	COOMET Recommendation	COOMET R/LM/25:2015
	Procedure for recognizing technical devices as measuring instruments	
Approved at the 25th COOMET Committee Meeting (27–28 May 2015, Khujand, Tajikistan)		

1 Scope

1.1 This Recommendation has been prepared under the Project COOMET 523/BY/11 and specifies a procedure for recognizing technical devices as measuring instruments (hereinafter referred to as "procedure") that may be applied by National Metrology Institutes (NMI) participating in COOMET.

2 Normative references

VIM ISO GUIDE 99 "International Vocabulary of Metrology – Basic and General Concepts and Associated Terms"

RMG 29-99 "State system for ensuring the uniformity of measurements. METROLOGY. General terms and definitions"

ISO/IEC 5725 "Accuracy (trueness and precision) of measurement methods and results"

3 Terms and definitions

For the purposes of this Recommendation, the following terms and definitions apply:

Technical device: single unit of an industrial product

Medical technical device: single unit of an industrial product designed solely for medical applications.

COOMET: Euro-Asian Cooperation of National Metrological Institutions

NMB: National Metrology Body

NMI: National Metrology Institute

4 General

4.1. This Procedure is developed for the purpose of implementation of requirements of the national metrology laws of the COOMET member countries and providing guidance to those legal entities and private entrepreneurs who need to assess the range of works necessary for metrological assurance of technical devices that can be regarded as measuring instruments, when they are supplied to the market of the respective COOMET member countries.

4.2. The Procedure involves issuance of a formal conclusion on recognizing a technical device as a measuring instrument only and shall not include evaluation of correctness of its accuracy specifications or of regularity of any related maintenance and technical documentation.

4.3. The procedure describes a process and criteria used for recognizing technical devices as measuring devices subject to the national metrology laws of the respective COOMET member countries.

4.4. A decision about recognizing a technical device as a measuring instrument shall be taken by the National Metrology Body (hereinafter referred to as NMB) itself or by an NMI it has designated. The results of reviewing documents submitted by the applicant shall serve as a basis for taking that decision. A review, which requires specific knowledge, may involve some other competent organizations, in particular scientific institutions or institutions capable of issuing conclusions on the matters of conformity assessment (e.g. accreditation ones).

4.5. Basic principles of performing a review are the following:

- scientific approach to and impartiality of the review;
- adequate competence of the experts engaged ;
- systematic arrangement of the expert activities;
- openness of the results of the review unless state, professional or commercial secrecy shall be kept in accordance with the national legislation.

5 Review process and criteria applied

5.1. The review shall be performed by experienced personnel having specific skills and knowledge in testing sophisticated technical products and measuring quantities determinable by the technical device being reviewed.

5.2. The criteria of recognizing technical devices as measuring instruments mean their compliance with one of the following points:

a) the technical device under review conforms to the definition of a measuring instrument given in the national metrology law of the respective COOMET member country[1];

b) measurements made by the technical devices under review provide accuracy that is capable of being assessed against requirements of applicable laws and technical regulations, as well as local regulations published by the state administration bodies of the respective COOMET member country;

c) the manufacturer expects the technical device under review to be subject to metrological control (verification, calibration, metrological certification), as a whole or in its individual functional components;

d) specific metrological characteristics are set for the device under review.

Notes:

1) The relevant unit of measurement together with its multiples and submultiples may be indicated on the display unit of the measuring instrument or stored in its permanent memory for further processing and display.

2) For medical technical devices, any claimed or indirectly estimated accuracy of physiological and/or anatomical parameters shall be taken into account, as well as generation of quantitative or quantitatively expressed energy or substances given in legal units of measurement, which are supplied to or removed from the patient's body and failing to control which would affect health and safety of the patient.

3) Although for some medical technical devices with measuring functions the manufacturer may have omitted specifying their accuracy characteristics, any such technical device capable of performing

[1] Additionally, definitions of РМГ 29-99 and VIM ISO GUIDE 99 may apply.

measurements shall still be regarded as a measuring instrument according to the criteria given above, and the measurements it performs shall comply with the principles of ensuring the uniformity of measurements.

4) Certain types of technical devices shall not be regarded as measuring instruments subject to the national metrology law of a COOMET member country, i.e.:

- technical devices with measurement functions that are used for provisional estimations only, which are then followed, if necessary, by more accurate measurements.
- technical diagnostic tools that read measurement data from measurement transducers or from any other electronic devices;
- tolerance control devices, e.g. go and no-go gauges, templates, probes etc.;
- limit switches, such as protective cutout devices, alarm devices, heat regulators etc. However, an exception may apply to line switches that are designed for use within the scope of legal metrology;
- numerical controllers that perform formatting and transmission of various data, including measurement information;
- technical devices with measurement functions that have been supplied to the market by the manufacturer as "household measuring appliances".

Graduation, calibration or adjustment of the abovementioned technical devices may be performed by legal entities and private entrepreneurs according to their own procedure. Some technical devices with measurement functions may be reclassified as indicators though.

5) If appropriate, the owner of a technical device with a measurement function also may ensure uniformity of its measurements in a distinct manner, e.g. by implementing internal laboratory control based on the ISO/IEC 5725 series.

6) Lack of relevant national measuring standards that could be used to control accuracy characteristics specified must not contribute to drawing a negative conclusion as regards recognition of a technical device as a measurement instrument.

5.3. An application submitted by a state body, legal entity, private entrepreneur or individual (hereinafter referred to as "applicant") shall serve as a basis for consideration of recognizing a technical device as a measuring instrument.

