	COOMET Recommendation	
	GENERAL REQUIREMENTS FOR THE COMPETENCE OF VERIFICATION LABORATORIES	**COOMET R/LM/__:2015**
Approved at the 25 meeting of COOMET Committee (_____ 2015, _____)		

1 SCOPE

This COOMET Recommendation (hereinafter – recommendation) sets the requirements to the competency of the verification laboratories which provide qualitative verification of measuring instruments (hereinafter - MI). This recommendation can be used:

- for competency evaluation of the laboratories by the third party for the officially determining of its competency in accreditation (authorization or notification);
- to make management decisions by the verification laboratory, aimed at improving the level of competence of laboratory and the quality of carried out verifications of measuring instruments;
- for the development of national standards which specify the requirements for the competency of the verification laboratories;
- to simplify the recognition of verification results between countries while the procedure of conformity assessment of the verification laboratories to this recommendation;
- for adjustment of corporate procedural documents of the verification and calibration laboratories within a single legal entity, including quality manuals.

The recommendation was developed on the basis of the international standard ISO / IEC 17025 considering the specific requirements for the verification laboratories, established in the COOMET countries.

This recommendation can be used by customers of services which can be verification laboratories, government and accreditation bodies in confirming or recognizing the competence of laboratories.

Note. Term “verification” used in this document corresponds to VIM, namely: provision of objective evidence that a given item fulfils specified requirements.

2 GENERAL REQUIREMENTS

2.1 The competence criteria set in this recommendation apply to the laboratories, which conduct verification of MI, regardless of:

- their purpose of verification of MI - for other legal persons and / or for their own needs;
- the number of personnel;
- the scope of verification activity.

Note. Accreditation of laboratories in accordance with international practice is voluntary, and its obligatory passing in specific areas, for example in the field of legal metrology, is established by

legislative acts.

2.2 In its work the verification laboratory can use both standardized methods of verification an ones developed within works carried out to set the metrological characteristics of measuring instruments, for example, during the state acceptance tests for type approval of measuring instruments.

2.3 The verification laboratory can use this recommendation in the process of the development of quality management systems.

Note. Term "management system" in the present standard means the systems of quality management, administration, technical organization which are used for the laboratory management.

2.4 If the verification laboratory corresponds to the requirements of present recommendation then in its activity it should use quality management system which also complies with ISO 9001 requirements. Wherein conformity of quality management system of laboratory to the requirements of ISO 9001 standards is not the confirmation of the competency of the verification laboratory. Confirmation of competence of the verification laboratory in accordance with this recommendation does not mean that the laboratory's quality management system meets the requirements of ISO 9001.

2.5 Present recommendation sets the requirements for technical competence which are not considered in ISO 9001.

Note 1: To guarantee the correct application of the requirements of this recommendation the accreditation bodies are allowed to set the additional requirements in specific areas.

Note 2. If the laboratory wishes to obtain accreditation for part or the whole scope of their activities on verification, then it should choose an accreditation body that operates in accordance with ISO / IEC 17011.

2.6 This recommendation does not address the compliance of laboratories with legal requirements, for example, established to perform work on licensed activities and safety standards.

3 NORMATIVE REFERENCES

This standard refers to the following standards:

ISO 9000:2000 Quality management systems. Fundamentals and vocabulary.

ISO 9001:2008 Quality management systems. Requirements.

ISO/IEC 17000:2004 Conformity assessment. Vocabulary and general principles.

ISO/IEC 17011:2004 Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies.

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

ISO/IEC Guide 99:2007 International vocabulary of metrology. Basic and general concepts and associated terms (VIM)

VIML (2CD-2010) International vocabulary of terms in legal metrology.

4 TERMS AND DEFINITIONS

4.1 In this recommendation the terms with the definitions are used contained in the international standards ISO/IEC 17000 series, ISO Guide 99 (VIM) and VIML (2CD-2010).

Note. Basic definitions related to the quality management system are given in ISO 9000 and those concerning the accreditation of laboratories and certification - in the ISO/IEC 17000. If the definitions of the same term don't match, those contained in ISO/IEC 17000, VIML and VIM are preferable ones.

4.2 For the internal needs of the state terms can be used in accordance with the laws

of the country or the national official normative documents on metrology, accreditation, certification, and quality management systems. However, difficulties may arise in the implementation of agreements on the recognition of accreditation results.

4.3 For the countries that have signed the Agreement on coordinated policy in the field of standardization, metrology and certification can be used terminology agreed at the level of the Interstate Council of the CIS countries.

5 MANAGEMENT REQUIREMENTS

5.1 Organizational structure

5.1.1 The laboratory or the organization, which includes this laboratory, shall be a legal entity.

5.1.2 The laboratory is responsible for the realization of its verification activities in accordance with the law and the present recommendation.

5.1.3 Management system shall cover the work carried out by the laboratory on and outside the permanent production areas, at the appropriate temporary used working places or in the transportable laboratories.

5.1.4 If the laboratory is the part of the organization that engages in activities different from MI verification, the responsibility of personnel of the organization participating in or influencing on the verification activity of the laboratory shall be clearly defined in order to identify potential conflicts of interests.

Note 1. If the laboratory is the part of an organization, the organizational structure shall be such that departments having contradictions in the interests (e.g., industrial, commercial, marketing or finance), will not affect negatively on the laboratory's compliance with this standard.

Note 2. If the laboratory wants to be recognized as the third party laboratory, it shall be able to confirm the impartiality and independence of its employees from any commercial, financial and other pressures which might influence their technical evaluation. The verification laboratory of the third party shall not engage in any activity which could jeopardize the independence of its technical evaluation and its impartiality towards its verification activities.

