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Laboratory accreditation

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ISO 17025 for Laboratory Accreditation

- ISO 17025 Certification ISO/IEC 17025 is the global quality standard for testing and calibration laboratories. It is the basis for accreditation from an accreditation body.
- There are two main clauses in ISO 17025 – Management Requirements and Technical Requirements. Management requirements are related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements address the competence of staff; testing methodology; equipment and quality; and reporting of test and calibration results.

ISO 17025 for Laboratory Accreditation

- Accreditation is an objective way to assure that you have demonstrated technical competence to provide reliable and accurate test results.
- Accreditation is objective because an independent, third party accreditation body performs annual assessments to verify whether your system is meeting all of the requirements of ISO/IEC 17025. This independent evaluation is important, because it is an unbiased guarantee that your laboratory is performing at its highest level.

ISO 17025 for Laboratory Accreditation

- The accreditation body is responsible for assessing the quality system and technical aspects of your system to determine your compliance to the requirements of ISO/IEC 17025. It is the accreditation body that ultimately decides whether or not a laboratory is complying with the standard.

ISO 17025 for Laboratory Accreditation

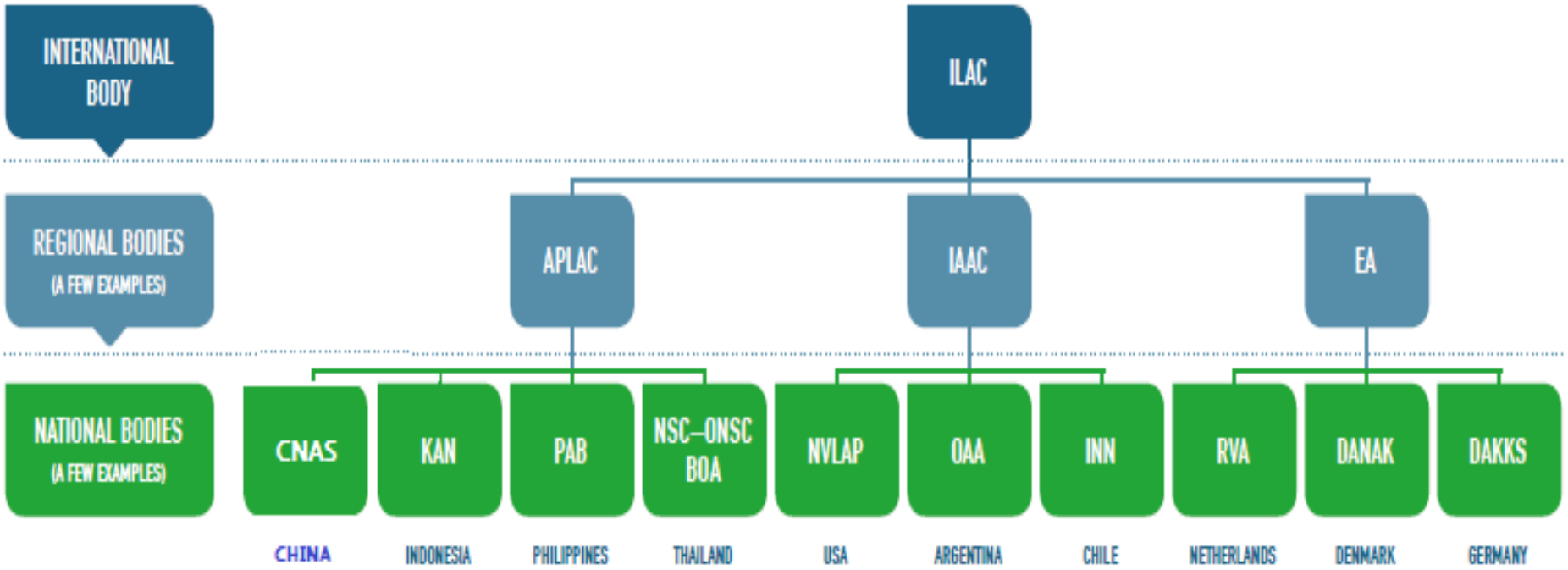
- Time require achieving ISO 17025 Accreditation Typically, it takes a laboratory six months to one year to prepare for the accreditation assessment. The assessment itself, from the day of closure of any applicable non conformances to the issuance of a certificate, takes approximately 8 weeks to complete. This includes Executive Committee review and administrative time required for paperwork and approval.

About ILAC

- ILAC is the international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189) and inspection bodies (using ISO/IEC 17020)..

About ILAC

- The regional arrangements are managed by the recognized regional co-operation bodies that work in harmony with ILAC and IAF. The recognized regional co-operations are also represented on the ILAC and IAF Executive Committees. ILAC works closely with the regional co-operation bodies involved in accreditation, notably IAAC in the Americas.