The applicant shall send such application for recognizing a technical device as a measuring instrument to the NMB or a designated NMI.

A recommended application form can be found in Annex A to this Procedure.

The application shall be enclosed with the following:

- letter or explanatory note containing reasons for recognizing a technical device as a measuring instrument;
- technical specification providing technical characteristics of the device to be reviewed;
- description of the device and its maintenance documentation;
- scope of application, intended use and method of application of the device;
- documentation for means used to control the accuracy of the technical device, i.e. material measures, reference materials, test solutions, indicators etc., including documents that contain information about their rated metrological characteristics;
- manufacturer declaration indicating the necessity to verify accuracy characteristics of the technical device or its measurements or a reference to a document where an appropriate control procedure is specified.

- link to the manufacturer's official website.

Notes:

1) Documents provided in electronic form shall be allowed for consideration only if they have come from the applicant's or manufacturer's official e-mail accounts or, alternatively, are linked from the manufacturer's official web-site.

2) The declaration regarding the necessity to verify accuracy characteristics of the technical device or its measurements shall be submitted by post or fax or sent from the manufacturer's official e-mail account. Official opinions issued by the state authorities or their subordinate institutions may also be taken into consideration.

5.4. The NMB or a designated NMI (wherever the application has been submitted) shall proceed to the review of the submitted documentation within 5 working days.
The review of the documentation submitted shall be completed within 20 calendar days. If necessary, the NMB or designated NMI may additionally request submission of an adequate clarification and/or any missing documents; in this case the time required to prepare a response may be increased by a pending period to receive these documents.
The response to the applicant shall be prepared within 5 working days after completing the review.

6 Outcomes of the review

6.1. The outcomes of the review performed shall be a well-justified conclusion either on recognizing a technical device as a measuring instrument subject to the national metrology law of a COOMET member country or on the absence of grounds for recognizing it as a measuring instrument.
6.2. The conclusion regarding recognition of a technical device as a measuring instrument shall be drawn as a result of a meeting of the expert group in form of a technical report.

Notes:

1) The technical report and a copy of the conclusion letter shall be retained by the executor for the period required by the applicable document management procedure. Any documents provided in electronic form may be stored without producing a hard copy in case the related technical report contains their check sums calculated using MD5 or SFV algorithms.

2) The set of documents submitted by the applicant for review shall be kept as an attachment to the technical report. The originals of the maintenance documents, e.g. operating instructions, may be returned to the applicant if the information used for making the decision can be readily copied from there.

6.3. The conclusion sent to the applicant shall be in form of a letter (done on the NMB or designated NMI letterhead).

7 Claims and appeals

7.1. Should the applicant be not satisfied with the decision taken, he/she may approach the institution that has carried out the initial review about a renewed consideration of recognizing the technical device as a measurement instrument, provided that he/she has presented additional documents to support his/her position.
7.2. Should the applicant and the expert organization have failed to achieve mutual consent about recognizing a particular technical device as a measuring instrument

through discussion, the materials under consideration will be referred to the NMB for taking a final decision.

8 Payment for services

8.1. The document review shall be performed on a contractual basis.

8.2. A repeated review can be performed at no charge only if additional information supplementing the previously submitted documents has been provided.

8.3. The date of sending the letter about the outcomes of the review to the applicant shall be regarded as the completion date of the review for recognizing a technical device as a measurement instrument.

Annex A

Recommended application form

NMB / NMI

APPLICANT

_____

Full name of the legal entity or private entrepreneur

_____

_____

Legal address, phone number

APPLICATION

for recognition of the technical device

_____

full name of the technical device

_____

name of manufacturer/designer

as a measuring instrument. _____

Enclosures:

- ☐ technical specification containing technical characteristics of the device;
- ☐ description of the technical device and its maintenance documentation;
- ☐ scope of application, intended use and method of application of the technical device;
- ☐ documentation for means used to control the accuracy of the technical device with measurement functions, i.e. material measures, reference materials, test solutions, indicators etc.;
- ☐ explanatory note describing reasons for recognizing a technical device as a measuring instrument;
- ☐ manufacturer declaration indicating the necessity of verifying accuracy characteristics of the technical device or its measurements or a reference to a document where an appropriate procedure is specified.
- ☐ link to the manufacturer's official website.

Head

Stamp _____ _____

Signature *Name, initials*

"___" _____ 20__

Appendix B
Recommended form of a report on recognizing the technical device as a measuring instrument

1 General

1.1 applicant, address, contact data
1.2 place of review
1.3 technical device to be reviewed, name of manufacturer and contact data of manufacturer
1.4 list of documents submitted for review
1.5 reference to "Procedure for recognizing a technical device as a measurement instrument"
1.6 list of enclosures

2 Outcomes of the review

2.1 General description of the technical device:
- operating principle;
- Rated characteristics (technical and metrological);
- scope of use, including estimation of possible use of the technical device with regard to the ensurance of the uniformity of measurements.

2.2 Similar devices already registered in the national register of measuring instruments of the COOMET member country.
2.3 Certificates, declarations etc. proving recognition of the technical device as belonging into a particular product category.
2.4 Conclusion on compliance with one of the criteria specified in the Procedure.
2.5 Additional requirements to be fulfilled when using the technical device for measurements
- availability of accuracy control measures, reference solutions, reference materials etc.
- maintenance of special operation conditions;
- use of software;
- associated devices
- other requirements.

3. CONCLUSION

Technical device is/is not a measuring instrument.

4. Recommendations

Means and measures to ensure uniformity of measurements, depending of the scope of use of the technical device and in accordance with the actual regulations of the COOMET member country.