements on measuring instruments and measurements within the framework of procedures and measures to ensure the detection of a radiation emergency.

IAEA document: *Safety STANDARDS SERIES No. NS-G-1.10* (clauses 4.216, 6.28 to 6.32) and the Appendix (in particular points A.11 – A.15) specify, among other things, safety-relevant measuring instruments that must be used for early detection of developing deviations from normal operating conditions.

To support the implementation of this IAEA safety document, the relevant international standard is *IEC 60910:1988,* (see reference Containment monitoring instrumentation for early detection of developing deviations from normal operation in light water reactorshttps://webstore.iec.ch/publication/3893&preview=1).

A radiological emergency is defined in § 4(1)(a) of the Atomic Act.

A radiological emergency means an event that leads or may lead to exposure limits being exceeded and that requires measures to prevent them from being exceeded or deteriorating from the point of view of providing radiation protection.

Pursuant to the Atomic Act, a radiological emergency has three levels (according to severity):

- level one radiation emergency
- radiation accident
- major radiation accident

The draft introduces a type of measuring instruments that are used to detect deviations from normal operation in order to prevent the occurrence or development of a radiation emergency of all levels, including level one, as even in a level one radiation emergency, exposure limits may be exceeded.

At the stage of detection of deviations, it is not possible to predict what classification a radiation emergency will receive during its development (level one, radiation accident, major radiation accident).

In § 6(4), Decree 359/2016 on details for ensuring the management of radiological emergencies does not limit the obligation to use measuring instruments and measured quantitative variables according to the level of radiation emergency.

At the same time, the item includes the original part of item 8.7 – Non-spectrometric activity and dose measuring instruments used to check compliance with radiation protection limits …, and thus covers instruments measuring such deviations from normal operation that lead or may lead to radiation limits being exceeded, i.e. used for measurements to comply with those limits. The ranges and design of the measuring instruments correspond, unlike item 9.7 (of the new draft decree), to normal operation. Therefore, they do not need to be broad-range measuring instruments or specially qualified measuring instruments (safety class of selected equipment important for nuclear safety).

The wording and definitions of the above-mentioned IAEA document and IEC standard have been incorporated. The term 'normal operation' is defined by the international document *IAEA Safety Glossary, Terminology Used in Nuclear Safety and Radiation Protection*2016 Revision: *Normal operation - operation* within specified *operational limits and conditions*. Decree No 329/2017 of 26 September 2017 on requirements on the design of a nuclear installation also defines normal operation in § 2(d) as the state of a nuclear installation in which the limits and conditions are complied with.

The frequency of impulses is a standard quantitative variable. Although mostly activity or dosimetric quantitative variables are used by measuring instruments to detect deviations, in a number of cases, frequency and trends are sufficient to determine deviations.

These are mainly measuring instruments designed for detection of leakage in technological barriers, especially special dose power monitors and volumetric activity monitors of radioactive gases and liquids. One possible example of such a measuring instrument is, for example, a noble gas monitor in the generating block containment of Temelín Nuclear Power Plant (NPP)

The regulation will affect an estimated dozens of measuring instruments. Two manufacturers of the measuring instruments in question were identified in the Czech Republic. The cost of type-approval is estimated to be up to CZK 1 million, initial verification costs up to CZK 700,000. The cost of subsequent verifications is estimated at CZK 500,000. Verification will be carried out by the CMI.

Current long-standing practice corresponds to the proposed period of validity of verification (2 years) for measuring instruments of atomic and nuclear physics quantitative variables that

do not apply to direct radiation protection of persons, but rather to technical facilities. This period seems to be optimal.

II. Items subject to a change in the period of validity of the verification or a change in the specification

1. Material length meters(item 1.1.1)

In the current Decree No. 345/2002, the group measuring instruments of geometrical quantitative variables contains item 1.1.1. Length measuring instruments for goods sold by length. As the name suggests, these are measuring instruments used for a defined specific purpose (measuring goods sold by length, especially in the retail network). Within the framework of harmonisation of the placing on the market of (specified) products (pursuant to Act No 90/2016 and the related Act No 120/2016) with conformity assessment procedures, a situation occurred when measuring instruments – material measures, which also include length measuring instruments – are placed on the market within the EU. These are measuring instruments intended to be used for measurements in contractual relationships, in consumer protection, in the determination of penalties, fees, tariffs and taxes, in connection with the protection of the environment, in ensuring public security and order, in connection with the protection of public health, or in connection with the protection of other public interests protected by other legislation, i.e. used with the same meaning for which the types of specified measuring instruments are listed in the annex to Decree No 345/2002 pursuant to the Metrology Act. Therefore, where material measures length meters are placed on the market (EU), it is necessary to accept conformity assessment procedures for the same purpose as for which length meters for goods sold by length are introduced into the national regulation in metrology for the purposes of national regulation (use of specified measuring instruments). For this reason, the existing entry in the type list of specified measuring instruments ‘Length measuring instruments for goods sold by length’ is replaced by the entry ‘material length meters’. Material length meters include both rigid or semi-flexible measures, as well as tape and folding measures. The amendment of the item changes the specification of the specified measuring instrument (in accordance with the requirements of Government Decree No 120/2016) and thus also broadens the options for using a measuring instrument for this purpose in the public interest (specifically in a contractual relationship) on the market. The number of length gauges used for goods sold by length is estimated at approximately 3 to 4 thousand (according to the number of verifications). The change in the specification of the measuring instrument will widen the range of users to include all those who use a length gauge in the commitment relationship to determine the correct measure of goods (compared to the current definition for metric goods: heavy goods sold by length, light goods sold by length and white goods). Taking into account the characteristics of material length meters, a validation period of 5 years is proposed.

2. Meters measuring water flow quantity (item 2.1.1)

a) meters measuring the flow quantity of cold drinking water and hot water - mechanical water meters

b) meters measuring the flow quantity of cold drinking water and hot water - static water meters

This is a materially modified item bringing together the existing differentiation of water meters in item 1.3.9 of Decree No 345/2002, for which harmonisation of the period of validity

of the verification to 5 years is also proposed. Water meters belong among meters whose measurement results (water consumption) play an increasingly important role in contractual relationships. Legislation, for example Act No. 274/2001 on water supply and sewerage systems, Act No 67/2013 regulating certain issues related to the provision of services connected with the use of apartments and non-residential premises in an apartment house, and in general the Metrology Act require the guarantee of correct measurement of water consumption.

Water meters are measuring instruments made available on the market by conformity assessment procedures (see previous entry 1.1.1) according to Directive 2014/32/EU. Their importance (the guarantee of correct measurement of water consumption in contractual relationships) is increasing and is crucial with regard to the number of measurements (the proportion of the population of the Czech Republic supplied with water from water distribution system reached 96% on 31 December 2021, the number of water meters installed in the Czech Republic was 2,243,616 units for 2,241,314 connections on the same date) and the rising price of water from public water distribution system (in 2022 the average price of water in the Czech Republic was almost CZK 50/1 m ^{3} and of sewerage CZK 46/1 m^3). The total water price in the Czech Republic amounted to almost CZK 21 billion in 2021 (according to Czech Statistical Office (CSO) data). To water meters that measure the amount of water supplied from public water supply systems (billing meters) a significant amount number of water meters (so-called apartment meters) must be added, which are used to allocate the costs of supplying cold drinking water and hot water in residential buildings.

Billing water meters are the most common meters to which billing complaints for water supply relate. The accuracy of the measurement is influenced to a large extent by the quality of the water, which depends on the state of the water supply network. In order to find out the actual errors of water meters in operation after different periods of use and under different conditions of use, technical development tasks focused on this issue were executed within the scope of the metrology development programme from 2004 to 2006. From the solution of the task in 2004 it is important to conclude that the results clearly confirm that a considerable part of water meters installed in the water supply network most likely do not have the required metrological properties and that the issue of determining the validity period of verification is complicated in relation to the individual technical characteristics of the types of water meters and especially to the conditions of their installation and use. The conclusions presented in the 2006 Task Report show that after four years of operation, a sharp deterioration of the metrological parameters of the tested water meters (mechanical measurement principle) can already be clearly observed. According to expert opinions, the change in metrological parameters is not significantly dependent on the amount of water flowing, but on the time of operation and is mainly dependent on the locality (purity) of the water.

Independently of these projects, data collection on water meters that are tested on the basis of consumer complaints started in 2014. Statistical data on the actual errors detected and their distribution in relation to the highest permissible errors for measuring instruments in operation (twice the maximum permissible error (MPE) applicable to the verification of water meters) shows that the weighted average of the actual errors of the tested water meters at nominal flow rate Q_n is +10.68% (MPE for operation = 4%), at so-called transition flow Q_t is +11.36% (MPE for operation = 4%) and at minimum flow rate Q_{min} is +12.03% (MPE for operation = 10 %).

Between 2018 and 2019, the behaviour of water meters based on the principle of measurement without a mechanical element (electromagnetic water meter), in the water supply network was investigated. The life expectancy of the water meters, as stated by the manufacturer, is 15 years, in case of intelligent water meters (smart meters) equipped with

remote reading functions. Due to its design, an electromagnetic water meter is suitable for measuring even unclean water (i.e. water with mechanical admixtures), i.e. the correctness of the measurement should not be affected by any mechanical impurities (potentially influencing water meters on a mechanical principle of measurement) contained in the water supply network. Due to the small number of water meters tested and the short period of use of water meters in the real water network (3 years), the results were not statistically conclusive, nevertheless they showed that the water meters tested met the requirements for not exceeding the largest permissible error with a relatively large margin even after (compared to the standard) extended tests of service life of the product. In 2021 electromagnetic water meters made up only 1% of all water meters verified. Ultrasound water meters also reached the same value.

The installation of water meters without a mechanical sensor (i.e. on the electromagnetic or ultrasonic measurement principle) has been carried out by some water companies since about 2012. The results of the subsequent verification (i.e. after 6 years of operation) show very good preservation of metrological properties. As part of the update of the item for water flow quantity, the validity period of water meters without a mechanical sensor (static water meters) is therefore adjusted by extending the validity period of the verification to 8 years.

