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ISO / IEC 17025
2017 vs 2005 edition

General requirements for the competence of testing and calibration laboratories

EPPO Training Workshop

on ISO Standard 17025 (2017) and PM 7/98 (4)

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Laboratory accreditation

- Widely accepted process of evaluation of a **laboratory's** quality, performance, reliability and efficiency
- Means to promote and enforce better quality in **laboratory** testing and to ultimately reduce testing errors

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Laboratory accreditation

- Previous Standard
  - **EN ISO/IEC 17025:2005 (second edition)**
- New revised standard
  - **EN ISO/IEC 17025:2017 (third edition)**

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Objectives of revision

- Align structure and content with other recently revised ISO standards
  - CASCO QS-CAS-PROC/33, Common elements in ISO/CASCO Standards
  - Other CASCO toolbox standards
  - ISO 9001:2015
- Focus on outcomes rather than prescriptive requirements
- Update language to reflect current practices and technologies
- Retain language from 2005 version whenever possible

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Main changes

ISO/IEC 17025:2005

- 1. Scope
- 2. Normative references
- 3. Terms and definitions
- 4. Management requirements
- 5. Technical requirements
- Annex A Nominal cross references to ISO 9001: 2000
- Annex B Guidelines for establishing interpretative notes for specific domains

ISO/IEC 17025:2017

- 1. Scope
- 2. Normative references
- 3. Terms and definitions
- 4. General requirements
- 5. Structural requirements
- 6. Resource requirements
- 7. Process requirements
- 8. Management requirements
- Annex A Metrological traceability
- Annex B Management system

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Main changes

- From the Foreword of ISO/IEC 17025:2017
  - The risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements
  - There is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities
  - A definition of “laboratory” has been added

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Main changes

- Scope of the standard: laboratory activities
  - Testing, calibration, sampling associated with subsequent testing
- Defined range of activities for laboratory
  - Excludes externally provided laboratory activities on an ongoing basis
- Emphasis on “Impartiality” vs. “Independence”
- Process orientation
- Information Technology: Risks, data integrity, confidentiality, validation of software, considering electronic documents
- Metrological traceability
- Decision Rules for statements of conformity (pass/fail)

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ISO / IEC 17025:2017 Scope

- Specifies the general requirements for the competence, impartiality and consistent operation of laboratories
- Is applicable to all organizations performing laboratory activities, regardless of the number of personnel
- Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories

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ISO / IEC 17025:2017

3 Terms and definitions

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ISO / IEC 17025:2017 Terms and definitions

- **3.1 Impartiality**
- Presence of objectivity
  - Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory (3.6)
  - Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”

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ISO / IEC 17025:2017 Terms and definitions

- **3.4 Intralaboratory comparison**
  - Organization, performance and evaluation of measurements or tests on the same or similar items, within the same laboratory (3.6), in accordance with predetermined conditions
  - [New, based on ISO/IEC 17043:2010 definition for “interlaboratory comparison”, which is included as 3.3 in ISO/IEC 17025:2017]

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ISO / IEC 17025:2017 Terms and definitions

- **3.5 Proficiency testing**
  - Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (3.3)
  - [SOURCE: ISO/IEC 17043:2010, 3.7, modified — Notes to entry have been deleted.]

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ISO / IEC 17025:2017 Terms and definitions

- **3.6 Laboratory**
  - Body that performs one or more of the following activities:
    - Testing;
    - Calibration;
    - Sampling, associated with subsequent testing or calibration
  - Note 1 to entry: In the context of this document, “laboratory activities” refer to the three above-mentioned activities.

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ISO / IEC 17025:2017 Terms and definitions

- **3.7 Decision rule**
  - Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

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ISO / IEC 17025:2017

4 General requirements

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ISO / IEC 17025:2017 General requirements

- **4.1 Impartiality**
  - Language taken from CASCO Procedure document (consistent with other conformity assessment standards)
  - New/changed requirements:
    - Identifying risks to impartiality on an on-going basis
    - Addressing risks to impartiality

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ISO / IEC 17025:2017 General requirements

- **4.2 Confidentiality**
  - Language taken from CASCO Procedure document (consistent with other conformity assessment standards)
  - New/changed requirements:
    - Stronger emphasis on customer awareness
    - More detail regarding specific cases where confidentiality could be affected

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ISO / IEC 17025:2017

5 Structural requirements

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ISO / IEC 17025:2017 Structural requirements

- Removed terms "technical management" and "quality manager"
    - Retained same essential functions
- Introduced requirement for laboratory to identify range of laboratory activities for which it conforms with ISO/IEC 17025
- Restricts claims of conformity to the defined range
- Excludes externally provided laboratory activities on an on-going basis

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ISO / IEC 17025:2017 Structural requirements

