


GUIDELINES FOR SAMPLING ACTIVITIES ACCREDITATION

	Full name	Position	Date	Signature
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1. SUBJECT AND SCOPE OF APPLICATION

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This guideline further explains the requirements of the standard MEST EN ISO/IEC 17025:2018, as well as the requirements of the standard MEST EN ISO/IEC 17020:2013, regarding the accreditation of sampling as an independent activity or as an activity related to testing or calibration that follows.

2. ABBREVIATIONS AND DEFINITIONS

2.1 ABBREVIATIONS

MEST – Montenegrin Standard

EN – European Standard

ISO/IEC – International Organization for Standardization / International Electrotechnical Commission

2.2 DEFINITIONS

Accreditation – Assessment of conformity assessment bodies conducted by a third party (accreditation body) to officially confirm their competence to perform specific conformity assessment tasks.

Laboratory – A body that performs one or more of the following activities: testing; calibration; sampling related to testing or calibration that follows.

Inspection Body – A body that performs inspection (examining products, processes, services, or installations, or their design, and determining their conformity with specific requirements and general requirements based on professional judgment).

3. RELATIONSHIP WITH OTHER DOCUMENTS

MEST EN ISO/IEC 17025:2018 – General requirements for the competence of testing and calibration laboratories.


MEST EN ISO/IEC 17020:2013 – Conformity assessment - Requirements for the operation of various types of bodies performing inspection.

PA.01 – Accreditation Rules.

PA.02-1 – Rules for the use of the ATCG logo, accreditation mark, and reference to accreditation

4. ACCREDITATION OF SAMPLING ACTIVITIES

ATCG accredits testing laboratories that perform sampling as an independent activity, or in connection with testing that follows, according to the reference standard MEST EN ISO/IEC 17025. Inspection bodies according to MEST ISO/IEC 17020 may be accredited to perform sampling as an independent activity, provided they meet the relevant requirements of the MEST

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EN ISO/IEC 17025 standard. Sampling activities can be part of inspection activities in accordance with the requirements of prescribed or other established inspection schemes, and in such cases, accreditation of inspection bodies for performing sampling as part of an inspection scheme is possible, according to the reference standard MEST ISO/IEC 17020. In this case, the inspection body must also fulfill and be evaluated according to all relevant requirements of the MEST ISO/IEC 17025 standard for the sampling activities.

4.1 Requirements for Laboratories / Inspection Bodies Regarding Sampling

The accreditation body carries out the accreditation process for conformity assessment bodies, including laboratories and inspection bodies, in accordance with the relevant harmonized accreditation standards and related accreditation rules (e.g., PA.01). The following text provides an explanation of the requirements of the MEST EN ISO/IEC 17025:2018 standard, as well as the requirements of the MEST EN ISO/IEC 17020:2013 standard, regarding the accreditation of sampling as an independent activity or as an activity related to testing or calibration that follows (hereinafter referred to as: sampling).

4.1.1 Requirements for Impartiality, Confidentiality, and Structure

The laboratory/inspection body performing sampling must fully meet the general requirements for impartiality and confidentiality (as outlined in sections 4.1 and 4.2) and the requirements for structure (as outlined in section 5) of the MEST EN ISO/IEC 17025:2018 standard, as well as the requirements of section 4 (requirements for inspection body type A) and the requirements of section 5 of the MEST EN ISO/IEC 17020:2013 standard.

4.1.2 Requirements for Management System


The laboratory/inspection body performing sampling must fully meet the management system requirements specified in section 8 of the MEST EN ISO/IEC 17025:2018 standard, as well as the requirements of section 8 of the MEST EN ISO/IEC 17020:2013 standard.

The laboratory/inspection body must define its sampling policy and clearly identify the scope of its sampling activities.

Special attention should be given to the mutual influence between the sampling activities and the actual testing and/or inspection.

4.1.3 Personnel

A laboratory/inspection body performing sampling must fully meet the personnel requirements outlined in section 6.2 of the MEST EN ISO/IEC 17025:2018 standard, as applicable to sampling activities, and the requirements of section 6.1 of the MEST EN ISO/IEC 17020:2013 standard.

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The laboratory/inspection body must ensure a sufficient number of competent personnel to carry out the sampling, including personnel responsible for developing the sampling plan and providing appropriate supervision/control over the sampling process.

The laboratory/inspection body must ensure that all personnel involved in sampling activities have adequate qualifications, are trained, and technically competent, including knowledge of statistical techniques, if relevant to the sampling in question. The laboratory/inspection body must have documented procedures for training and authorization to ensure that only authorized and competent personnel perform sampling and related activities.

Personnel authorized to review sampling requirements, reporting, reviewing, and approving results must demonstrate relevant knowledge of sampling activities as well as the subsequent activities (testing/inspection).