For water meters with a mechanical sensor (mechanical water meters), it is proposed, based on the collected data and information about the parameter setting of the verification period in other countries, to adjust (unify) the validity period of the verification to a period of 5 years (with the validation period calculated from the beginning of the calendar year following the year in which the verification was carried out. It is expected that further statistical data on this issue will be collected in the coming years, which will allow for further adjustment of this period on the basis of a more statistically significant set of data. In addition to manufacturers' assumptions, the priority of measuring accuracy was taken into account for both water companies and their customers, i.e. consumer protection. The extension of the validity of the verification without the knowledge of the preservation of the technical and metrological properties of the measuring instrument may bring savings in the cost of replacing water meters and simplifying administration, but it can also bring problems, e.g. a reduction in the quality (reliability) of measurement, the possibility that manufacturers with a poorer product quality will enter the market, etc.

The harmonisation of the validation period will also affect hot water meters, where there are currently different validity periods: hot water meters – 4 years, hot water meters used to allocate costs to final consumers – 5 years.

Merging meters for cold drinking water and hot water into one category – water meters – corresponds to the terminology of Government Regulation No 120/2016, OIML documents and EN and ISO standards. In connection with the harmonisation of the national legislation with the legislation for the marketing of water meters under Directive 2014/32/EU and in particular with regard to the content of the term "water meter" under this legislation, it is also proposed, as a secondary regulation, to reduce the current item 1.3.11 of the Annex to Decree No. 345/2002 by deleting the members under a), b) and h).

The (staggered) increase in the annual cost of verifying the cold water meter will not be significant for individual users It will affect water companies (the period of validity of the water meter verification is 6 years) as opposed to housing cooperatives and unit owners' associations in apartment buildings, where the current validity of the verification of the water meter used for the allocation of costs to final consumers is already 5 years. The cost of verifying a main water meter is about CZK 1,500 to 3,000 depending on its type.

3. Meters and measuring assemblies for compressed gas for the propulsion of motor vehicles (item 2.2.2)

For this item, the specification of the original item 1.3.14 of the Annex to Decree No 345/2002 is amended to extend from the original definition as only for natural gas to the determination of compressed gas without defining the type of gas. The modification will extend the regulation of the originally defined medium (compressed natural gas) to hydrogen. The change responds to rapid progress in the application of renewable sources used for motor vehicle propulsion units. The period of validity of the verification of these measuring instruments remains 1 year.

4. Electronic contact-type medical thermometers (subheading 4.1.1)

Amendment of the specification is proposed for electronic thermometers. Veterinary thermometers are proposed for elimination from regulation (part of the current item 3.1.1 of the Annex to Decree No 345/2002), as this type of measuring instrument is not linked to the purpose of use pursuant to § 3(3) of Act No 505/1990 on metrology with a link to the protection of public health, nor are they a medical device with a measuring function placed on the market under Directive 2014/31/EU of the European Parliament and of the Council. Moreover, there is no evidence that such thermometers have been verified in the last years. In this case, the uniformity and accuracy of the measuring instruments shall be ensured by their user by calibration, in accordance with the provisions of § 5(6) of the Metrology Act.

It is proposed that regulation shall be restricted to only electronic medical thermometers, specifically contact thermometers. Electronic medical thermometers operating on the principle of measuring human body temperature by non-contact methods (forehead, ear, etc.) are not proposed for inclusion in regulation. The problem with these thermometers is their accuracy. The manufacturer's declared accuracy of 0.2 °C for non-contact electronic medical thermometers does not correspond to reality and it is not possible to demonstrate compliance with the criteria requirements (in the form of the greatest permissible errors) laid down in the legally binding legislation with the currently used verification methods and reference standards of 0.5 °C accuracy.

5. Heat energy meters and elements thereof [items 4.1.2 (a), (b) (c) and (f)]

In the case of thermal energy meters, i.e. compact thermal energy meters and the elements of combined thermal energy meters (flow rate sensors and flow quantity meters, temperature sensors and evaluation units of combined thermal energy meters) it is proposed, based on the knowledge from the previous verifications and checking of the measuring instruments, to extend the validity of the verification from four to five years.

6. Thermometers used by inspection authorities for checking temperatures laid down by food and food legislation (item 4.1.3)

The current Decree No 345/2002 specifies the type of measuring instruments (thermometers) used to check frozen foodstuffs used by state inspection authorities. Food legislation sets temperature limits for foodstuffs/meals and ambient temperatures in which foodstuffs/meals are processed, kept and stored. The accuracy of the thermometers used by (state) supervisory authorities is currently ensured by verification for the area of frozen foodstuffs and by calibration for the area of plus temperatures. The proposed modification aims to ensure that these thermometers are subject to a uniform verification regime, both for the area of frozen foodstuffs/meals and for other temperatures (the area of refrigerated foodstuffs/meals), including plus (positive) temperatures for foodstuffs/meals and the environment in which they are stored/processed. Measuring instruments made available on the market specifically for the

purpose of checking the above temperatures of foodstuffs/meals allow appropriate measurements (within the required temperature range).

The following legislation governs the area of measurement in question:

- Decree No 366/2005 on requirements applicable to certain frozen foods

- Decree No 137/2004 on hygiene requirements for catering services and on the principles of operational hygiene in epidemiologically serious activities

- Commission Directive 92/2/EEC laying down the sampling procedure and the Community method of analysis for the control of quick-frozen foodstuffs intended for human consumption, Annex II, Article 5 of the General Specification for temperature measuring instruments

- Commission Regulation (EC) No 37/2005 on the monitoring of temperatures in means of transport, storage and storage for quick-frozen foodstuffs intended for human consumption.

The amendment to the regulation will ensure a higher degree of objectivity of temperatures measurement of foodstuffs and meals, as laid down in food legislation, in relation to inspected entities. The use of specified measuring instruments will promote confidence in the accuracy of food temperature measurements carried out by the Czech Agricultural and Food Inspection Authority (CAFIA) and eliminate the double method of ensuring metrological continuity of thermometers (verification + calibration) used for the same purpose of measurement, by unifying them into one method – verification. At the same time, the proposed measure will improve the guarantee of the protection of the health of persons and within the framework of the ATP agreement will increase the objectivity of checks on compliance with temperature in the international transport of perishable foodstuffs.

In many EU countries, thermometers for food temperature checks are under national metrological regulation. CAFIA uses the thermometers in question (namely TESTO 112), which are used in Germany for official food control and are type-approved for this purpose by the German National Metrology Institute – PTB. It can be assumed that the CMI will recognise the type-approval in question and it will not need to be re-implemented. The extension of the regulation to 'plus' temperatures will thus have no financial impact on the users of these measuring instruments – state authorities.

Based on the knowledge from previous verifications and calibrations of the thermometers in question, it is proposed to extend the validity period of the verification from one to two years.

7. Thermometers for checking ambient and hot water temperature with 0.1 °C or better scale division used by inspection authorities (item 4.1.4)

a) glass

The current period of validity of verification set out in the Annex to Decree No 345/2002 is 4 years. Due to the design and immutability of metrological parameters (properties) of glass thermometers over time, it is proposed that the validity period of verification be changed to unlimited.

8. Inductive electricity meters for alternating current (item 5.1.1)

b) for measuring electric energy in conjunction with measuring transformers

Inductive electricity meters in conjunction with measuring transformers manufactured after 1. 1. 1990 were divided into two groups: 1) for use at low voltage and 2) for use at high voltage and very high voltage levels. Based on an analysis of test results in authorised metrology centres, it has been demonstrated that the verification validity period of the first group is too long, also due to the large volumes of electricity measurements by indirect electricity meters, even on the low voltage side. The reason for changing the verification validity period is

therefore to ensure the correctness of the measurement for inductive electricity meters in conjunction with measuring transformers for use at low voltage level. A secondary effect is the unification of the validation periods for both groups, the initial subdivision whose according to the use in the grid lost its significant.

The proposed change will affect about 5 types of measuring instruments with about 5000 units in operation; while it have to be noted that the electricity meters in question have not been manufactured for about 15 years now and distribution companies are replacing them en masse with static meters. Another important fact is that inductive meters have no potential to reflect the new and future technical requirements necessary for their use in so-called smart grids. The increase in the verification frequency of inductive electricity meters in conjunction with measuring transformers for low voltage use does not have a significant impact on the user, given the cost of verification.

9. Static electricity meters for alternating current (item 5.1.2)

b) for measuring electric energy in conjunction with measuring transformers

Similarly to inductive electricity meters, static electricity meters in conjunction with measuring transformers were divided into 2 groups: 1) for use at low voltage and 2) for use at high voltage and very high voltage levels. The reason for the change in the verification validity period is similar to that for induction meters.

The proposed change will affect about 25 types of measuring instruments with about 100,000 meters in operation. Any impact on meter users will not be significant.

III. Items subject to a change in the type-approval obligation

1. Butyrometers (item 8.4.1)

Glass butyrometers are produced from a dimensionally stable homogeneous material, where there are no changes in basic metrological properties. These metrological characteristics are sufficiently demonstrated during initial verification (directly by the manufacturer) and it is therefore not necessary to carry out type-approval. According to information from the only Czech manufacturer of these measuring instruments (KAVALIERGLASS, a.s), no new types of butyrometers are being produced or developed. The proposed abolition of type-approval is practically consistent with other measuring instruments for which this has already occurred in the past (volumetric flasks, burettes and pipettes).

IV. Items that are deleted from the existing list of specified measuring instrument types

1. Measuring tapes - this type of measuring instrument is newly included in item 1.1.1 material length meter, according to the MID specification. At present, no type of this kind of measuring instrument is approved (according to national legislation).

2. Taxi meters - this type of measuring instrument is newly included in item 3.2.3 ‘Taxi meter assemblies’. Taxi meters have not been used separately for a long time now, they are placed on the market by harmonised conformity assessment procedures, are subsequently installed in taxi meter assemblies and are verified as part of the verification of the entire taxi meter assembly.