5.1.5 The laboratory shall to:

a) have managerial and technical personnel who, irrespective of other responsibilities, would have the authority and resources necessary to perform the functions associated with the usage, maintenance and improvement of the management system and the identification of deviations from the management system or from the procedures of verification, and to initiate actions to prevent or reduce such deviations (see also 5.2).

b) hold activities to ensure that the management and personnel of the laboratory are independent of on any kind of internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) develop policies and establish procedures to ensure the privacy of information and property rights of customers, including the protection during storage and transferring of results by electronic means;

d) develop policies and establish procedures to avoid engagement in any activities that would diminish confidence in its competence, impartiality, technical evaluation and objectivity during the performance of work;

e) determine the organizational and management structure of the laboratory, its place in the organization or enterprise which it belongs to, and the relations between the processes according the quality management, technical operations and support service;

f) establish responsibilities and authorities for all personnel who manage, perform or

check the work affecting the quality of verifications, as well as to determine the relations between them;

g) ensure the appropriate control over the personnel conducting the verification, including trainees, by individuals who are competent in the methods of verification, the purpose of each verification and have mastered the evaluation of verification results;

h) appoint a technical manager, which shall be absolutely responsible for the technical operations and the provision of resources necessary to achieve the required quality of the laboratory activities;

i) appoint the quality manager from among the personnel, which, irrespective of other his/her duties and responsibilities shall bear specific responsibility and have the authority to ensure the implementation of quality management system and consistent compliance to its requirements; quality manager shall have the direct access to the highest level of management where decisions on the defining of the quality policy and resourcing of the laboratory are maked;

j) appoint the deputies in case of the absence of technical manager, quality manager and other leading specialists of the laboratory;

k) ensure that employees are aware of the value and importance of their activities and their contribution to the achieving the objectives of the management system;

5.1.6 Top management shall ensure the relevant information exchange in the laboratory and that this information relates to effectiveness of management system.

5.2 Management system

5.2.1 The laboratory has to create, implement and maintain the management system relevant to its field of activities at the proper level. The laboratory shall document its quality policy, programs, procedures and instructions in as much detail as is necessary for laboratory to ensure the quality of the verification results. The documentation of management system must be brought to the attention of the relevant personnel; it shall be clear to him, available and shall be used.

5.2.2 Quality management system of the laboratory, as well as a statement of quality policy shall be defined in the quality manual (or any other similar document). Common quality objectives shall be stated and the results on goals shall be reviewed by management. Statement of quality policy must be signed by the highest executive head. Policy statement shall include:

a) responsibilities of the laboratory management according to the good professional practice and the quality of the verifications carried out by it;

b) list of standards in accordance with which the laboratory is to provide its services;

c) the objectives of quality management system;

d) requirement that all employees involved in the verification activities in the laboratory, get acquainted with the quality documentation and realize the policy and implement the procedures referred to above;

e) responsibilities of the laboratory management according to the compliance with this standard and continually improving of the effectiveness of their own management system.

Note. The statement of quality policy shall be clear, and may include the requirement to hold the verification only in accordance with institutionalized procedures of verification. If the verification laboratory is part of an organization, some elements of the quality policy may be contained in other documents.

5.2.3 Top management shall provide evidence of fulfillment of the obligations relating to the development and application of the management system and continually improving of its effectiveness.

5.2.4 Top management shall bring to the attention of personnel the importance of compliance with the requirements of the customer as well as with the legislative and regulated requirements.

5.2.5 The quality manual shall contain procedures for the management system, including technical procedures or references to documents that describe them. It shall set out the structure of the documentation used in the management system.

5.2.6 The quality manual shall contain the information about the role and responsibility of the technical manager and quality manager and their responsibility for ensuring the compliance with this recommendation, including the cases of absence of nominal heads (delegation of powers).

5.2.7 Top management shall ensure that while the planning and introduction of changes in the management system, it must continue to comply with the set requirements.

5.3 Management of documentation

5.3.1 General provisions

The laboratory shall develop and maintain procedures to control all documents (developed directly in the laboratory or received from the outside), which form the part of its management system. These include regulations, standards, methods of verification, drawings, software, specifications, instructions and manuals, as well as other documents.

Note 1. For the purpose of this recommendation the documents mean policies, procedures, specifications, calibration charts, diagrams, manuals, posters, notices, warning notes, software, drawings, plans, etc. They can be on different data storage media (on paper, electronic media in digital, analog, photographic or written format).

Note 2. Management of data related to verification is according to 6.4.7. Management of registered data is according to 5.13.

5.3.2 Approval and issue of documents

5.3.2.1 All the documents of management system shall be reviewed and approved by authorized personnel prior to its issue. To prevent the usage of invalid and (or) obsolete documents inside the management system, the procedure of management of documentation must be established that shows the current status and distribution of documents.

5.3.2.2 The adopted procedure(s) shall ensure that the:

a) approved wording of the relevant documents are available at all workplaces where the essential for the effective functioning of the laboratory operations are performed;

b) documents are periodically reviewed and revised, if necessary, to ensure its continuing applicability and compliance with current requirements;

c) inoperative or obsolete documents are promptly removed from circulation or other protection is provided against their unintentional application;

d) obsolete documents retained for legal purpose or to preserve the information are to be appropriately marked.

5.3.2.3 Documents of the management system developed in the laboratory must have a unique (non-recurrent) identification. Such identification shall include:

– document number;

– paging;

– total number of pages;

– name of the department that have developed the document;

–date of issue and (or) revision or withdrawal.

5.3.3 Changes to documents

5.3.3.1 Changes to documents shall be reviewed and approved by the same personnel who have conducted the initial analysis, unless otherwise specified. The designated personnel shall have access to relevant initial information upon which the analysis and approval of change will take place.

5.3.3.2 Where practicable, the changed or the new text shall be marked in the document or in the appropriate attachments.

5.3.3.3 If the documentation control system of the laboratory includes correction of documents by hand before reissue of the documents, the procedures and authorities shall be defined for such corrections. These corrections must be clearly marked, signed and dated. The revised document shall be formally reissued as soon as practicable.

5.3.3.4 The procedures shall be established, which describe the changes to the documents stored in the automated computer systems as well as the procedures for change control.

5.4 Consideration of requests, tenders and contracts

5.4.1 The laboratory shall establish procedures for the consideration of requests, tenders and contracts and maintain them properly. Policies and procedures to consider the documents for making contracts shall ensure that:

a) the requirements, including the methods of verification, are defined in a proper way, documented and well understood (6.4.2);

b) the laboratory has capabilities and resources to meet these requirements.

Each contract shall be acceptable both for the laboratory and for the customer.