Personnel responsible for coordinating and performing sampling must possess the appropriate applicable knowledge about the subjects being sampled, as well as the processes and systems involved. This is necessary to determine the adequacy of the sampling locations and times, and the potential impact of the conditions under which sampling takes place on the adequacy of the sample.

The laboratory/inspection body must maintain up-to-date records on the competence of personnel involved in sampling activities.


4.1.4 Facilities, Environmental Conditions, Equipment, Metrological Traceability

The laboratory/inspection body performing sampling must fully meet the requirements related to facilities and environmental conditions outlined in section 6.3, equipment requirements outlined in section 6.4, and metrological traceability requirements outlined in section 6.5 of the MEST EN ISO/IEC 17025:2018 standard.

The laboratory/inspection body must have appropriate procedures in place for monitoring environmental conditions when these could negatively impact the sampling process or the characteristics of the equipment used for sampling.

All equipment used for sampling must be properly checked, both before and after the sampling process, to ensure that the equipment is in proper working condition and that its calibration status has not changed, where applicable.

The laboratory/inspection body performing sampling must implement special measures, where necessary, to ensure the sterility and inertness of materials for subsequent testing/inspection activities. It is essential to prevent contamination and absorption of materials, as these could have a potential impact on the properties of the sampled items.

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4.1.5 Externally Procured Products and Services

The laboratory/inspection body performing sampling must fully meet the requirements related to externally procured products and services as outlined in section 6.6 of the MEST EN ISO/IEC 17025:2018 standard and section 6.2.11 of the MEST EN ISO/IEC 17020:2013 standard. The laboratory/inspection body must define the products and services that impact the sampling activities.

4.1.6 Review of Requirements, Offers, and Contracts

The laboratory/inspection body performing sampling must fully meet the requirements outlined in section 7.1 of the MEST EN ISO/IEC 17025:2018 standard, which pertains to the review of requirements, offers, and contracts, and section 7.1.5 of the MEST EN ISO/IEC 17020:2013 standard.

Through the review of requirements, offers, and contracts, the laboratory/inspection body determines whether it has the capability and resources to perform sampling in accordance with the sampling method.

The laboratory/inspection body must ensure that the selected sampling method is suitable to meet all requirements for the relevant testing and/or inspection during the review of requirements, offers, and contracts. Each sampling procedure must be carried out in accordance with a pre-defined sampling plan, which clearly specifies the conditions under which it is conducted and the extent to which deviations from the plan are allowed during sampling.


Accompanying documentation that confirms the existence of an agreement between the laboratory/inspection body and the client regarding the requirements related to sampling must be available.

The agreement between the client and the laboratory/inspection body must clearly confirm whether the sampling is being performed as an independent activity or for testing or inspection purposes that follow. The activities for which the laboratory/inspection body is responsible must be clearly specified (e.g., sample transportation, sample storage conditions until collection, etc.).

4.1.7 Sampling Methods

The laboratory/inspection body performing sampling must fully meet the requirements outlined in sections 7.2 and 7.3 of the MEST EN ISO/IEC 17025:2018 standard, and section 7.1 of the MEST EN ISO/IEC 17020:2013 standard, regarding sampling methods.

The sampling procedure requires clearly defined methods that align with the purpose of the testing or inspection that will follow.

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A sampling method should generally include:

- a) The method for selecting samples or sampling locations;
- b) The sampling plan and protocol;
- c) The preparation and treatment of the samples taken from substances, materials, or products for the purpose of testing or inspection that follows.

The laboratory/inspection body must verify or validate the sampling methods to the extent necessary to demonstrate compliance with the acceptable criteria outlined in the sampling method. This validation ensures that the methods are suitable for the intended purpose.

The sampling plan and protocol must identify risks and critical factors that could influence the sampling process. These may include:


Random errors contributing to result heterogeneity,
 Systematic errors during the execution of the sampling plan,
 Possible contamination during sampling,
 The impact of interfering factors,
 Traceability of sample identity throughout the sampling process, etc.
 The sampling plan must include at least the following elements:

The purpose of sampling;

- User requirements;
- Sampling location selection;
- Sampling equipment and, where relevant, sample packaging;
- Timing and frequency of sampling;
- Record of the sample type, on-site measurements, environmental conditions, sample size, storage conditions, preservation, homogeneity, suitability of the sample, and any other relevant data.

If, at any stage, there is doubt that the sampling procedure deviates from the sampling plan and protocol, and this could affect the validity of the testing/inspection results, the laboratory/inspection body must immediately inform the client and notify them of any potential impact on the test/inspection results. Examples of deviations from the sampling protocol may include inadequate sample storage, exceeding the maximum allowed storage time, lack of information on the date and time of sampling, contamination during sampling, etc.