- 5.5 c) requires laboratory to "document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results"
  - Revised standard consistently uses term "procedure" when the intent is for laboratory to maintain documentation
  - The extend of detail in that documentation is up to the laboratory, subject to the conditions in 5.5 c)

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ISO / IEC 17025:2017

5 Resource requirements

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ISO / IEC 17025:2017 Resourse requirements

- **6.1 General**
- "The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to perform its laboratory activities"
  - Use of the term "available" indicates an approach in the revision to focus less on the status or ownership of resources and more on the relevant requirements for those resources
  - Examples:
    - 6.2.1 refers to all personnel, internal or external [vs. 2005 version requiring personnel be employed by or under contract]
    - 6.4.1 requires laboratory to have access to equipment
    - [vs. 2005 version requiring laboratory be furnished with all items]

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ISO / IEC 17025:2017 Resourse requirements

- **6.2 Personnel**
  - Terminology and requirements have been updated and reorganized in the revision
  - Otherwise, no significant changes to this clause compared to the 2005 version

ISO / IEC 17025:2017 Resourse requirements

- **6.2 Personnel**
  - Personnel shall act impartially, be competent and work in accordance with Management System
  - Document the competence requirements for education, qualification, training, technical knowledge, skills and experience
  - Communicate to personnel their duties, responsibilities and authorities
  - The laboratory shall have **procedure**(s) and retain records for:
    - a) determining the competence requirements
    - b) selection of personnel
    - c) training of personnel
    - d) supervision of personnel
    - e) authorization of personnel
    - f) monitoring competence of personnel
  - The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:
    - a) development, modification, verification and validation of methods
    - b) analysis of results, including statements of conformity or opinions and interpretations
    - c) report, review and authorization of results

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ISO / IEC 17025:2017 Resourse requirements

- **6.3 Facilities and environmental conditions**
  - Terminology and requirements have been updated and reorganized in the revision
  - Otherwise, no significant changes to this clause compared to the 2005 version

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ISO / IEC 17025:2017 Resourse requirements

- **6.4 Equipment**
  - The laboratory shall **have access** to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results
  - Description of items considered as equipment is more inclusive than in 2005 version
  - Notes provide more information regarding reference materials

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ISO / IEC 17025:2017 Resourse requirements

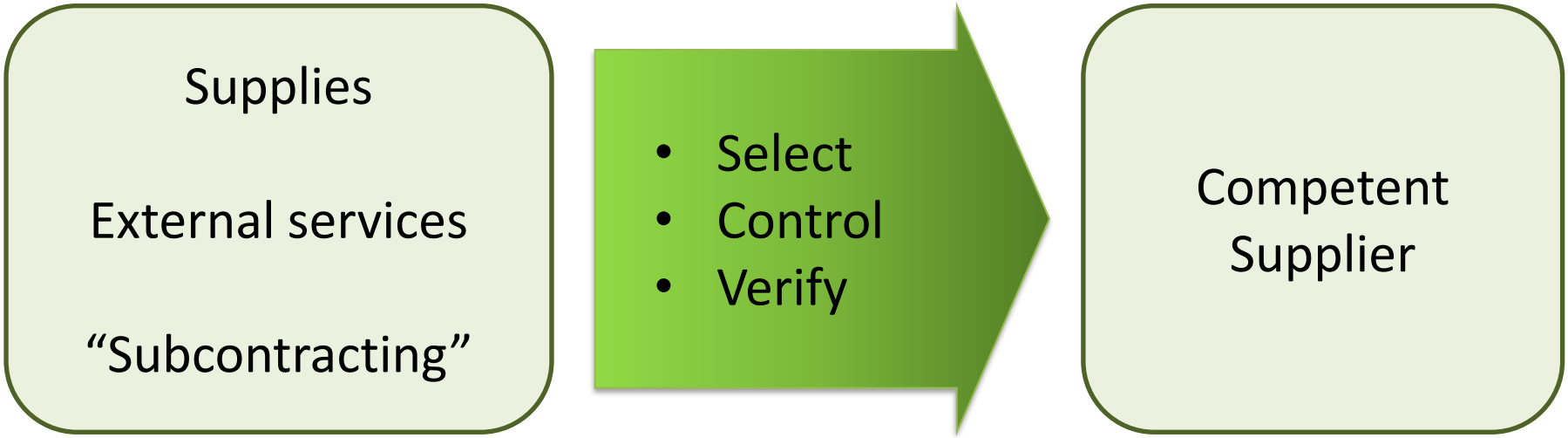
- **6.4 Equipment**
  - 6.4.6 identifies two criteria that determine when calibration of equipment is requirement
  - the measurement accuracy or measurement uncertainty affects the validity of the reported results, or
  - calibration of the equipment is required to establish the metrological traceability of the reported result
  - These criteria apply for all laboratory activities
    [2005 version had different requirements for calibration and testing]
  - Metrological traceability addressed in a separate clause (6.5)
    [2005 version included calibration in the traceability clause]