Note 1. The consideration of the request, the tender or the contract should be made from a practical point of view and effectively, taking into account the financial, legal aspects and the time factor. When holding the verification for the departments of the enterprise, which includes the verification laboratory, the consideration of requests, tenders and contracts can be performed in a simplified manner, according to the rules adopted at this enterprise.

Note 2. Analysis of the capabilities shall establish that the laboratory possesses the physical, human and information resources, and laboratory staff is qualified and has the specific knowledge and experience required to perform the verification. In addition, this analysis may include the results of the previous laboratory participation in interlaboratory tests (comparisons), including in the form of the technical competence evaluation with the use of measuring instruments with a known value.

Note 3. The contract can be presented in the form of any agreement in writing on supplying the customer with the verification services.

5.4.2 The laboratory shall be provided with accounting review of applications and contracts, including the account of all significant changes. In addition, during the term of the contract the records shall be kept about the relevant discussions with the customer regarding the customer's requirements or the results.

Note. For the consideration routine and other simple tasks it is sufficient to provide the date and the identification (e.g. surname) of the person from the laboratory who is responsible for the carrying out of contract works. For recurrent routine tasks it is necessary to make the analysis of only the initial stage of the request or upon receipt of the contract for the upcoming daily work performed under the basic agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or specialized tasks on verification, more detailed document shall be carried out.

5.4.3 The laboratory shall also consider any type of work for which the laboratory has concluded the contract with the subcontractor.

5.4.4 The customer shall be informed of any deviation from the contract.

5.4.5 If it is necessary to make changes to the contract after the work was started, it is required to re-consider the same procedure of the consideration of the contract and any amendments shall be brought to the attention of all personnel involved in this contract.

5.5 Conclusion of contracts with subcontractors to perform work on verification of MI

5.5.1 When the work is performed under the contract between the laboratory and the subcontractor, or due to unforeseen circumstances (e.g. due to the full load of the laboratory with orders, the need for additional specified knowledge or temporary inability to perform the work), or on a permanent basis (e.g. on the terms of permanent subcontracting, representation agreements or benefits), the work orders must be given to the competent subcontractor. Competent subcontractor is a subcontractor who performs work in accordance with this recommendation.

Subcontract works shall not exceed 50% of the volume of work performed by the laboratory for the verification of specific MI.

The laboratory shall notify the customer in writing of the agreement undertaken and if necessary to obtain the acceptance of the customer, preferably in writing.

5.5.2 The laboratory is responsible to the customer for the work performed by the subcontractor, except in those cases where the subcontractor is determined by the customer.

5.5.3 The laboratory shall keep a register of subcontractors with which it can enter the agreement for performance of works on MI verification with, and the data registration of their compliance to this recommendation.

Note. During accreditation the laboratory shall submit the register of subcontractors and data about compliance to this recommendation

5.6 Acquisition of services, materials and equipment

5.6.1 The laboratory shall develop the policy and the procedure(s) for choosing and obtaining of the services, materials and equipment, influencing the quality of the verification carried out, used by it. The procedures of purchase, acceptance and storage of reagents necessary for carrying out of the verification shall be developed.

5.6.2 The laboratory shall ensure that the purchased materials, equipment, influencing the quality of carrying out of the MI verification, are not applied until they are inspected and checked for compliance to technical specifications or requirements set up in the methods of verification of these MI. The applied materials, equipment and services shall correspond to the set up requirements. The accounts and records on actions taken for the conformance inspection shall be kept.

5.6.3 The documents for supply of items influencing the quality of the laboratory results shall contain the data describing the ordered services and auxiliary materials. These documents for supply shall be analyzed from the point of view of their technical contents till enforcement.

Note. Description of the supply can contain the type, class, sort, accurate identification, technical characteristics, drawings, inspection manuals, other technical data, including the testing results, required quality and standard for the management system, according to which they were made.

5.6.4 The laboratory shall evaluate suppliers of critical consumables, auxiliary

materials and services that affect the quality of the verification, and keep documents on these estimates and a list of suppliers that have received approval.

5.7 Provision of services to customer

5.7.1 The laboratory shall provide customers or their representatives the possibility of cooperation to clarify the request of the customer and for the current monitoring on the progress of the laboratory verification of MI, provided that the laboratory ensures confidentiality to other customers.

Note 1. Such cooperation may include the access for the customer to the areas, where the preparation, packing and shipping of the verified MI is held.

Note 2. The recommendations on technical issues, the conclusions of experts and the explanation of the results are provided at the request of the customer. Information exchange with the customer, especially in the case of large volumes of work, shall be maintained throughout the work. The laboratory shall inform the customer of any delays or significant deviations during the verification.

5.7.2 The laboratory should aim to obtain both positive and negative information (feedback) from their customers. The information received from the customers shall be analyzed and used to improve the management system, verification activities and customer service.

Note. The examples of such information include the results of surveys of the customers or peer review of certificates and protocols of verification together with the customers.

5.8 Claims

The laboratory shall develop a policy and work out a procedure for the adjustment of claims received from customers or other parties. There shall be registered all claims, their reviews and corrective actions taken by the laboratory. (see also 5.11).

5.9 Removal of nonconformities to specified requirements in verification

5.9.1 The laboratory shall develop a policy and work out the procedures that shall be used when any aspect of its verification activity or results of works on verification don't confirm to the internal methods of laboratory and the agreed requirements of the customer. Quality policy and procedures shall ensure:

a) the appointment of the authorized persons and determining their responsibility to control the work that does not meet the requirements, the determining and implementation of the actions (including, if necessary, the suspension of work and the refusal to issue the certificates of verification, when found work that does not meet the requirements);

b) assessment of the value of the work that does not meet the established requirements);

c) immediate correction actions, together with any decision about the acceptability of work that does not meet the requirements;

d) informing the customer and cancel of the results of the work, if necessary;

e) determination of responsibility for authorizing the resumption of work.

Note. Identification of work that does not meet the requirements or problems related to the management system or verification activities can occur at various points of the management system and technical stages of operations. Examples are the claims of customers, quality control, verification of measuring instruments, checking of consumable materials, supervision or control over personnel, inspection of protocols and certificates of verification, management reviews and internal or external audits.