3. Machines for measuring the area of leather - measuring instruments of this kind have not been verified for a long time now, and are no longer used in practice. It no longer makes sense to regulate this item.

4. Metal capacity measures - measuring instruments of this kind have not been verified for a long time, and in practice they are no longer used for the purposes of § 3(3) of the Metrology Act. It no longer makes sense to regulate this item.

5. Sedimentation (Westergren) pipettes - these pipettes have not been verified for a long time now, in practice disposable (plastic) pipettes are used, and it no longer makes sense to regulate this item.

6. Item 1.3.5 **a) transport drums, with the exception of barrels set out in point (b)** - measuring instruments of this kind have not been verified for a long time, and in practice they are no longer used for the purposes of § 3(3) of the Metrology Act. Transport drums used for the purposes of § 3(3) of the Metrology Act made solely of corrosion-resistant materials [see point (b) of existing item 1.3.5]. It no longer makes sense to regulate this item.

7. Item 1.3.6 **c) concrete and masonry storage tanks - measuring instruments of this kind have not been verified for a long time, and in practice they are no longer used for the purposes of § 3(3) of the Metrology Act.** Storage tanks used for the purposes of § 3(3) of the Metrology Act are made of other materials. It no longer makes sense to regulate this item.

8. Induction electricity meters produced until 31 December 1989 - the proposal to abandon the regulation is related to long-term practice. These are obsolete electricity meters that electricity distributors are already replacing by newer types of electricity meters (static ones).

9 Optical radiometers for the 400 nm to 2800 nm spectral range and radiation measurements in the range 10^{-3} W · m^{-2} to 10^{2} W · m^{-2} – optical radiometers are not used in detecting exposure to UV radiation (with significance pursuant to § 3(3) of the Metrology Act). The problem is the extreme dependence of the effects of UV radiation on the wavelength and the need to measure with a frequency resolution of less than 1 nm. Conventional radiometers do not allow this and therefore optical spectral analysers (two-grid monochromators) are used in practice. Optical radiometers have not been verified for a long time now because they are not used as specified above. It no longer makes sense to regulate this item.

10. Prism refractometers with refractive index measurement error less than or equal to ± 2. 10^{4} and prism refractometers with a refractive index measurement error less than or equal to ± 5. 10^{-5} - these measuring instruments were originally used by the state inspection authorities for the purposes of significance pursuant to §3(3) of the Metrology Act. They are no longer used with this significance (according to the statement of the State Agricultural and Food Inspection Authority). These are technical measuring instruments whose regulation has lost its original importance. Currently, the number of verified prism refractometers with a refractive index measurement error less than or equal to ± 2. 10^{4} is less than five per year and the number of prism refractometers verified with a refractive index measurement error less than or equal to ≤ ± 5. 10^{-5} is long-term zero. It no longer makes sense to regulate this item.

Re: 5) Items where the name, division or content is changing

1. Measuring vessels (item 1.1.2)

The item replaces item 1.3.2 Capacity serving vessels according to the Annex to Decree No 345/2002. The terminological change (name) is triggered by harmonisation in the field of the placing of measuring instruments on the common market of the EU, i.e. the concept of a capacity measure is used, which is also referred to in Government Regulation No 120/2016 (Annex 10), while the specification of the requirements for the measuring instrument is maintained.

2. Automatic level gauges for stationary tank measuring systems (item 1.3.1)
a) automatic level gauges without automatic checking of metrological parameters

The name of the item is supplemented with an attribute: ‘ … without automatic checking of metrological parameters ‘in such a way that there is a certain definition of the type of specified measuring instruments. Measuring instrument type ‘Automatic level gauges with automatic checking of metrological parameters’ is listed in item 1.3.1(b).

3. Volumetric flasks, burettes and pipettes of precision class A and AS used for volume checks (item 1.3.2)

The definition of the measuring instruments in question – volumetric flasks of precision class A and burettes and pipettes of accuracy class A and AS is being narrowed so as to meet the requirements (greater accuracy and verifiability) for measuring instruments used for: volume checks when measuring with significance pursuant to § 3(3) of the Metrology Act (in a contractual relationship). This involves updated content of the item.

4. Transport tanks (cisterns) for liquids (item 1.3.5)
a) transport tanks with one or more volume marks

This is an amendment to the current item 1.3.5 according to the Annex to Decree No 345/2002 (transport drums and tanks) and its division according to the method of volume measurement (volume marks or automatic level gauges – see new type list item 1.3.5 b).

5. Fixed storage tanks used as volume gauges (item 1.3.6)

b) wooden non-transport barrels

c) non-transport barrels made of other materials

This is an amendment to the current item 1.3.6 according to the Annex to Decree No 345/2002 (stationary tanks used as volume gauges) and refinement of the formulation ('non-transport') in the case of barrels that are used as stationary tanks.

6. Measuring instruments and measuring systems for gas flow rate and quantity and their components (item 2.2.1)

b) Coriolis mass flow meters and gas meters
c) turbine gas meters
d) rotary gas meters
e) ultrasound gas meters
j) static gas pressure transducers
k) differential gas pressure transducers
m) gas temperature sensors with transducer
n) gas density and (relative) density measuring instruments

This involves modification of existing items 1.3.10 and 1.3.11 according to the Annex to Decree No 345/2002 (gas flow quantity meters and elements of meters and metering assemblies for liquid flow quantity) consisting of splitting elements of meters and metering

assemblies for the flow quantity of liquids and flow quantity of gases. At the same time the grouping of gas flow rate and quantity meters and their elements is adjusted and at the same time a new breakdown of measuring instruments and their elements is carried out (see the breakdown above, where the items whose wording has undergone changes are listed). In the case of sub-item (e), based on a positive result of a statistical sample test of a specified set of ultrasound gas meters up to size G6, the validity period of verification can be extended by 3 years.

7. Non-automatic scales (item 3.1.2)

c) axle or wheel load scales for rolling stock

d) scales for static inspection weighing of vehicles

This involves a change to existing items 2.1.2 and 2.1.5 according to the Annex to Decree No 345/2002, consisting of grouping items into one item (non-automatic scales) with subsequent subdivisions into sub-items.

8. Automatic scales (item 3.1.3)

e) continuous summing scales

f) gravimetric filling scales

g) dosing scales

h) discontinuous summing scales

This is a modification to current item 2.1.3 according to the Annex to Decree No 345/2002, consisting of the transposition of subdivision of automatic scales pursuant to Government Regulation No 120/2016 on the conformity assessment of measuring instruments when making them available on the market.

9. Eye tonometers (item 3.3.1)

a) contact mechanical

b) contactless and contact electronic

This involves a change to existing item 2.3.1 in accordance with the Annex to Decree No 345/2002, consisting of a change in the title of the sub-items.

10. Heat energy meters and elements thereof (item 4.1.2)

b) flow sensors and flow quantity meters

e) pressure transducers

This involves a change to existing item 3.1.2 in accordance with the Annex to Decree No 345/2002, consisting of a change in the title of the sub-items.

11. Measuring instruments and measuring systems for measuring sound as a Class 1 and 2 sound meter or analyser (item 7.1.1)

This involves modification of existing items 6.1.1, 6.1.2 and 6.1.4 according to the Annex to Decree No 345/2002 consisting of changing the subdivision of sound pressure measuring instruments according to contemporary labelling and of defining the meaning of the use of specified measuring instruments of those types in the public interest.

12. Activity quantitative variables meters for aerosols, gases and liquids released in the workplace (item 9.1)

Updated item content – includes part of the original item 8.1 according to the annex to Decree No 345/2002, (*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…*)

13. Activity quantitative variables meters used to check the content of radionuclides in solid substances, items and equipment released in the workplace (item 9.2)

Updated item content – includes part of the original item 8.8 according to the annex to Decree No 345/2002, (*Activity and dose meters used … to check release levels and conditions when introducing radionuclides into the environment*).

14. Activity quantitative variables meters used to determine the content of radionuclides in the environment (item 9.3)

Updated item content – includes part of the original item 8.1 (*Measuring instruments used … to determine the radiation load on the environment due to effluents*) and also includes part of the scope of original item 8.6 (*Spectrometry assemblies for analysis of alpha, beta, gamma and neutron radiation sources or fields*) according to the annex to Decree No 345/2002.

The item includes activity quantitative variables measuring instruments used for checking that the parameters and values of permissible surface water pollution and environmental quality standards have not been exceeded. Indicators and values of permissible surface water pollution and environmental quality standards are defined in Annex 3, Table 1a and Table 1c of Government Regulation No 401/2015 of 14 December 2015 concerning the indicators and values of permissible surface water and wastewater pollution, details of the permit to discharge wastewater into surface water and sewage systems, and on sensitive areas.

15. Measuring instruments for activity and dosimetric quantitative variables[1]) used to check the compliance with the criteria set out in the limits and conditions of a nuclear installation (item 9.4)

Updated item content – the definition is narrowed only for the limits and conditions of nuclear installations. Includes the reduced range of part of the original item 8.7 (*Non-spectrometric activity and dose measuring instruments used to check compliance with radiation protection or nuclear safety limits*) according to the Annex to Decree No 345/2002 Coll.
Limits and conditions of a nuclear installation means a document of the operator of a nuclear installation for an activity authorised on the basis of the Atomic Act.

16. Activity quantitative variables meters and dosimetric quantitative variables meter used to check the compliance with the criteria set out in the limits and conditions for the management of radioactive waste (item 9.5)

Updated item content – the definition is narrowed only for the limits and conditions for handling nuclear waste. It includes reduced scope of the original item 8.8 according to the annex to Decree No 345/2002 (*Activity and dose measuring instruments used for checking limits when managing radioactive waste...).*

Limits and conditions for the management of radioactive waste means an operator's document for activities authorised under the Atomic Act.