ISO / IEC 17025:2017 Resourse requirements

- **6.5 Metrological traceability**
  - Terminology and requirements have been updated in the revision to reflect current practice in traceability
  - Reduced the number of Notes compared to 2005 version
  - Additional explanatory information included in Annex A

ISO / IEC 17025:2017 Resourse requirements

- **6.6 Externally provided products and services**
  - Combines 4.5 Subcontracting and 4.6 Purchasing services and supplies from 2005 version
  - In all cases, have requirements and controls
  - Focuses on communication with customer



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ISO / IEC 17025:2017

7 Process requirements

ISO / IEC 17025:2017 Process requirements

- **7.1 Review of requests, tenders and contracts**
  - New/updated requirements
  - 7.1.3 requires statements of conformity and associated decision rules be addressed during contract review
  - 7.1.4 states that deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results

ISO / IEC 17025:2017 Process requirements

- **7.2 Selection, verification and validation of methods**
  - Terminology and organization of clause updated from 2005 version
  - Note after 7.2.1.1 clarifies that “method” as used in this document can be considered synonymous with the term “measurement procedure” as defined in ISO/IEC Guide 99

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ISO / IEC 17025:2017 Process requirements

- **7.3 Sampling**
  - Definition of laboratory (3.6) clarifies that the sampling activity is associated with subsequent testing or calibration
  - Otherwise, no significant changes to this clause compared to the 2005 version

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ISO / IEC 17025:2017 Process requirements

- **7.4 Handling of test or calibration items**
  - 7.4.3 includes a new requirement:
  - "When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation"
  - Otherwise, no significant changes to this clause compared to the 2005 version

ISO / IEC 17025:2017 Process requirements

- **7.5 Technical records**
  - Technical records placed in this clause as process requirements
  - Other types of records (e.g., management system records) addressed in Clause 8
  - Otherwise, no significant changes to this clause compared to the 2005 version

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ISO / IEC 17025:2017 Process requirements

- **7.6 Evaluation of measurement uncertainty**
  - 7.6.1 requires all laboratories to identify contributions to measurement uncertainty
  - 7.6.2 requires evaluation of measurement uncertainty for all calibrations, including those a laboratory performs on its own equipment (i.e. “in-house” calibrations)
  - 7.6.3 includes essentially the same requirements for evaluation of uncertainty for testing as the 2005 version
  - Note 2 applies to all laboratories, and clarifies that a laboratory is not required to calculate a unique uncertainty every time a test or calibration is performed provided the stated conditions are met

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ISO / IEC 17025:2017 Process requirements

- **7.7 Ensuring the validity of results**
  - Clause separates requirements for monitoring done within the laboratory (7.7.1) and those involving comparison with other laboratories (7.7.2)
  - Data from internal activities (7.7.1) required to be recorded such that trends can be detected and, where practicable, statistical techniques applied
  - Both required to be planned and reviewed, analyzed, used to control and (if applicable) improve laboratory activities
  - Action required when results of analysis of data found to be outside pre-defined criteria

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ISO / IEC 17025:2017 Process requirements

- **7.8 Reporting of results**
  - Language reflects current approaches to reporting
  - New/updated requirements
    - 7.8.2.2 addresses data provided by a customer, including a disclaimer when those data can affect validity of results
    - 7.8.5 reporting sampling
    - 7.8.6 reporting statements of conformity
      - Include decision rule

ISO / IEC 17025:2017 Process requirements

- **7.9 Complaints**
  - Language taken from CASCO Procedure document (consistent with other conformity assessment standards)
  - New/updated requirements
  - 7.9.2 requires a description of the complaints handling process be available to any interested party upon request
  - 7.9.6 requires the outcomes to be communicated to the complainant be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question

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ISO / IEC 17025:2017 Process requirements

- ## 7.10 Nonconforming work
  - No significant changes to this clause compared to the 2005 version
    - Procedure to be implemented when activities or results do not conform to its own procedures or the agreed requirements of the customer. The procedure shall ensure that:
      - » Responsibilities and authorities are defined
      - » Actions are based upon the risk levels established by the laboratory
      - » Evaluation of the significance of the nonconforming work, including an impact analysis on previous results
      - » Decision on the acceptability of the nonconforming work
      - » Where necessary, the customer is notified and work is recalled
      - » The responsibility for authorizing the resumption of work is defined
    - The laboratory shall retain records of nonconforming work and actions
    - If the nonconforming work could recur, the laboratory shall implement corrective action