5.9.2 In cases when the assessment shows that the work that does not meet the

requirements may be carried out again or there is a doubt in compliance of laboratory operations to its own quality policy and procedures, laboratory shall immediately follow the procedures for the implementation of the corrective actions listed in 5.11.

5.10 Improvement

The laboratory shall constantly improve the effectiveness of its management system through the implementation of quality policy and objectives aimed at maintaining the quality and the audit results, analysis of data, corrective and preventive actions and management reviews.

5.11 Corrective action

5.11.1 General provisions

The laboratory shall develop the policy, the procedure and appoint the relevant authorized persons for the implementation of corrective action in cases when the work that does not meet the requirements was found or the deviations from policies and procedures of management system or technical operations were identified.

Note. The problem according the management system or the technical operations of the laboratory can be determined by a number of actions, such as the removal of inconsistencies in the requirements, internal or external audits, management reviews, information from customers or control over personnel.

5.11.2 Analysis of causes

The procedure for corrective action shall start with finding out the main reason of the problem.

Note. Analysis of the reasons the key and sometimes the most difficult part in the procedure for corrective action. Often, the main reason is not obvious, and therefore requires careful analysis of all potential causes of the problem. Potential causes could include customers' requirements, the samples, sample specifications, methods and procedures, qualification and training of personnel, consumable materials or the measuring equipment and the results of its metrological control.

5.11.3 Selection and implementation of corrective actions

The laboratory shall select and implement the corrective actions to eliminate the causes of non-compliance and prevent its reappearance.

Corrective actions shall to some extent correspond to the scale of the problem and the risk associated.

The laboratory shall document and implement every required changes resulting from analysis of the causes of corrective actions.

5.11.4 Current control (monitoring) of corrective actions.

The laboratory shall conduct the monitoring of results for the effectiveness of actions taken.

5.11.5 Additional audits

In the case when identification of unconformities or deviations causes doubts in laboratory compliance to its own objectives and procedures or in its compliance to the present standard, the laboratory must immediately provide audits in the relevant areas of activity in accordance with 5.14.

Note. Such additional audits often follow the implementation of corrective actions to confirm their effectiveness. Additional audit should be carried out only when a serious problem or risk was identified in the activity.

5.12 Preventive action

5.12.1 There are shall be identified areas that require improvement, as well as potential sources of unconformities that may relate to management system or technical

operations. If the areas that require improvement were identified, or a preventive action is needed, in order to reduce the probability of occurrence of inconsistencies and to use opportunities for improvements the appropriate plans for operation should be developed and implemented, and the monitoring of their implementation shall constantly be done.

5.12.2 The procedures for the preventive actions shall include the initiation of such actions and inspections to ensure its effectiveness.

Note 1. Preventive action is an active sequential process of identifying the favorable opportunities for improvement rather than a reaction to the identified problems or claims.

Note 2. Besides the analysis of the methods of work the preventive action can include analysis of data with the analysis of trend, risk and the results of quality review of the verification.

5.13 Management of accounts and records.

5.13.1 General provisions

5.13.1.1 The laboratory shall establish and maintain the proper level of procedures for identification, collection, indexing, access, registration, storage, management and destruction of documents containing data on quality, and technical documents. Documents containing data on quality shall include records of internal audits and analyzes made by management, as well as documents of corrective and preventive actions.

5.13.1.2 All accounts and records shall be made in a readable way and kept in the places where there are appropriate conditions to quickly find them, as well as to prevent its damage, quality deterioration and loss. The retention periods of accounts and records shall be set.

Note. The accounts and records can be presented on any type of media, both paper and electronic.

5.13.1.3 All accounts and records shall be adequately protected or stored in a safe place and kept confidential.

5.13.1.4 The laboratory shall have procedures to protect the integrity and backup procedures of accounts and records stored by electronic means, as well as procedures to prevent unauthorized access to the documents or changes in them.

Note. For the accounts and records stored in the laboratory and sent to the customer in electronic form, the checksum calculation (CRC) by MD5 algorithm is sufficient. The program of checksum calculation shall be validated before use.

5.13.2 Technical documents

5.13.2.1 The laboratory shall retain the initial observations for the certain period (usually in the form of protocol of verification), derived data and the necessary amount of information of MI verifications carried out for the checkup analysis, personnel records. These documents should contain information on the personnel responsible for carrying out the verification and inspection results.

Note 1. In some areas, it may be impossible or impractical to store the documents of all initial observations. In this case the protocols of MI verification shall be kept.

Note 2. The technical data are the accumulated data (6.4.7) and information obtained as a result of the verification and indicates whether the specified indicators of quality or processes were achieved. These may include forms, contracts, worksheets, workbooks, checklists, working notes, protocols of verification, inspection schedule, certificates of internal verifications, notes and documents of customers and their information.

5.13.2.2 Observations, data and calculations shall be recorded at the time of their performance in the protocols of MI verification and identified with a specific kind of work.

5.13.2.3 When errors are found in the documents, each error shall be crossed out, it is not necessary to rub it, make illegible or remove, and next to it shall be written the

correct version. All such changes in the documents shall be signed or witnessed by the person who has made this correction. In the case of storage by electronic means the similar measures shall be taken to avoid loss or change of original data.

5.14 Internal audits

5.14.1 The laboratory periodically and in accordance with the schedule approved by senior management and the procedure relevant to the documents of quality management system shall conduct internal audits of its activities in order to check that the ongoing work on the MI verification continues to meet the requirements of the management system and the present recommendation. Internal audit program shall address all the elements of the management system related to the verification activities. The responsible for the planning and organization of audits is the quality manager as required by the schedule and management of the organization. Such audits shall be carried out by trained and qualified personnel independent of the activities for which the audit is carried out.

Note. The cycle of internal audit, which includes all the elements of a quality management system in relation to the verification of all MI groups, which are verified by the laboratory shall usually be completed within a year.

5.14.2 When results of the audit cast doubt on the correctness or reliability of the results of verification, the laboratory shall take timely corrective action and notify customers in writing if the researching show that something has probably influenced on the laboratory results.

5.14.3 The elements of quality management system or a group of verified MI, which have been audited, results of the audit and corrective actions arising from them should be recorded.

5.14.4 At the follow-up audit activities the implementation and effectiveness of the corrective action shall be checked and recorded.