[1] Dosimetric quantitative variables are defined by ČSN EN ISO 80000-10:2013 and ICRU Report No. 51

17. Measuring instruments for activity and dosimetric quantitative variables designed to monitor the radiation situation during and after a radiological emergency (item 9.7)

The updated content of the item includes part of the original item 8.7 (*Non-spectrometric activity and dose measuring instruments used…* for emergency measurement) according to the Annex to Decree No 345/2002.

The definition of a radiological emergency is identical to item 9.6 [see above part Re 1) point 12].

18. Measuring instruments for activity and dosimetric quantitative variables used to determine personal doses, including personal doses from a radiation emergency (item 9.8)

Updated item content – the definition is narrowed only for the measurement of personal doses. Includes reduced scope of original item 8.5 (*Assemblies used for checking the limits of exposure of persons collectively operated by personal dosimetry)* pursuant to the Annex to Decree No 345/2002.

The item includes measuring instruments used for the determination of personal doses from emergency exposure, i.e. from exposure of a person other than the responding person as a result of an accidental exposure situation and from the exposure of the responding person in an accidental exposure situation. Exposure situation means, in accordance with the Atomic Act, all relevant circumstances leading to the exposure of an individual to ionising radiation; an accidental exposure situation may occur in a planned exposure situation or be triggered by an arbitrary act.

The purpose of the use of measuring instruments of this kind is therefore to demonstrate that exposure limits or reference levels have not been exceeded. Exposure limit in accordance with the Atomic Act means a quantitative indicator for limiting the total exposure of an individual from activities as part of planned exposure situations. Reference level means the level of exposure or risk of exposure in an accidental exposure situation or in an existing exposure situation that is undesirable to exceed.

Personal operational dosimeters do not belong under this item, as according to the Atomic Act and implementing legislation (Decree No 422/2016 on radiation protection and security of a radionuclide source), operative personal dosimeters can only be used for clearly indicating a set level being exceeded, not for the measurement of personal doses.

19. Measuring instruments for dosimetric quantitative variables used to determine diagnostic and therapeutic doses applied in medical irradiation (item 9.10)

Updated wording of the original item 8.3 (*Measuring instruments used for the determination of diagnostic and therapeutic doses in medical irradiation*) according to the Annex to Decree No 345/2002. The added text refines the existing wording. The definition of the type of these specified measuring instruments is limited to measuring instruments used for the determination of diagnostic and therapeutic doses applied during medical irradiation and does not include devices that are not used for dose determination, e.g. measuring instruments used to check the stability of the radiation generator and not to determine the dose.

Medical irradiation in accordance with the Atomic Act means irradiation within the scope of

- examination or treatment of a patient;
- occupational health services and preventive health care;
- voluntary participation by healthy individuals or patients in the medical investigation of non-established methods associated with medical irradiation; or

- providing assistance to an individual undergoing medical irradiation.

20. Volumetric activity meters for natural radionuclides in the air, equivalent volume activity of radon and dosimetric quantitative variables used for the purposes of preventing the penetration of radon into buildings and for protection against exposure from natural radionuclides in buildings and workplaces with the possibility of increased exposure from a natural source of radiation and with possible increased irradiation from radon (item 9.11)

The updated formulation of original item 8.4 according to the Annex to Decree No 345/2002, (*Activity concentration measuring instruments for 222Rn in air and water and equivalent volumetric activity of 222Rn in the air, instantaneous, short-term, as well as long-term averages)* defines the measuring instruments more precisely by their use for specific measurements.

21. Activity quantitative variables meters used to check the content of natural radionuclides in building materials and drinking water (item 9.12)

The updated content of the item includes part of the original item 8.10 according to the Annex to Decree No 345/2002., (*Activity meters for checking limit values of natural radionuclides in building materials and water…)* reduced to measuring instruments for checking drinking water, which (as regards radionuclides content) is regulated by the Atomic Act.

Measuring instruments for checking surface water that are included in the existing version, which including radionuclide content are regulated by Act No. 254/2001 on waters and amending certain acts (the Water Act) and Government Regulation No 401/2015 of 14 December 2015 on indicators and values of permissible pollution of surface water and waste water, requirements for permitting discharges of waste water into surface water and sewerage and sensitive areas, are now included in item 9.3.

22. Activity quantitative variables meters used to check the content of radionuclides in food and dosimetric quantitative variables meters used for routine and validation measurements in food irradiation (item 9.13)

The updated wording of the item includes the entire original item 8.11 (*Dose measuring instruments used for approval measurements in food irradiation*) and part of item 8.10 (*Activity meters for checking … the maximum permitted levels of radioactive contamination of foodstuffs)* according to the Annex to Decree No 345/2002. It defines measuring instruments more precisely in accordance with the requirements for routine and validation measurements defined in Annex 2 to Decree of the Ministry of Health No 133/2004 of 12 March 2004 on the conditions of irradiation of foodstuffs and ingredients, on the maximum permitted dose of radiation and on the method of labelling irradiation on the packaging.

23. Measuring instruments for pulse frequency, activity and dosimetric quantitative variables used to prevent and detect unauthorised activity associated with fissile and other radioactive substances (item 9.14)

Updated wording of the item – includes part of the original item 8.9. (*Assemblies used to detect the presence of sources of ionising radiation during illegal … transport)* according to the Annex to Decree No 345/2002

The item concerns, in particular, the use of measuring instruments in the protection against terrorism using radioactive or fissile substances and in the protection against illegal trade in such substances. The IAEA framework includes in unauthorised (illegal) activities not only

illegal transportation and trafficking, but also the acquisition, delivery, possession, use, transfer and disposal of nuclear and radioactive material. Similar activities carried out without a permit (i.e. unauthorised) are also punishable in the Czech Republic.

European law (Council Directive 2013/59/EURATOM of 5 December 2013) uses, for an analogous purpose, the concept of activity outside regulatory control, i.e. outside any form of administration or direction that applies to human behaviour in order to enforce radiation protection requirements. Czech law (the Atomic Act) uses the concept of activities outside of supervision laid down by law.

These are, in particular, measuring instruments used to detect cases where a fissile or other radioactive substance is outside of supervision provided for by legislation or international agreements, especially when it is transported without permission for unauthorised use (e.g. air cargo) and in the protection of critical infrastructure buildings. Metrological control of measuring instruments used for the prevention and detection of unauthorised activities associated with fissile and other radioactive substances is particularly important in view of the serious consequences of their possible malfunction.

Examples of measuring instruments of this kind are gate monitors for checking vehicles and persons, so-called invisible curtain detectors (personal pagers, crowd-sourced monitoring using networks of telecommunications operators, networks of public transport operators, networks of police vehicle locations and radiation monitoring networks), means for protection of the intakes of air-conditioning systems of critical infrastructure buildings and other special equipment, especially on unmanned aircraft. Another example is the analytical systems for determining the so-called fingerprint (typical composition) of nuclear material used to reveal its origin.

The new wording of the original item 8.9 is split into the area of prevention and detection of unauthorised activity, which is regulated in particular by the Police Act and the Criminal Code (§ 281) and the area of the search for orphan sources by operators of specific operations, which is regulated by the Atomic Act (§ 91) and where the relevant type of specified measuring instruments is included in item 9.15.

24. Measuring instruments for pulse frequency, activity and dosimetric quantitative variables used for the detection and identification of a radionuclide source in the search for an orphan source by operators of a scrap metal smelting, collection and processing facilities and operators of waste incineration plants and co-incineration plants (item 9.15)

Updated wording of the item – includes part of the original item 8.9. (*Assemblies used to detect the presence of sources of ionising radiation during … undesirable transport)* according to the Annex to Decree No 345/2002 so that it is in accordance with the Atomic Act.

These are measuring instruments used in the search for lost radionuclide sources without a known owner, most often thrown into waste intentionally or out of ignorance. The most serious consequences in terms of radiation protection occur during metallurgical treatment of metal waste (contamination of the furnace and radioactive discharge). This why the Atomic Act contains § 91(1), which requires the operator of an installation for smelting, collecting and processing metal waste to take measures to locate an orphan source.

An orphan source is defined, in accordance with the Atomic Act, as a radionuclide source that is not under the supervision prescribed by legislation, in particular if it has never been under supervision prescribed by legislation, was abandoned or lost by the holder, was stolen or

acquired by the holder accidentally or without notification to the State Office of Nuclear Safety (SONS).

European legislation also emphasises the detection of orphan sources (Article 92 of Council Directive 2013/59/Euratom of 5 December 2013):

Detection of orphan sources

2. Member States shall encourage the establishment of systems aimed at detecting orphan sources in places such as large metal scrap yards and major metal scrap recycling installations where orphan sources may generally be encountered, or at significant nodal transit points, wherever appropriate.

Every year more than 500 steel plants in EU Member States produce more than 200 million tonnes of steel. Raw material (about 50% scrap) is checked for the presence of orphan radioactive sources of various origins by transporting scrap containers through detectors. If the inspection fails or is not performed, the radioactive source could be melted down. The result is a possible release of radioactive substances into the environment. At the same time, radionuclides of various origins also contaminate production furnaces, smelted materials and slag, smoke dust, filters and channels.

Operators of facilities for smelting, collecting and processing scrap metal and operators of large waste incineration plants and co-incineration plants in the Czech Republic have been equipped with these measuring instruments for many years. They were included among specified measuring instruments more than 20 years ago at the request of their professional association due to trade (quality of goods) during the export and processing of scrap metal after an affair with the return of train loads to the Czech Republic by other countries due to contamination of cargo or wagons. All measuring instruments used in the Czech Republic have been type-approved and are regularly verified.

The use of the measuring instruments in question is not mandatory under the Atomic Act, the purpose of which in this case is protection against ionising radiation, but the measuring instruments are acquired and used by the operator mainly for reasons of protection of equipment and contractual relationships. If the operator is not equipped with measuring instruments and does not use the measuring instruments, they will not be subject to mandatory metrological checks. However, if the operator is equipped with the measuring instruments and uses them, whether for reasons of radiation protection, public safety or contractual relations, they will be type-approved and subject to periodic verification.