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ISO / IEC 17025:2017 Process requirements

- **7.11 Control of data and information management**
  - Extends and updates 5.4.7 in the 2005 version to address current laboratory practice
  - 7.11.2 Note 1 clarifies that use of the term "laboratory information management system(s)" in this document includes both computerized and non-computerized systems
  - 7.11.4 requires laboratory to ensure that off-site or external providers of information management comply with applicable requirements of ISO/IEC 17025

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ISO / IEC 17025:2017

8 Management system requirements

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ISO / IEC 17025:2017

Management system requirements

- **8.1 Options**
  - The revision now provides two distinct options (A or B) for establishing a management system
    - Option A: As a minimum the management system of the laboratory shall address the requirements in clauses 8.2 to 8.9
    - Option B: Establish and maintain a management system in accordance with the requirements of ISO 9001
  - Both options require that the management system is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025 clauses 4 to 7 and assuring the quality of the laboratory results
  - Laboratories need only conform to one of the options (not both)

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ISO / IEC 17025:2017

Management system requirements

- **8.1 Options**
  - 8.1.2 Option A
  - As a minimum the management system of the laboratory shall address the following:

Similar to 2005 version

- management system documentation (see 8.2)
- control of management system documents (see 8.3)
- control of records (see 8.4)

Aligned with ISO 9001:2015

- actions to address risks and opportunities (see 8.5) NEW
- improvement (see 8.6)
- corrective action (see 8.7)
- internal audits (see 8.8)
- management review (see 8.9)

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ISO / IEC 17025:2017

Management system requirements

- **8.2 Management system documentation (Option A)**
  - Laboratory management shall establish, document, and maintain policies and objectives
  - Policies and objectives shall address the competence, impartiality and consistent operation

ISO / IEC 17025:2017

Management system requirements

- **8.3 Control of management system documents (Option A)**
  - The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document
    - Documents approved prior to issue by authorized personnel
    - Documents are periodically reviewed, and updated
    - Changes and the current revision status are identified
    - Relevant versions of documents are available at points of use
    - Documents are uniquely identified
    - Unintended use of obsolete documents is prevented

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ISO / IEC 17025:2017

Management system requirements

- **8.4 Control of records (Option A)**
  - Establish and retain legible records to demonstrate fulfilment of the requirements
  - Implement the controls for identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of records
  - Retain records for a period consistent with its contractual obligations

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ISO / IEC 17025:2017

Management system requirements

- **8.5 Actions to address risks and opportunities (Option A)**
  - Revision incorporates "risk-based thinking"
  - Introduction and Note after 8.5.2 include two important points:
    - There is no requirement for formal methods for risk management or a documented risk management process
    - The laboratory is responsible for deciding which risks and opportunities need to be addressed

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Management system requirements

- **8.6 Improvement (Option A)**
  - Identify and select opportunities for improvement and implement necessary actions
  - Seek feedback from its customers
  - Use feedback analysis to improve the management system

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ISO / IEC 17025:2017

Management system requirements

- **8.7 Corrective actions (Option A)**
  - React to the nonconformity
    - Take action to control and correct it
    - Address the consequences
  - Evaluate the need for action to eliminate the cause of the nonconformity
    - Reviewing and analyzing the nonconformity
    - Determining the causes of the nonconformity
    - Determining if similar nonconformities exist, or could potentially occur
  - Implement any action needed
  - Review the effectiveness of any corrective action taken
  - Update risks and opportunities determined during planning, if necessary
  - Make changes to the management system, if necessary

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ISO / IEC 17025:2017

Management system requirements

- **8.8 Internal audits (Option A)**
  - Conduct internal audits at planned intervals
    - plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits
    - Define audit criteria and scope
    - Ensure the results of the audits are reported to management
    - Implement appropriate correction and corrective actions
    - Retain records as evidence of the implementation of the audit programme and the audit results

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Management system requirements

- **8.9 Management reviews (Option A)**
  - Review management system at planned intervals
    - Inputs to management review
      - changes in internal and external issues that are relevant to the laboratory
      - fulfilment of objectives
      - suitability of policies and procedures
      - status of actions from previous management reviews
      - outcome of recent internal audits
      - corrective actions
      - assessments by external bodies
      - changes in the volume and type of the work or in the range of laboratory activities
      - customer and personnel feedback
      - complaints
      - effectiveness of any implemented improvements
      - adequacy of resources
      - results of risk identification
      - outcomes of the assurance of the validity of results
      - other relevant factors, such as monitoring activities and training
    - Outputs from the management review
      - the effectiveness of the management system and its processes
      - improvement of the laboratory activities
      - provision of required resources
      - any need for change

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Thank you !

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Mod. CI-005/1 (04.2020)