5.15 Management reviews

5.15.1 In accordance with the set schedule and procedure the laboratory management shall periodically review the laboratory management system and its verification activities to ensure their continuing suitability, effectiveness and implementation of any necessary changes or improvements. In the course of this analysis the following items shall be taken into account:

- suitability of the quality policy and procedures;
- reports of management and inspection personnel;
- results of last internal audits;
- corrective and preventive actions;
- external audits;
- results of inter-laboratory comparisons;
- changes in the volume and type of works;
- information from customers;
- claims;
- recommendations towards improvement;
- other relevant indicators such as quality control activities, resources and personnel training.

Note 1. The normal frequency of management analysis is once a year.

Note 2. The results of this analysis shall be considered in the planning system of the laboratory, and shall include the objectives, tasks and action plans for the next year.

Note 3. The analysis conducted by management includes consideration of related items at regular management meetings.

5.15.2 The results of analyzes conducted by management and the resulting actions shall be recorded. Management shall ensure that these actions will be implemented in an acceptable and coordinated timescale.

6 TECHNICAL REQUIREMENTS

6.1 General provisions

6.1.1 Correctness and reliability of verification performed by the laboratory are determined by many factors. These factors have such components:

- personnel (see 6.2);
- production and environmental conditions (6.3);
- verification methods (6.4);
- equipment (6.5);
- traceability of measurements (6.6);
- handling and transportation of measuring instruments after verification (6.8).

6.1.2 The influence of these factors on the accuracy of measurements differs significantly for the verification of different types of measuring instruments (e.g., for measurement standards and working measuring instruments). The laboratory shall consider these factors when performing verification, as well as the training and qualification assessment of personnel, and when selecting and during metrological control of its equipment.

6.2 Personnel

6.2.1 The laboratory management shall ensure the competence of all employees who work with the specific equipment, perform verification, evaluate the results, sign the certificates of verification. The personnel conducting the verification of measuring instruments has to be qualified as the specialist of the verification in the relevant field of measurements, confirmed in accordance with national requirements.

When the trainees are involved in these works the relevant supervision of their work shall be provided. The competence of the personnel performing special tasks (taking into account education, qualification, experience and (or) shown ability to carry out verification operations) shall be assessed.

Note 1. In some technical fields (e.g., verification of high voltage measuring instruments) the personnel performing certain tasks may be required to pass a special certification or to have a permit to work. The laboratory is responsible for fulfilling the set requirements for the personnel certification or for the obtaining the permit to perform the certain operations. Requirements for certification or personnel permit may be regulatory, may be included in the standards for the specific technical field, or may be required by the customer.

Note 2. The personnel responsible for the experts' reports and explanations of the results, in addition to appropriate qualification, training, experience and knowledge relevant to the ongoing work shall also have:

– necessary knowledge about the design features and operating principle of verified measuring instruments, the specific features of the reference materials, etc, as well as knowledge of possible defects or performance degradation that may occur during or in service;

– knowledge about the general requirements expressed in the legislative acts and regulations;

– understanding of the importance of discovered nonconformities for the metrological characteristics of measuring instruments to correspond to set values in the operating documents.

6.2.2 The laboratory management shall formulate the objectives for education,

training and qualifications of the laboratory personnel. The laboratory shall develop policy and procedures for identifying training needs of the personnel and ensure its training. The training program shall comply with the current and projected tasks of the laboratory. The effectiveness of the training shall be assessed.

6.2.3 The laboratory shall have the permanent or contract personnel. In the case of contract personnel or additional technical and support one, the laboratory shall ensure that the work of the personnel is under control, that the personnel is competent and work in accordance with the laboratory's management system.

6.2.4 The laboratory shall maintain updated the position descriptions for managerial, technical personnel and support specialists involved in the work on verification.

Note. The position descriptions may be formulated in different ways. At least, there shall be determined the following:

– responsibility for the reliability of carried-out verifications;
– responsibility for the planning of verification and evaluation of results;
– responsibility to present the reports and interpret of results, if required;
– responsibility for the application of legal methods of verification;
– required special knowledge and working experience;
– qualification and training programs;
– responsibilities of management personnel.

6.2.5 Management shall authorize specific personnel to perform the verification of certain types of measuring instruments, to draw up the certificates of verification, reports of specialists and interpretations of the results, to work on certain types of equipment. Laboratory shall maintain the records about the necessary authorities, competence, professional training, education, qualification and experience of all technical personnel, including personnel working under the contract. This information should be readily accessible and shall contain the date of authorization and (or) the confirmation of competence.

6.3 Production and environmental conditions

6.3.1 Equipment and premises of the laboratory for MI verification, including power sources, lighting, environmental conditions shall provide the proper verification.

The laboratory has to ensure that the impact of the environment does not lead to incorrect results, and does not adversely affect the required quality of any measurement. The special measures shall be taken when verification is carried out at the workplaces for MI verification out of the permanent production areas of laboratories (at the customer's premises, portable laboratories, etc.). Technical requirements for production areas and environmental conditions that may affect the results of the verification shall be documented.

6.3.2 The laboratory shall monitor, control and record environmental conditions, if they affect the quality of the results or it is required by the appropriate verification procedure. Proper attention shall be given to influential factors, such as electromagnetic interference, radiation, humidity, power supply, temperature, noise and vibration levels, i.e. the factors that affect the verification of specific types of MI. The verification shall be stopped when the environmental conditions jeopardize the results.

6.3.3 Adjacent areas, where it is incompatible to conduct the verifications of various types of MI, shall be properly separated. The measures shall be taken to prevent cross-contamination of common environment.

6.3.4 The access to the working area shall be controlled in the case of its impact on

the quality of the verification. The laboratory shall determine the amount of control according to particular circumstances.

6.3.5 The measures shall be taken to ensure the order in the laboratory. The special procedures shall be developed, if necessary.

6.4 Methods of verification

6.4.1 General provisions

The laboratory shall use the appropriate procedures to perform verifications within its scope of activities, which include: the loading and unloading operations, transportation, storage and preparation of verifiable measuring instruments, analysis of the results of verification.