The definition of the measuring instruments in the given item are measuring instruments for the initial detection of the radionuclide source, which is the most important, and the subsequent identification of the radionuclides. Meters for tracing the source are intentionally omitted here.

25. Activity quantitative variables spectrometers used to check radionuclide content in metallurgical products and radiopharmaceuticals (item 9.16)

The updated content of the item means a definition that is narrowed down to only two specified areas of spectrometric measurements and radionuclide activity meters, which are not included in the other items of the new Decree. Includes the reduced range of the original item 8.6 (*Spectrometry assemblies for analysis of alpha, beta, gamma and neutron radiation sources or fields*) according to the Annex to Decree No 345/2002. The measuring instruments are therefore regulated according to current metrology legislation.

In the field of metallurgy, determination of the mass activity of radionuclides in melt samples is an important part in ensuring the quality and safety of metallurgical products. The inclusion of melt sample meters among specified measuring instruments was brought about by the need

to avoid commercial disputes between producers and customers in the case of the sale of contaminated steel and to avoid unwanted contamination of the environment by radionuclides. The measuring instruments in question are therefore important for the protection of health, the protection of the environment and, in particular, for contractual relations; specifically this involves the prevention of undesirable pollution of the environment by radionuclides and the avoidance of commercial disputes in the sale of metallurgical products. Proof of under-limit radionuclide content in a product is important within the framework of contractual relations and has an analogous character as another parameter important for trade that is checked by specified measuring instruments. Ionising radiation metrology in the metallurgical industry was addressed by a joint European metrology research project under the EMRP programme and a method for measuring melt samples based on gamma spectrometry was developed with the participation of several European metrology institutes. Research in the field on the European level underlines the importance of this measurement. The measuring instruments used are gamma-ray spectrometers.

In the field of radiopharmaceutical production, correct determination of their activity and demonstration of radionuclide purity are an essential requirement to avoid excessive irradiation of patients during their application and to ensure correct analytical determination of radiopharmaceutical activity and detection of possible radionuclide impurities. The requirements for measuring the activity of radiopharmaceuticals and radionuclide purity in their production are also specified in the European and Czech pharmacopoeia (paragraph 8.0 2.2.66 – Detection and measurement of radioactivity, paragraph 8.7 5.19 Preparation of radiopharmaceuticals) and in international standards. The relationship to the Metrology Act and the related decrees follows from the provisions of § 27 of Decree No 84/2008 on good pharmaceutical practice, more detailed conditions for the treatment of pharmaceuticals in pharmacies, medical facilities and other operators and establishments issuing medicinal products. Purity is important for in-vitro methods for the accuracy of the analytical determination on which diagnosis or therapy depends. Aside from health protection, proof of product purity is important within the framework of contractual relations and has an analogous character as another parameter important for trade that is checked by specified measuring instruments.

Measuring instruments according to item 9.16 do not intersect with measuring instruments according to item 9.9. When using instrument types according to item 9.9, only the activity of a specific radionuclide before in vivo application to patients is measured non-spectrometrically, using the kinds of measuring instruments according to 9.16, the spectrometry activity of various radionuclides is measured in the production of preparate to check compliance with its radiochemical purity. In the first case this is a radionuclide calibrator (ionisation chamber), in the second case a multi-channel gamma spectrometer (HPGe solid phase detector).

4. DETERMINATION OF THE ORDER OF THE OPTIONS AND SELECTION OF THE MOST SUITABLE SOLUTION

Option 2 was assessed as the most effective option, this will result in the necessary updating of the legislation, coherence of the legislation and harmonisation of national and European legislation. The amended Decree also addresses the introduction of new kinds of specified measuring instruments with regard to technical progress in the given area and regulates the validity period of the verification based on the latest empirical knowledge.

When choosing an option, the aim was to choose an option that would be in the interests of consumers and the state and which at the same time would not have a significant economic impact on manufacturers and users of measuring instruments. At the same time, the level of regulation takes into account areas of measurement where the importance of measurement is essential, is in the public interest and requires the state to guarantee its correctness.

Impacts of the chosen solution

1. Environmental impact
The proposed amendment does not have an impact on the environment.

2. Impacts on the state budget and other public budgets
The proposed amendment has no significant impact on the state budget or other public budgets.

3. Territorial impacts
The proposed amendment does not have territorial impacts, including impacts on local authorities.

4. Social impacts
The proposed regulation does not have social impacts, does not concern specific population groups and does not affect the protection of children’s rights.

5. Impact on families
The proposed amendment does not affect issues related to families.

6. Impact on the business environment
The proposal represents a slight increase in costs for businesses placing on the market or using any of the newly specified measuring instruments. These costs are counterbalanced by the public interest in ensuring the uniformity and accuracy of measuring instruments and measurements, which in many areas are a prerequisite for fair pricing of goods, services, taxes and charges.

7. Effects in relation to non-discrimination and equality between men and women

The draft legislation, like the current legislation, does not create any discrepancies contrary to the prohibition of discrimination.

The impact on gender equality was evaluated according to the 'Methodology of evaluation of impacts on gender equality for materials submitted to the Government of the Czech Republic'. In accordance with point 3.3 of the Methodology, the submitter notes that the document does not relate to the status of individuals and does not affect gender equality.

8. Impacts on the performance of the state statistical service

The proposed amendment does not affect the performance of the state statistical service.

9. Impact on privacy and personal data protection

The proposed amendment, like the current situation, does not affect the protection of privacy and personal data.

10. Corruption risks and impact on the level of corruption

Corruption risks were assessed in accordance with C.I.A. methodology. – Corruption Impact Assessment. The submitter concluded that the proposed legislation does not give rise to corruption opportunities.

11. Impacts on national security or defence

State security and defence are not relevant to the legislation in question.

12. Compliance with the principle of digitally friendly legislation

The proposed amendment is in line with the principles of digitally friendly legislation. The proposal does not create a risk of digital exclusion (impairment of access due to digitalisation).

5. IMPLEMENTATION AND ENFORCEMENT OF THE RECOMMENDED OPTION

The authority responsible for implementing the proposed legislation is the Ministry of Industry and Trade (the Ministry). Decree No 345/2002 laying down measuring instruments for mandatory verification and measuring instruments subject to type approval, is one of the implementing regulations of the Metrology Act.

Responsibilities in the performance of state administration will be entrusted to the Ministry (as the central administrative body), the Office for Technical Standardization, Metrology and State Testing (the Office) and to a certain extent the Czech Metrology Institute (the Institute). Delegated competence in the performance of state administration is delegated to entities authorised by the Office for Verification of Specified Measuring Instruments (authorised metrology centres). Checks will be carried out in accordance with the scope laid down by the Metrology Act and other legal regulations. Enforcement of statutory obligations will be carried out by the Office or by another supervisory authority to the extent specified by other legislation.

6. REVIEW OF EFFICACY OF THE LEGISLATION

The review of the effectiveness and impact of the regulation will be carried out by continuously monitoring the results of supervisory authorities' inspection activities and evaluating the data on the reliability of the measuring instruments over time during the specified validation periods. The data obtained will be evaluated within three years of the effective date of the legislation.

7. CONSULTATION AND DATA SOURCES

Solution variants and individual items of the type list of specified measuring instruments were consulted in advance with the central and other public authorities concerned as part of direct contact and through a questionnaire on the concept of the development of the national metrology system (UV No 961/2021). The questionnaire was also sent to academic institutions, special-interest organisations and economic entities. Consultations were also conducted bilaterally with some central and other government bodies (e.g. the State Office for Nuclear Safety, the Ministry of Transport, the Ministry of Health, the State Energy Inspectorate) were also carried out by sector with distributors of measuring instruments (e.g. Kamstrup, SENSUS/Xylem), with operators (users) of specified and non-specified measuring instruments (e.g. PVK, EGD), with metrology service providers, manufacturers and profile associations (e.g. the Union of Scales Manufacturers, SOVAK) in the Czech Republic.

A key source of data were the statistical information from the Office (e.g. annual metrological performances of authorised metrological centres and Institute) and from the Czech Statistical Office. The Institute's data were also used (e.g. from the process of approval of a measuring instrument, from the conformity assessment of a measuring instrument, from the verification of specified measuring instruments, from experiments on the stability of measuring instruments, etc.). The results of the relevant tasks of the Metrology Development Programme of the Office were also used. Data obtained from users of specified measuring instruments were also used.

Annex

Comparison of the current version of the Annex to Decree No 345/2002 with the draft amended text

Item	Current text	Item	Amendment	Comparison
1	**MEASURING INSTRUMENTS FOR GEOMETRIC QUANTITATIVE VARIABLES**	**1**	**MEASURING INSTRUMENTS FOR GEOMETRIC QUANTITATIVE VARIABLES**	unchanged
1.1	**Length meters**	**1.1**	**Material measures**	new subgroup name
		1.1.1	Material measures of length	update of the name according to Government Regulation No 120/2016 including the original item 1.1.1; extension to the scope identical to Annex 10 to Government Regulation No 120/2016 (MI-008); verification validity period 5 years
1.1.1	Length meters for goods sold by length			included in the new Decree — Item 1.1.1
1.1.2	Measuring tapes			item deletion
		1.2	**Measuring instruments for measuring dimensions**	new subgroup name
1.1.3	Measuring equipment for measuring the length of coiled goods	1.2.1	Measuring instruments for measuring the length of coiled goods	modification of the wording of the item in accordance with Government Regulation No 120/2016, Annex 11
		1.2.2	Multi-dimensional measuring instruments	a new item within group 1.2; the wording the sub-item in accordance with Government Regulation No 120/2016, Annex 11; verification validity period 2 years
1.1.4	Taxi meters			deletion of item, content transformed into item 3.2.3
		3.2	**Mechanical motion measuring instruments**	reclassified sub-group
1.1.5	Taxi meter assemblies for taxi vehicles	3.2.3	Taxi meter assemblies for taxi vehicles	reclassification (and renumbering) of the item
1.1.6	Automatic level gauges on stationary tanks	1.3.1	Automatic level gauges on stationary tanks	reclassification (and renumbering) of the item
	a) automatic level gauges		a) automatic level gauges without automatic checking of metrological parameters	modification of the wording of the sub-item
	b) automatic level gauges with automatic checking of metrological parameters		b) automatic level gauges with automatic checking of metrological parameters	no changes (reclassification only)
1.2	**Instruments for measuring surface area**	**1.2**	**Measuring instruments for measuring dimensions**	new item name and reclassification
1.2.1	Machines for measuring the area of leather			item deletion
1.3	**Volume meters, flow meters**	**1.1** **1.3**	**Material measures** **Other length and volume measuring instruments**	reclassification of original sub-group 1.3 items to sub-groups 1.1 and 1.3