In special cases, the client may request that samples with deviations from the sampling procedure still be tested/inspected. In such cases, the laboratory/inspection body must clearly state in the test/inspection report that there was a deviation from the sampling procedure and that the results may be considered inadequate.

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The laboratory/inspection body must ensure that the sample, taken according to the plan and protocol, is representative and reflects the properties required for that sample. The sampling method must be compatible with the testing methods/inspection procedures that follow.

4.1.8 Sample Handling

The laboratory/inspection body performing sampling must fully comply with the requirements outlined in section 7.4 of MEST EN ISO/IEC 17025:2018, regarding sample handling, and section 7.2 of MEST EN ISO/IEC 17020:2013.

4.1.9 Technical Records

The laboratory/inspection body performing sampling must fully comply with the requirements outlined in section 7.5 of MEST EN ISO/IEC 17025:2018, and section 7.3 of MEST EN ISO/IEC 17020:2013, regarding technical records of sampling.

4.1.10 Evaluation of Measurement Uncertainty

The laboratory/inspection body performing sampling must fully comply with the requirements outlined in section 7.6 of MEST EN ISO/IEC 17025:2018, which relate to the evaluation of measurement uncertainty.


The laboratory/inspection body must identify the contributions to measurement uncertainty that originate from the sampling process. When evaluating measurement uncertainty, all significant contributions must be considered using appropriate analysis methods.

4.1.11 Ensuring the Validity of Sampling

Laboratory/inspection bodies performing sampling must fully comply with the requirements outlined in section 7.7 of MEST EN ISO/IEC 17025:2018, which relates to ensuring the validity of sampling results.

The laboratory/inspection body must have appropriate procedures in place to ensure the validity of sampling. These procedures should include, at a minimum, the following:

- Identification of Critical Stages in the Sampling Process: The laboratory/inspection body must identify the critical phases in the sampling process to ensure compliance with the relevant sampling methods. These critical stages represent key steps in the sampling methodology (e.g., necessary criteria for accepting or rejecting a sample).
- Verification of Sampling Records: There should be a method for verifying the sampling records before they are approved by authorized personnel. This process ensures that sampling has been carried out according to the established sampling plan and protocol.

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- Independent Control Program: The laboratory/inspection body must establish a program for independent control of all results arising from sampling activities. This control should cover all relevant data to ensure that sampling activities and requirements are met. This may include reviewing specific sampling techniques to ensure equivalence in the performance of sampling personnel (samplers) through on-site validation of sampling techniques.
- Functional Verification and Calibration of Sampling Equipment: The laboratory/inspection body must have procedures in place to verify the functionality and conduct intermediate checks of sampling equipment to ensure it operates as required.
- Ongoing Monitoring and Review of Sampling Plans and Protocols: There should be continuous monitoring and review of sampling plans and protocols to ensure their alignment with the applicable sampling methods. This ensures that the sampling procedures remain valid and fit for purpose over time.
- Oversight of Sampling Activities: Oversight must be provided by personnel authorized for the relevant sampling methods, who are aware of the goals of the sampling. This oversight must be conducted systematically and in a planned manner. Among other things, it should include verifying that the procedure is being followed according to the sampling plan, documenting, and reporting any deviations if they are identified.

4.1.12 Reporting


Laboratory/inspection bodies performing sampling must fully comply with the requirements outlined in section 7.8 of MEST EN ISO/IEC 17025:2018, as applicable to sampling activities, and section 7.4 of MEST EN ISO/IEC 17020:2013.

If the conformity assessment activity consists of sampling and testing, a Testing Report must be issued that includes all relevant details regarding the sampling, as required by section 7.8 of MEST EN ISO/IEC 17025:2018.

If the conformity assessment activity consists of sampling and inspection, an Inspection Report must be issued that includes all relevant details regarding the sampling process.

4.1.13 Use of the Accreditation Symbol

Laboratory/inspection bodies accredited for sampling activities must use the accreditation symbol in accordance with the *PA.02-1 Rules for the Use of the ATCG Logo, the Accreditation Mark, and Reference to Accreditation*.

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4.1.14 Complaints and Non-Conforming Work

The laboratory/inspection body performing sampling must fully comply with the requirements related to complaints and non-conformities as specified in clauses 7.9 and 7.10 of the MEST EN ISO/IEC 17025:2018 standard, as well as the requirements for complaints outlined in clause 7.5 of the MEST EN ISO/IEC 17020:2013 standard.

4.1.15 Data Management and Information Management

The laboratory/inspection body performing sampling must fully comply with the requirements for data management and information management specified in clause 7.11 of the MEST EN ISO/IEC 17025:2018 standard, and clauses 7.1.7 and 7.1.8 of the MEST EN ISO/IEC 17020:2013 standard.

5. FORMS

This instruction does not have accompanying forms.