The laboratory shall have the instructions for application and operation of all necessary equipment, for loading and unloading operations and for the preparation of measuring instruments or both, in cases when the absence of such instructions could jeopardize the results of verification. All instructions, standards, manuals and reference data necessary for the work of the laboratory shall be kept up to date and be readily available to personnel (5.3). Deviation from legitimate methods of verification is not allowed.

Note. International, regional or national standards, procedures or recognized specifications that contain sufficient and clear description of the procedure of verification do not need to be rewritten as own internal methods of verification if their use is legalized. Legalized verification procedure shall be observed in full.

6.4.2 Selection of methods of verification

The laboratory shall apply legislated methods of verification designed for specific types of measuring instruments. At the national level, the methods are applied that have passed approval in accordance with established procedure. Under appropriate conditions, based on the requirements of this recommendation, for the customers from other countries the methods of verifications that have been published in international and regional standards can also be used. The laboratory shall ensure that it uses the latest valid edition of the standard. If necessary, the standard shall be amended to provide unambiguous application.

Note. For measuring instruments, which were commissioned prior to the entry into force of the new legislative requirements for metrological control, outside of legal metrology the methods of verification can be applied that were legalized during the approval of type of this MI or during the metrological certification of a particular instance.

6.4.3 Verification methods developed by the laboratory.

Testing of the methods of verification, developed by the laboratory as part of MI type approval, shall be carried out by qualified personnel who performs the work of this type approval with the involvement of qualified experts on verification in the relevant sphere of measurements.

6.4.4 The effective communication between all personnel involved in this work shall be provided during the testing.

Before the approval of the method of verification, the results of testing of the verification method are for reference only and shall not be given to the customer as the official results of the MI verification.

6.4.5 Validation of methods of verification is usually not carried out, as the method of verification is approved during certain procedures of metrological control of MI, in particular, during the tests for MI type approval. It is recommended to use the term

"metrological confirmation of the method of verification" for the methods of verification. As and when required the metrological confirmation of the method of verification, for example, during the state testings or metrological certification, the evidences are given by review and experimental studies that this method meets the legal requirements, the requirements of regulatory and operational documents.

6.4.6 Uncertainty evaluation

6.4.6.1 The verification laboratory that carries out the verifications, including those for their own use, shall have and apply the methods of evaluation of accuracy characteristics for all measurements performed in the laboratory.

If it is necessary to provide a detailed description of the separate stages of the accuracy evaluation, the laboratory can develop and implement a separate document with taking into account the requirements 5.4.5.

Note.. Typically, methods of evaluation of accuracy of measurements shall be a separate section in the methods of verification. The accuracy of the result of verification is always expressed by uncertainty.

6.4.6.2 When evaluating the accuracy of the measurements all its components being listed in the methods of verification shall be taken into account.

Note. Sources of uncertainty include, but are not necessarily limited to, existing reference measurement standards and reference materials, methods and equipment, environmental conditions, properties and condition of verifiable measuring instrument, as well as the qualification of the specialist who is conducting the verification.

6.4.7 Data management

6.4.7.1 Data calculation and transmission shall be inspected regularly.

6.4.7.2 When the computers or automated equipment are used for the collection, processing, recording, storage or retrieval of verification data and the making reports about them, the laboratory shall ensure that:

a) custom-developed software for computers were documented with sufficiently amount of details and their validation was properly carried out in accordance with the application sphere;

b) procedures to protect data were established and implemented; such procedures shall ensure the integrity and confidentiality of entry or collection, storage, transmission and processing of data;

c) maintenance and servicing of computers and automated equipment as well as the maintenance of environmental and operating conditions to ensure the proper operation of this equipment.

Note. Commercially available commercial software (e.g., word processing systems, databases and programs of statistical analysis) in their ordinary use according their purpose can be considered sufficiently tested for proper operation. Nevertheless, the suitability of configuration / modification of software tools for the laboratory shall be checked (6.4.7.2).

6.5 Instrumentation

6.5.1 The laboratory shall be equipped with all the measuring equipment required for the proper conduct of verification. In those cases where it is necessary for laboratory to use equipment outside the permanent control, it shall ensure that the requirements of this recommendation will be met.

6.5.2 Equipment and the software used for verification shall ensure the required accuracy and must comply with the technical requirements of the performed verification. Prior to the commissioning the measuring equipment shall pass metrological control

(verification, calibration etc.) in order to establish that it meets the technical requirements of the laboratory and meets the required standard specifications.

The measuring equipment shall have metrological characteristics required for its use (range, accuracy, stability, resolution etc.).

6.5.3 Equipment shall be operated by personnel who have a right to do it in accordance with their official duties. The instructions applied for operation and maintenance and repair (including any necessary operations manual developed by the manufacturer of the equipment) shall be readily available to the relevant laboratory personnel.

6.5.4 Each unit of equipment with its software, that is used for verification and influencing the results of verification, shall be identified.

6.5.5 Each unit of equipment that influence considerably on the quality of works carried out, shall be recorded. These documents shall contain the following information:

a) originality of unit of equipment and its software;

b) name of the manufacturer, identification of the type and serial number or other unique identification;

c) reviews for compliance with technical specifications (6.5.2);

d) current location, if required;

e) manufacturer's instructions, if available, or reference to their location;

f) dates, results and copies of certificates of verification / calibration / metrological certification / comparisons, records of adjustments, acceptance criteria and the date of regular metrological control;

g) scheme of maintenance and servicing, if necessary, and maintenance and servicing that have been carried out on a given date;

h) any damage, malfunction, modification or repair of equipment.

6.5.6 The laboratory shall have procedures for safe loading and unloading operations, transportation, storage, usage and planned maintenance and servicing of measuring equipment to ensure the proper operation and prevent its contamination or deterioration of the technical characteristics.

Note. When measuring equipment is used for verification on the areas outside the laboratory permanent production ones, there may be required additional procedures.

6.5.7 The equipment that was overloaded, or mishandling, or gives questionable results, or it has been demonstrated that it is defective, or its characteristics are out-of-range, shall be removed from work. It shall be isolated to prevent its use or have a marking on the prohibition of its usage until the repairing and confirmation of its operability by the metrological control. The laboratory shall investigate the effect of the defect or departure of the characteristics from the established limits obtained during previous verifications, and approve the procedure “Removal of nonconformities to specified requirements in verification” (5.9).