1.3.1	Metal measuring containers			item deletion
1.3.2	Serving measures	1.1.2	Measuring vessels	new item name and reclassification
		1.3	**Other length and volume measuring instruments**	new subgroup name
1.3.3	Volumetric flasks, burettes and pipettes used for volume checks	1.3.2	Volumetric flasks, burettes, precision class A and AS pipettes used for volume checks	amendment of the item, clarification of the definition – TP A volumetric flasks and TP AS burettes and pipettes – verifiable
		1.3.3	Precision Class A volumetric cylinders used for volume checks	new item – introduction for inspection authorities as well as for possible volume checks by the consumer; verification validity period unlimited
1.3.4	Sedimentation (Westergren) pipettes			item deletion
1.3.5	Transport drums and tanks			modification of the name of the item; split of the original item into two new, separate ones – 1.3.4 and 1.3.5 (barrels, tanks)
	a) transport barrels with the exception of barrels referred to in point (b)			deletion of sub-item
	b) transport barrels made of corrosion-resistant materials, permanent shape	1.3.4	Transport barrels made of corrosion-resistant materials, permanent shape	reclassification to separate item 1.3.4
	c) transport tanks (cisterns) for liquids	1.3.5	Transport tanks (cisterns) for liquids	reclassification to separate item 1.3.5
			a) transport tanks with one or more volume marks	division of the original sub-item; modification of sub-item content
			b) transport tanks with automatic level gauges	a new sub-item under item 1.3.5; verification validity period 2 years
1.3.6	Stationary storage tanks used as volume gauges	1.3.6	Stationary storage tanks used as volume gauges	unchanged
	a) cooling and storage tanks for milk		a) cooling and storage tanks for milk	unchanged
	b) wooden barrels		b) wooden non-transport barrels	change in the wording of the name of the sub-item (barrels functioning as fixed tanks, i.e. non-transport)
	c) concrete and masonry storage tanks		d) tanks excluding concrete and masonry storage tanks	modification of the name of the sub-item content change (leaving in tanks made of other materials and deleting concrete and masonry storage tanks)
	d) barrels and tanks of other materials		b) non-transport barrels made of other materials	change in the wording of the name of the sub-item [barrels functioning as fixed tanks, i.e. non-transport; tanks moved to a separate sub-item (d)]
		8.4	**Other measuring instruments for physiochemical quantitative variables**	new subgroup
1.3.7	Butyrometers	8.4.1	Butyrometers	item reclassification, type testing waived (analogy with burettes and pipettes)
1.3.8	Alcohol measuring instruments used to measure the volume of alcohol produced	1.3.7	Alcohol measuring instruments used to measure the amount of alcohol produced	no changes (formal adjustment only)
		2	**FLOW RATE AND FLOW QUANTITY METERS**	a redefined group of measuring instruments; now flow rate and flow quantity meters (subsequent split into liquids and gases)

		2.1	**Flow rate and flow quantity meters for liquids**	redefined subgroup name
1.3.9	Meters measuring water flow quantity	2.1.1	Meters measuring water flow quantity	name change
	a) for cold water		a) meters measuring the flow quantity of cold drinking water and hot water - mechanical water meters b) meters measuring the flow quantity of cold drinking water and hot water - static water meters	modification of the name in accordance with the formulation pursuant to Government Decree No 120/2016, Annex 3; new division of water meters according to the principle of measurement and purpose of use; change of the verification validity period for water meters to 5 years [(a) and (c)] or 8 years [(b)]
	b) for hot water			
	c) drum water meters			
	d) volumetric water meters			
	e) water meters for cold and hot water, used to allocate costs to final consumers			
			c) water flow meters – water meters other than those referred to in points (a) and (b)	new sub-item (includes water meters for 'unclean' water, e.g. for the measurement of drained or discharged water) verification validity period 5 years
	*) Based on a positive result of a statistical sample test of a specified set of volumetric water meters, the validity period of the verification of the water meters in this set is extended by 3 years.			deleted in connection with the modification of the whole item
1.3.10	Meters measuring gas flow quantity	**2.2**	**Gas flow rate and flow quantity meters**	modification of the subgroup name
		2.2.1	Measuring instruments and measuring systems for gas flow rate and flow quantity and their elements	item name change
	a) diaphragm (including gas meters with temperature correction)		a) diaphragm gas meters (including gas meters with mechanical temperature correction)	modification of sub-item name – specification of mechanical temperature correction
	*) Based on a positive result of a statistical sample test of a specified set of diaphragm gas meters up to size G6, the validity period of the verification of the gas meters of this set is extended by 4 years.		*) Based on a positive result of a statistical sample test of a specified set of diaphragm gas meters up to size G6, the validity period of the verification of the gas meters of this set is extended by 5 years.*	extension of the validation period from 4 to 5 years
	b) rotary-piston and velocity		c) turbine gas meters	name change – the item is split into three separate ones (c,d,e)
			d) rotary gas meters	ditto (c)
	c) laboratory			item deletion
	d) gas quantity calculators *) *) The validation deadlines apply provided that the gas calculators are subjected to a regular short test with a validity period of 1 year*		g) compact and combined gas quantity calculators	name change, reflects Governemnt Regulation 120/2016
	1. compact		*The verification validity period applies contingent on the gas quantity calculator passing a shortened test during the third year of verification validity.*	introduction of validation condition – performance of short test with positive result

	2. combined		*Alternatively, for combined gas quantity calculators, the verification of separate members may be used:*	introduction of validation condition – performance of short test with positive result; alternatively, verification of separate calculator elements (see below)
	A) evaluation unit		i) evaluation unit	unchanged
	B) temperature sensor		ii) temperature sensor iii) temperature sensor with transducer	addition of temperature sensor with transducer
	C) pressure sensor		iv) pressure transducer	name change
			e) ultrasound gas meters **) Based on a positive result of a statistical sample test of a specified set of ultrasound gas meters up to size G6, the validity period of the verification of the gas meters of this set is extended by 3 years.*	ditto (c) validation period extension is possible based on a positive statistical sample test result
			f) thermal mass gas meters	new sub-item verification validity period 2 years
1.3.11	Elements of measuring instruments and measuring assemblies for fluid flow quantity	2.1.4	Components of measuring instruments and measuring systems for fluid flow that are not integral parts of measuring instruments and measuring systems pursuant to 2.1.1 or 2.1.2, or 2.1.3	name change and refinement of the contents of the item, separation of liquids and gases into 2.1.1, 2.1.4 and 2.2.1
	a) sensors for cold water flow quantity			inclusion into item 2.1.1
	b) sensors for hot water flow quantity			inclusion into item 2.1.1
	c) sensors for gas flow quantity			inclusion into sub-items 2.2.1(b) and (h)
	d) pressure sensors		j) static pressure transducers	name change
	e) pressure difference sensors		k) pressure difference measuring transducers	name change
	f) temperature sensors		l) temperature sensors	unchanged
	g) flow-through vibrating densitometer		n) density and relative density measuring instruments	name change, split according to the medium - in this case **gas**
		2.1.4	d) flow-through oscillating densitometers	— in this case **liquid**
	h) water evaluation units			inclusion into item 2.1.1
	i) evaluation units for liquids other than water or liquefied gases			inclusion into item 2.1.2
	j) gas evaluation units	2.2.1	i) evaluation units	name change
	k) temperature sensors with built-in transducer	2.2.1	m) temperature sensors with transducer	name change

	l) flow quantity sensors for liquids other than water or liquefied gases	2.1.4	Components of measuring instruments and measuring systems for fluid flow that are not integral parts of measuring instruments and measuring systems pursuant to 2.1.1 or 2.1.2, or 2.1.3	change of item name and content
	m) flow quantity sensors for liquefied gases			inclusion in item 2.1.3
1.3.12	Measuring instruments and measuring assemblies for measuring the flow quantity of liquids other than water or liquefied gases	2.1.2	Measuring instruments and measuring systems for flow quantity of liquids other than water or liquefied gases	unchanged, partial name change
1.3.13	Measuring instruments and measuring assemblies for the flow quantity of liquefied gases	2.1.3	Measuring instruments and measuring systems for the flow quantity of liquefied gases	unchanged, partial name change
1.3.14	Measuring instruments and measuring assemblies for the flow quantity of natural gas	2.2.2	Measuring instruments and measuring assemblies for the flow quantity of compressed gas for the propulsion of motor vehicles	modification of the item name – '…for propulsion of motor vehicles', further generalisation for compressed gases (e.g. extended to hydrogen)
2.	**MEASURING INSTRUMENTS FOR MECHANICAL QUANTITATIVE VARIABLES**	**3.**	**MEASURING INSTRUMENTS FOR MECHANICAL QUANTITATIVE VARIABLES**	unchanged
2.1.	**Weight measuring instruments**	**3.1.**	**Weight measuring instruments**	unchanged
2.1.1	Commercial weights and special standard (class 5), precise (class 4) and fine (class 2 and 3) scales	3.1.1	Weights	item name change, deletion of accuracy class specification
2.1.2	Non-automatic scales	3.1.2	Non-automatic scales	unchanged
	a) class I, II and III weighing scales		a) class I, II and III weighing scales	unchanged
	b) class IIII scales used for weighing sand, natural aggregates, municipal solid waste, recycled materials, building debris, mineral and broken materials and weighing of mortar and concrete by their manufacturers and transporters		b) class III scales used for weighing sand, natural aggregates, municipal solid waste, recyclable materials, building debris, mineral broken materials and weighing mortar and concrete	unchanged, partial name change
2.1.3	Automatic scales	3.1.3	Automatic scales	unchanged
	scales for weighing rolling stock in motion of class 0.2; 0.5 and 1		a) rail scales for weighing rolling stock in motion	name change (deletion of accuracy classes, will be stipulated in a measure of a general nature)
	b) scales for weighing road vehicles in motion of class 0.5; 1 and 2 for stipulating penalties, fees, tariffs and taxes; for low-speed inspection weighing pursuant to special legislation; for weighing sand, natural aggregates, municipal solid waste, recycled materials, building debris, mineral and broken materials and weighing of mortar and concrete by their manufacturers and transporters		b) scales for weighing sand, natural aggregates, municipal solid waste, recyclable materials, building debris, mineral and broken materials and weighing of mortar and concrete	name change, scales for low-speed inspection weighing – reclassified under sub-item 3.1.3(c)
			c) scales for low-speed inspection weighing of vehicles	see above, reference to Act No 13/1997

	c) scales for high-speed inspection weighing of road vehicles while in motion pursuant to other legislation with a relative measurement error of less than or equal to ± 5% for total vehicle mass and ± 11% for axle load		d) scales for high-speed inspection weighing of vehicles	name change (deletion of accuracy classes, will be stipulated in a measure of a general nature), reference to Act No 13/1997
	d) belt scales of class 0.25; 0.5; 1 and 2		e) continuous summing scales	name change pursuant to Government Resolution No 121/2016, accuracy classes deleted
	e) filling and dosing scales		f) gravimetric filling scales	name change pursuant to Government Resolution No 121/2016, split into sub-items (f) and (g)
			g) dosing scales	ditto
			h) discontinuous summing scales	adaptation to Government Resolution No 121/2016
2.1.4	Automatic and non-automatic scales used by manufacturers and importers of pre-packaged goods to measure the true content of a product packaged	3.1.4	Automatic and non-automatic inspection scales used by packaging plant operators to measure the true content of product packaged	name change, specification of '…used by packaging plant operators …'
2.1.5	Measuring equipment for determining load:	3.1.2	Non-automatic scales	
	a) per axle or wheel in the case of rolling stock		c) axle or wheel load scales for rolling stock	name change, reclassification of sub-item to item 3.1.2
	b) per axle for road vehicles		d) scales for static inspection weighing of vehicles	name change, reclassification of sub-item to item 3.1.2
2.1.6	Grain testers	3.1.5	Grain testers	unchanged
2.2	**Mechanical motion measuring instruments**	**3.2**	**Mechanical motion measuring instruments**	
2.2.1	Road speedometers used to check compliance with road traffic rules	3.2.1	Road speedometers used to check compliance with road traffic rules	unchanged
2.2.2	Tachographs recording the work activities of drivers of motor vehicles that are compulsorily equipped with them	3.2.2	Tachographs in road transport	name change pursuant to Regulation of the European Parliament and of the Council No 165/2014
	a) analogue		a) analogue	unchanged
	b) digital		b) digital	unchanged, item now also includes smart tachographs
2.3	**Pressure gauges**	**3.3**	**Pressure gauges**	
2.3.1	Eye tonometers	3.3.1	Eye tonometers	unchanged
	a) mechanical		a) contact mechanical	name change
	b) electronic		b) contactless and contact electronic	name change
2.3.2	Blood pressure measuring instruments	3.3.2	Blood pressure measuring instruments	unchanged
2.3.3	Tyre pressure gauges for road motor vehicles, excluding pressure gauges used exclusively for the measurement of tyre pressure by users of motor vehicles	3.3.3	Tyre pressure gauges for road motor vehicles, excluding pressure gauges used exclusively for the measurement of tyre pressure by users of motor vehicles	unchanged
2.4	**Force gauges**	**3.4**	**Force gauges**	unchanged

2.4.1	Tendon assemblies for prestressed concrete and rock anchors	3.4.1	Tendon assemblies for prestressed concrete and rock anchors	unchanged
3	**MEASURING INSTRUMENTS FOR TECHNICAL THERMAL QUANTITATIVE VARIABLES**	**4**	**MEASURING INSTRUMENTS FOR TECHNICAL THERMAL QUANTITATIVE VARIABLES**	
3.1	**Temperature and heat measuring instruments**	**4.1**	**Temperature and thermal energy measuring instruments**	name change
3.1.1	Electronic medical and veterinary thermometers	4.1.1	Electronic contact-type medical thermometers	name change, deleted 'veterinary' – alignment with legislation on medical devices (MD) with measuring function and the Act on MD (No 264/2014); restricted to only contact-type methods for measuring body temperature, where the metrological continuity of thermometers can be ensured
3.1.2	Heat and cold meters and elements thereof	4.1.2	Thermal energy meters and elements thereof	modification of terminology in accordance with Government Regulation No 120/2016
	a) compact heat and cold meter		a) compact thermal energy measuring instrument	modification of terminology in accordance with Government Regulation No 120/2016 validity period of verification revised to 5 years
	b) transfer medium flow quantity meters		b) flow sensors and flow quantity meters	name change; validity period of verification revised to 5 years
	c) temperature sensors		c) Temperature sensors:	validity period of verification revised to 5 years
	d) temperature sensors with built-in transducer		d) temperature sensors with transducer	name change
	e) pressure and pressure difference sensors		e) pressure transducers	name change
	f) evaluation units of combined heat and cold meters		f) evaluation units	name change; validity period of verification revised to 5 years
3.1.3	Thermometers used by state inspection authorities for checking the temperature of frozen foods	4.1.3	Thermometers used by inspection authorities for temperature checks stipulated by legislation on foodstuffs and meals	name change, extension of temperature ranges to chilled foods and critical temperatures for meals added; validity period of verification revised to 2 years footnote reference to food legislation
3.1.4	Thermometers used by state inspection authorities for checking ambient and hot water temperature with 0.1 °C or better scale division	4.1.4	Thermometers used by inspection authorities for checking ambient and hot water temperature with 0.1 °C or better scale division	unchanged
	glass		a) glass	adjusted period of validity of verification to 'unlimited’
	electronic		b) electronic	unchanged
		4.1.5	Temperature gauges used on stationary tanks for conversion to reference conditions	new item
			a) temperature sensors	new sub-item
			b) temperature sensors with transducer	new sub-item
4	**MEASURING INSTRUMENTS FOR ELECTRICAL AND MAGNETIC QUANTITATIVE VARIABLES**	**5**	**MEASURING INSTRUMENTS FOR ELECTRICAL QUANTITATIVE VARIABLES**	name change – deleted 'magnetic’
4.1	**Measuring instruments for electrical quantitative variables**	**5.1**	**Measuring instruments for electrical quantitative variables**	

4.1.1	Induction electricity meters manufactured up to 31 December 1989			item deletion
	a) for measuring electric energy in direct connection			
	b) for measuring electric energy in conjunction with measuring transformers			
4.1.2	Induction electricity meters produced after 1 January 1990	5.1.1	Induction electricity meters for alternating current	name change
	a) for measuring electric energy in direct connection		a) for measuring electric energy in direct connection	unchanged
	b) for measuring electric energy in conjunction with measuring transformers at LV		b) for measuring electric energy in conjunction with measuring transformers	item content change – merging the original sub-items for LV, HV and VHV, aligning the verification validity period to 5 years
	b) for measuring electricity in conjunction with measuring transformers at HV and VHV			ditto
4.1.3	Static electricity meters	5.1.2	Static electricity meters for alternating current	name change
	a) for measuring electricity in direct connection		a) for measuring electricity in direct connection	unchanged
	b) for measuring electric energy in conjunction with measuring transformers at LV		b) for measuring electric energy in conjunction with measuring transformers	item content change – merging the original sub-items for LV, HV and VHV, aligning the verification validity period to 5 years
	b) for measuring electricity in conjunction with measuring transformers at HV and VHV			ditto
4.1.4	Current and voltage measuring transformers	5.1.3	Current and voltage measuring transformers	unchanged
	a) induction-type used in conjunction with electricity meters		a) induction-type used in conjunction with electricity meters	unchanged
	b) capacitive used in conjunction with electricity meters		b) capacitive used in conjunction with electricity meters	unchanged
		5.1.4	Measuring instruments and measuring systems for recharging stations	new item
5	**MEASURING INSTRUMENTS FOR OPTICAL QUANTITATIVE VARIABLES**	6	**MEASURING INSTRUMENTS FOR OPTICAL QUANTITATIVE VARIABLES**	unchanged
5.1	**Measuring instruments for quantitative variables of light**	**6.1**	**Measuring instruments** for photometric **quantitative variables**	modification of the subgroup name
5.1.1	Optical radiometers for the 400 nm to 2800 nm spectral range and radiation measurements in the range $10^{-3}W \cdot m^{-2}$ up to $10^{2}W \cdot m^{-2}$			item deletion
5.1.2	Luxmeters	6.1.1	Luxmeters	unchanged