6.5.8 When practicable, all equipment under the control of the laboratory and requiring verification / calibration must be marked with labels, bar codes, or shall be identified in any other way to indicate its metrological status, including the date of the last metrological control, date or expiration criteria when the equipment has to be re-verified / calibrated.

Note. The term “identification” means marking that enable uniquely identifying an instance of the number of similar equipment.

6.5.9 In all cases, when, for whatever reasons, equipment goes outside the direct

control of the laboratory, the laboratory shall ensure the testing of function and status of the verification / calibration of equipment and demonstrate that they are satisfactory before the equipment is returned to service.

6.5.10 When to maintain the credibility to the status of the equipment the intermediate inspections are required, they shall be conducted in accordance with the established procedure.

6.5.11 In the case when the results of metrological control lead to the introduction of amendments, the laboratory shall have procedures to ensure the correct changes to the copies (e.g., to the software).

6.5.12 Measuring equipment, including both hardware and software shall be protected from adjustments that may lead to incorrect results of verification.

Adjustment devices shall be sealed or protected by other means, to prevent intervention by unauthorized personnel. Seals shall be designed so that the intervention will be immediately noticed. The software is to be protected at least at the level of access control using passwords.

6.6 Traceability of measurements

6.6.1 General provisions

All equipment used for verification including equipment for ancillary measurements (e.g., for environmental conditions) that significantly affect the accuracy or reliability of the results of verification shall pass metrological control prior to putting to the operation. The laboratory shall have the approved program and procedure for the metrological control of its equipment, also taking into account existing verification schemes.

Note. Such a program shall include a system for the selection, usage, verification / calibration / metrological certification, inspection, monitoring and maintenance of the measurement standards, reference materials used as measurement standards for verification.

6.6.2 Special requirements

6.6.2.1 Metrological control

6.6.2.1.1 The verification laboratory shall develop and implement the program of metrological control of equipment to ensure that the equipment is traceable to the measurement standards of the International System of Units (SI).

The verification laboratory establishes traceability of its measurement standards and measuring instruments to the measurement standards of SI units through an unbroken chain of verifications / calibrations or comparisons that link them with the relevant primary measurement standards of units of physical quantities of SI. The traceability to SI units can be achieved by reference to the national measurement standards. The national measurement standards can be primary measurement standards, which realize the primary reproductions of measurement units or are the consistent representations of SI units based on fundamental physical constants, or they can be secondary measurement standards which are standards being verified / calibrated by another national metrological institute. In case of verification / calibration provided by external organizations the traceability of measurement shall be ensured by means of services for verification / calibration, provided by those laboratories, which can demonstrate competence, the ability to perform measurements and to ensure traceability. Certificates of verification / calibration / metrological validation, issued by these laboratories, shall contain the measurement results, including the characteristics of the measurement accuracy and (or) statement of compliance with the specified metrological characteristics.

Note 1. The measurement standards of verification laboratories can pass any type of statutory metrological control (verification, calibration, metrological validation).

Note 2. The verification laboratories, meeting the requirements of this Recommendation are considered to be competent. The certificate of verification issued by the verification laboratory accredited in accordance with the requirements of this recommendation, on which stands the logo of the accreditation body of this laboratory is the sufficient proof of the traceability of verification results presented in the protocol.

Note 3. Traceability to the measurement standards of SI units can be achieved by the reference to the relevant primary measurement standard or to the natural constant, the value of which being expressed in terms of the relevant SI unit is known and recommended by General Conference on Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

The verification laboratories that have their own primary measurement standard or reproduction of SI units based on fundamental physical constants can declare the traceability only after the comparison of these measurement standards, directly or indirectly, with other similar measurement standards of the national metrological institute.

Note 4. The term "specified metrological characteristics" means that it shall be clear from the certificates of verification with what characteristics the comparison was held: these characteristics are inserted in the certificate of verification, or the unambiguous link shall be given to them.

Note 5. When the terms "International measurement standard" or "National measurement standard" are used in connection with traceability, it is assumed that these measurement standards fulfill the properties of primary measurement standards for the reproduction of SI units.

Note 6. It is non-obligatory that the traceability to national measurement standards requires the use of the measurement standards of the national metrological institute of the country where the laboratory is located.

Note 7. If the verification laboratory wishes or is required to receive the traceability to the measurement standards of the national metrological institute belonged not to its country, this laboratory shall select the national metrology institute that actively participates in the activities of BIPM either directly or through the regional groups.

Note 8. The unbroken chain of verifications / calibrations of comparisons can be achieved in the several steps carried out by different laboratories, which can demonstrate traceability.

6.6.3 Reference measurement standards and reference materials

6.6.3.1 Reference measurement standards

The laboratory shall develop the program and methods of metrological control of its reference measurement standards. Metrological control of the reference measurement standards shall conduct the body that can provide traceability as described in 6.6.2.1. Such reference measurement standards of the laboratory are to be used only for verification / calibration / metrological certification and for no other purpose, if it is impossible to demonstrate that their operation as reference measurement standards would be substantiated. The reference measurement standards shall pass metrological control before and after any adjustment.

6.6.3.3 Intermediate inspections

The inspections needed to maintain confidence in the metrological status of the reference, primary, comparison measurement standards or working measurement standards and reference materials shall be carried out in accordance with established procedures and schedules.

The condition of measurement standards shall be continuously analyzed to study the performance properties and to correct the verification / calibration intervals.

6.6.3.4 Transportation and storage

The laboratory shall have procedures for safe loading-unloading, transportation, storage and usage of reference measurement standards and reference materials to prevent contamination or deterioration of their properties and to maintain their integrity.

Note. The additional procedures may be required when reference measurement standards and reference materials are used for verification outside the permanent production areas of the laboratory.

6.7 Sampling

The laboratory shall have a plan and methods of sampling, when it performs sampling during the verification based on statistical sampling. Sampling plans, when appropriate, are based on appropriate statistical methods. Sampling process shall be characterized by parameters that are monitored to ensure the validity of verification results.

Note. The application of methods of verification of measuring instruments based on statistical sampling depends on the requirements of the legislation.