6	**MEASURING INSTRUMENTS FOR TIME, FREQUENCY AND ACOUSTIC QUANTITATIVE VARIABLES**	7	**MEASURING INSTRUMENTS FOR TIME, FREQUENCY AND ACOUSTIC QUANTITATIVE VARIABLES**	unchanged
6.1	**Sound pressure gauges**	**7.1**	**Sound pressure gauges**	unchanged
6.1.1	Instruments for measuring sound of class 1 and 2	7.1.1	Measuring instruments and measuring systems for measuring sound as a Class 1 and 2 sound meter and/or analyser	name change, also includes original items 6.1.2 and 6.1.4
6.1.2	Band filters			included in 7.1.1
6.1.3	Tone audiometers	7.1.2	Tone audiometers	unchanged
6.1.4	Measuring microphones			included in 7.1.1
6.1.5	Personal sound exposure meters	7.1.3	Personal sound exposure meters	unchanged
7	**MEASURING INSTRUMENTS FOR PHYSIOCHEMICAL QUANTITATIVE VARIABLES**	**8**	**MEASURING INSTRUMENTS FOR PHYSIOCHEMICAL QUANTITATIVE VARIABLES**	unchanged
7.1	**Density gauges**	**8.1**	**Density gauges**	unchanged
7.1.1	Laboratory density meters with a scale division value of less than 1 kg · m^{-3} excluding density meters for measuring soil granularity (Casagrande)	8.1.1	Laboratory density meters with a scale division value of less than 1 kg · m^{-3} excluding density meters for measuring soil granularity (Casagrande)	unchanged
7.1.2	Laboratory alcoholometers with a scale division of ≤ 0.2%	8.1.2	Laboratory alcoholometers with a scale division of ≤ 0.2%	unchanged
7.1.3	Laboratory saccharimeters with a scale division value of 0.1%	8.1.3	Laboratory saccharimeters with a scale division value of 0.1%	unchanged
7.1.4	Laboratory must meters with a scale division value of 0.2 · hl^{-1}	8.1.4	Laboratory must meters with a scale division value of 0.2 · hl^{-1}	unchanged
7.1.5	Laboratory density meters for milk with a scale division value ≤ 0.5 kg · m^{-3}	8.1.5	Laboratory density meters for milk with a scale division value ≤ 0.5 kg · m^{-3}	unchanged
		8.1.6	Oscillating laboratory density meters with ability to temper the measured sample or with automatic temperature correction	new item
7.2	**Refractive index gauges (refractometry)**			deletion of the subgroup, i.e. both items
7.2.1	Prism refractometers with a refractive index measurement error less than or equal to ± 2·· 10^{-4}			
7.2.2	Prism refractometers with a refractive index measurement error less than or equal to ± 5·· 10^{-5}			
7.3	**Moisture measuring instruments for solids**	**8.2**	**Moisture measuring instruments for solids**	unchanged
7.3.1	Precision class 1 and 2 moisture meters for cereals and oilseeds	8.2.1	Moisture meters for cereals and oilseeds	name change
7.4	**Chemical composition measuring instruments**	**8.3**	**Chemical composition measuring instruments**	unchanged

7.4.1	Process gas chromatographs for determining the calorific value of natural gas	8.3.1	Process gas chromatographs for determining the calorific value of energy gases and their mixtures	name change and extension to all energy gases
7.4.2	Breath alcohol analysers	8.3.4	Breath alcohol analysers	unchanged
		8.3.2	Measuring systems for determining the energy value of energy gases and their mixtures *The period of validity of the verification is subject to the condition that the measuring system passes a shortened test during each year of validation.*	new item
		8.3.3	Degassing gas and biomethane chemical composition analysers	new item
	MEASURING INSTRUMENTS FOR ATOMIC AND NUCLEAR PHYSICS	**9**	**MEASURING INSTRUMENTS FOR ATOMIC AND NUCLEAR PHYSICS**	unchanged
8.1 (8.1)	Measuring instruments used to monitor activity limits and concentration of effluents from nuclear facilities, nuclear raw material mining or processing facilities, from the processing or application of radioactive materials and from radioactive waste processing plants, and used to determine environmental radiation exposure due to effluents	9.1	Activity meters for aerosols, gases and liquids released in the workplace	marked part included into item 9.1, name change
	Measuring instruments used to monitor activity limits and concentration of effluents from nuclear facilities, nuclear raw material mining or processing facilities, from the processing or application of radioactive materials and from radioactive waste processing plants, and used to determine environmental radiation exposure due to effluents	9.3	Activity meters used to determine the content of radionuclides in the environment	marked part included into item 9.3, name change
8.2	Activity meters for diagnostic and therapeutic preparations applied in vivo to patients	9.9	Activity quantitative variables meters for diagnostic and therapeutic preparations applied in vivo to patients	unchanged
8.3	Measuring instruments used for the determination of diagnostic and therapeutic doses in medical irradiation	9.10	Measuring instruments of dosimetric quantitative variables used for the determination of diagnostic and therapeutic doses applied in medical irradiation	name change

8.4 (8.4)	Volumetric activity gauges for ^{222}Rn in the air and water and equivalent volume activities of ^{222}Rn in the air, both instantaneous values and short-term and long-term averages	9.11	Volumetric activity meters for natural radionuclides in the air, equivalent volume activity of radon and dosimetric quantitative variables used for the purposes of preventing the penetration of radon into buildings and for protection against exposure from natural radionuclides in buildings and workplaces with the possibility of increased exposure from a natural source of radiation and with possible increased irradiation from radon	marked part included in item 9.11, name change for more precise definition
	Volumetric activity meters for 222Rn in the air and water and equivalent volume activities of 222Rn in the air, both instantaneous values and short-term and long-term averages	9.12	Activity meters used to check the content of natural radionuclides in building materials and drinking water	the marked part concerning drinking water is included into item 9.12, criteria for radon in surface water are not laid down in Government Regulation No 401/2015, narrowed definition
8.5	Assemblies used for checking the limits of exposure of persons, collectively operated by personal dosimetry	9.8	Meters for activity and dosimetric quantitative variables used to determine personal doses, including personal doses from a radiation emergency	name change, narrowed definition
8.6 8.7	Spectrometric assemblies for analysing alpha, beta, gamma, and neutron sources or fields	9.16	Activity spectrometers used to check radionuclide content in metallurgical products and radiopharmaceuticals	name change, substantially narrowed definition
	non-spectrometric activity meters and dosimeters used to monitor compliance with limits in the area of radiation protection or nuclear safety and for emergency measurement	9.4	Measuring instruments for activity and dosimetric quantitative variables used to check compliance with the criteria set out in the limits and conditions of a nuclear installation	marked part of the original item 8.7 transferred to items 9.4 and 9.6, name change
(8.7)	non-spectrometric activity meters and dosimeters used to monitor compliance with limits in the area of radiation protection or nuclear safety and for emergency measurement	9.6	Measuring instruments for pulse frequency, activity and dosimetric quantitative variables used for early detection of deviations from normal operation in order to prevent the occurrence or development of a radiological emergency	marked part of the original item 8.7 transformed into new item 9.7
	non-spectrometric activity meters and dosimeters used to monitor compliance with limits in the area of radiation protection or nuclear safety and for emergency measurement	9.7	Measuring instruments for activity and dosimetric quantitative variables designed to monitor the radiation situation during and after a radiological emergency	marked part of the original item 8.7 transferred to items 9.7 and 9.8, name change
8.8		9.8	Meters for activity and dosimetric quantitative variables used to determine personal doses, including personal doses from a radiation emergency	
(8.8)	Activity and dose meters used for checking limits for radioactive waste management and for checking release levels and conditions when introducing radionuclides into the environment	9.5	Measuring instruments for activity and dosimetric quantitative variables used to check compliance with the criteria set out in the limits and conditions for handling nuclear waste	marked part of the original item 8.8 transferred to item 9.5, name change, narrowed definition

	Activity and dose meters used for checking limits for radioactive waste management and for checking release levels and conditions when introducing radionuclides into the environment	9.2	Activity meters used to check the content of radionuclides in solid substances, items and equipment released in the workplace	marked part of the original item 8.7 included in item 9.3, name change
8.9 (8.9)	Assemblies used to detect the presence of sources of ionising radiation in illegal or undesirable transport	9.14	Measuring instruments for pulse frequency, activity and dosimetric quantitative variables used to prevent and detect unauthorised activity associated with fissile and other radioactive substances	marked part of the original item 8.9 included in item 9.14, name change
	Assemblies used to detect the presence of sources of ionising radiation in illegal or undesirable transport	9.15	Measuring instruments for pulse frequency, activity and dosimetric quantitative variables used for the detection and identification of a radionuclide source in the search for an orphan source by operators of a scrap metal smelting, collection and processing facilities and operators of waste incineration plants and co-incineration plants	marked part of the original item 8.7 included in item 9.15, name change
8.10	Activity meters for checking limit values of natural radionuclides in construction materials and water and the maximum permissible level of radiation contamination of foodstuffs	9.12	Activity meters used to check the content of natural radionuclides in building materials and drinking water	marked part of the original item 8.10 transferred to items 9.12 (construction materials and drinking water) and 9.3 (surface water – measurement of criteria according to Annex 3, Table 1a, Table 1c of Government Regulation No 401/2015), modification of names
(8.10)	Activity meters for checking limit values of natural radionuclides in construction materials and water and the maximum permissible level of radiation contamination of foodstuffs	9.3	Activity meters used to determine the content of radionuclides in the environment	the updated version of the item includes the marked part of the original item 8.10 and the entire original item 8.11
	Activity meters for checking limit values of natural radionuclides in construction materials and water and the maximum permissible level of radiation contamination of foodstuffs	9.13	Activity meters used to check the content of radionuclides in food and dosimetric quantity meters used for routine and validation measurements in food irradiation	marked part included in item 9.13, name change
8.11	Dose meters used for approval measurements in food irradiation	9.13	Activity meters used to check the content of radionuclides in food and dosimetric quantity meters used for routine and validation measurements in food irradiation	name change (correlation with Annex 2 to Ministry of Health Decree No 133/2004)
8.7	*Non-spectrometric activity and dose measuring instruments used to monitor compliance with limits in the area of radiation protection or nuclear safety and for emergency measurement*	9.6	Measuring instruments for pulse frequency, activity and dosimetric quantitative variables used for early detection of deviations from normal operation in order to prevent the occurrence or development of a radiological emergency	a partially new item with extended definition compared to the marked part of the original item 8.7, now reflecting the following provisions: • Act No 263/2016 as amended by Act No 183/2017 [§ 155(1)(a)] • Decree No 359/2016 [§ 6(4)] • *IAEA* Safety Standards Series No. NS-G-1.10, Appendix, points A.11 – A.15 • IEC 60910-1988 standards