6.8 Loading-unloading and transportation of verifiable measuring instruments

6.8.1 The laboratory shall have procedures for the transportation, receipt, loading-unloading, protection, storage of verifiable measuring instruments, including all provisions necessary to protect their integrity to protect the interests of the laboratory or the customer.

6.8.2 The laboratory shall have the system of identification of measuring instruments taken for verification. Identification shall be retained for the time the verifiable MI is in the laboratory. This system shall be developed and used in such a way as to ensure that the MI can not be mixed up physically or when referred to in the accounts and records or other documents. If necessary, the system shall include a breakdown MI groups and their transfer to and from the laboratory.

6.8.3 When taking MI to verification, any deviations from normal or specified conditions are to be registered, as described in the relevant method of verification. If there is any doubt as to the suitability of MI for verification, or when the MI do not correspond to the description, or when the required verification can not be carried out without special equipment (e.g., programming devices, connecting cables, adapters, etc.) or preparatory work (e.g., cleaning, transportation, etc.), the laboratory before continuing the work shall apply to the customer for the additional instructions and document the discussion of this issue.

6.8.4 The laboratory shall have procedures and appropriate means for the prevention of deterioration, loss or damage of verifiable measuring instrument during storage, loading-unloading and preparation operations. The instructions for loading and unloading operations supplied together with the verifiable MI shall be followed. When the MI shall be stored or maintained in a certain condition at the given environmental conditions, these conditions shall be maintained, controlled and registered.

When the verifiable MI or its part shall be adequately protected or stored in a safe place, the laboratory shall take measures for the storage and protection that protect the condition and integrity of stored MI or their parts.

Note 1. The persons responsible for the transportation of MI to the verification, shall be provided with the methods for storage and transportation of these means.

Note 2. The verifiable MI can be adequately protected or stored in a safe place in order to ensure registration, safety, value or for the later possibility to carry out additional verification.

6.9 Quality provision of the results of verification

6.9.1 Laboratory shall have quality control procedures to perform the current control (monitoring) of correctness of carried out verification. The resulting data shall be recorded so that it will be possible to detect trends in their changes and, where feasible, the statistical methods to analyze the results shall be applied. The plan of the current control

(monitoring) shall be made, it shall be analyzed, and it can include at least the following activities:

a) regular usage of the reference materials and (or) internal quality control using secondary measurement standards;

b) participation in programs of interlaboratory comparisons or laboratory inspections on the quality of the verifications;

c) recalibrations;

d) regular monitoring of the condition of measurement standards including the correction of the verification / calibration intervals.

Note. The selected methods shall correspond to the type and volume of work performed.

6.9.2 Quality control data shall be analyzed and, if found that they go beyond the established criteria, the planned corrective actions shall be to taken to remove the problem and to prevent the inclusion of incorrect results in reporting documentation.

6.10 Presentation of the results of verification

6.10.1 General provisions

The provided results of each verification carried out by the laboratory shall be accurate, clear, unambiguous and objective and shall be registered in accordance with special instructions of methods of verification in the form of verification protocols and certificate of verification.

Those results of verification shall be set out to the customer (usually in the certificate of verification), that are needed for the interpretation of results of verification, and the link to the used method of verification. Usually this is the information that is specified in 6.10.2, 6.10.3 and 6.10.4.

In the case of the verification carried out for internal customers or primary verification during production output, the certificate of verification can be replaced by a record of compliance of verifiable MI to the operational documents.

Any information listed in 6.10.2 - 6.10.3 and is not presented to the customer, shall be readily available in the laboratory that conducted the verification.

6.10.2 Certificate of verification

The certificate of MI verification shall contain the following information:

- the title of the document (Certificate of verification);
- name of the laboratory where the verification was carried out;
- name, address, phone number and location of the laboratory and the place of verification, if the address is different from the address of the laboratory;
- the number of the certificate, which shall be listed on each page and a clear identification of the end of the certificate of verification;
- name (type) of MI, its characteristics,
- description and unambiguous identification of verifiable MI;
- the date (start-end) of the verification and, if necessary, the date and time of receipt of the object;
- type, number of the measurement standards used in the verification and, if necessary, their characteristics, the provement of traceability of measurements;
- the name and indexing of documents on the base of which the verification is carried out;
- information related to the specificity of the verification (for example, environmental conditions, etc.);

− uncertainty evaluation of results of the verification (in the presence of respective requirement from the customer);

− the date of next verification for the MI that are used in the field of legal metrology;

− signature and title (or an appropriate identification) of the person responsible for the drawing up and content of the certificate and protocol, the date of its issue.

Note 1. The hard (documentary) copies of certificates of verification shall also include the page numbers and total number of pages.

Note 2. The laboratories are recommended to submit an application about that the certificate of verification is reproduced only in its entirety and with the written approval of the laboratory.

6.10.3 The protocol of verification shall contain the information specified on its basis in the certificate of verification, as well as visual inspection of MI, its testing and performed experimental studies. If during the verification the parameters of the verifiable MI have been changed, for example, bringing the current settings of MI to the standard ones, then this information shall be recorded in the protocol.

6.10.4 Verification results obtained from subcontractors

If the certificate of verification or the protocol contains the measurement results obtained from subcontractors, these results shall be clearly identified. The subcontractor shall submit the report on the results of performed work in writing or by electronic means to the laboratory-employer.

6.10.5 Transfer of the results by electronic means

In case of transfer of verification results by fax or by other electronic means the requirements of this recommendation (6.4.7) shall be fulfilled.

6.10.6 Form of the certificates

The form shall be created in such a way to be suitable for all types of verifications carried out and to minimize the possibility of its misunderstanding or misuse.

Note. The certificate of verification shall be drawn up in accordance with national or regional requirements to its form so that the data on the results of verification presented in them were understandable to the user.

6.10.7 Changes to the certificate of verification

The significant changes to the certificate of verification after its issue shall be made only in the form of additional document or transmitted data and include a statement of:

“Supplement to the certificate of verification, number ... (or other identification)” or an equivalent form of expression.

Such changes shall meet all requirements of this recommendation.

When it is necessary to issue the completely new certificate of verification, it shall be uniquely identified and shall contain a reference to the original that it replaces.