INTERNATIONAL BODY
ILAC
REGIONAL BODIES (A FEW EXAMPLES)
APLAC
IAAC
EA
NATIONAL BODIES (A FEW EXAMPLES)
CNAS
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PAB
NSC–ONSC BOA
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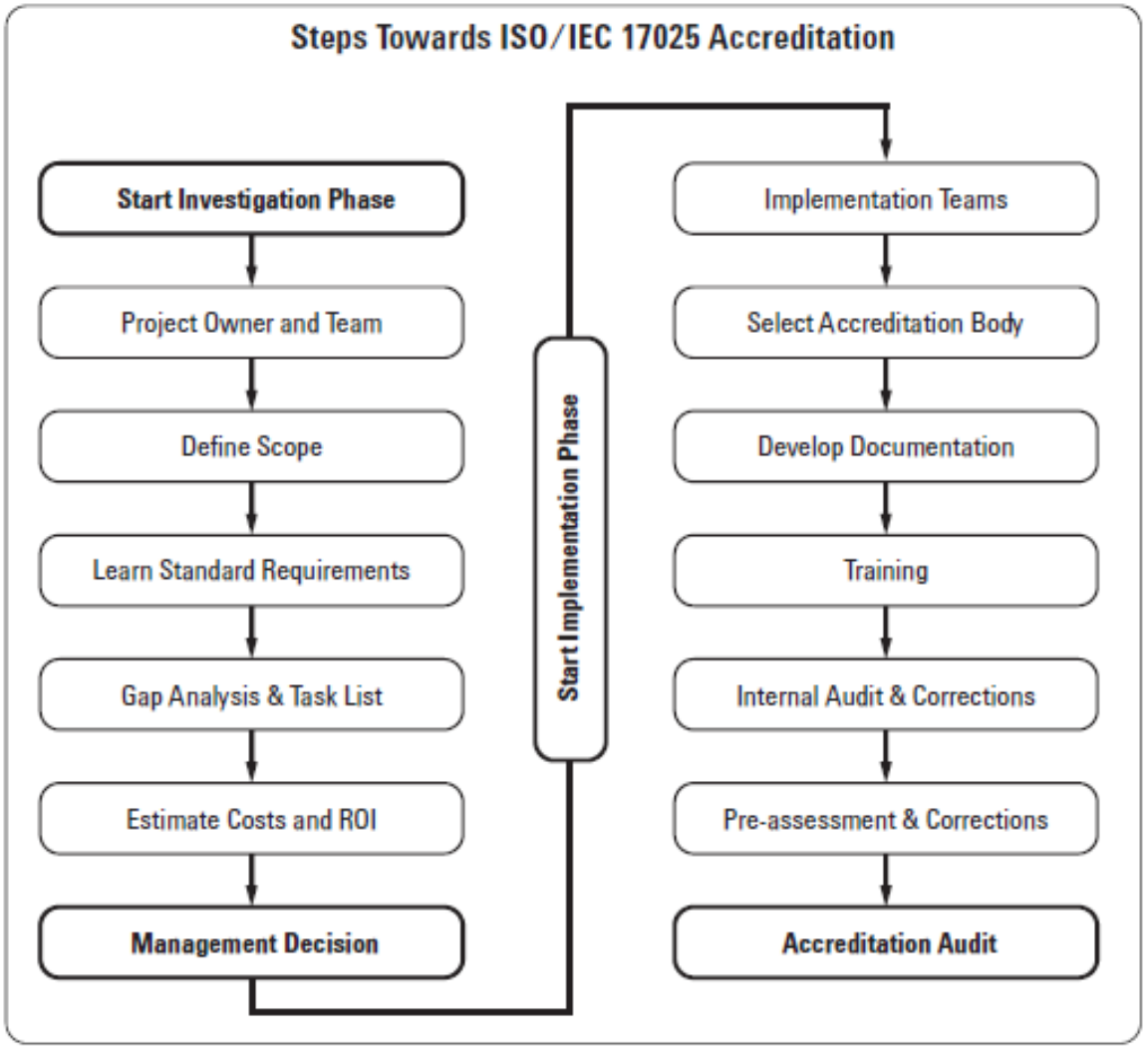
Steps Towards ISO/IEC 17025 Accreditation
Start Investigation Phase
Project Owner and Team
Define Scope
Learn Standard Requirements
Gap Analysis & Task List
Estimate Costs and ROI
Management Decision
Start Implementation Phase
Implementation Teams
Select Accreditation Body
Develop Documentation
Training
Internal Audit & Corrections
Pre-assessment & Corrections
Accreditation Audit

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CNAS Laboratory Accreditation Process

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Accreditation Rules

- CNAS-R01 Rules for the Use of Accreditation Symbols and for Claims of Accreditation Status
- CNAS-R02 Rules for Impartiality and Confidentiality
- CNAS-R03 Rules for Dealing with Appeals,. Complaints and Disputes
- CNAS-RL01 Rules for the Accreditation of Laboratory
- CNAS-RL02 Rules for Proficiency Testing
- CNAS-RL03 Rule for Accreditation Fees For Laboratories and Inspection Bodies
- CNAS-RL04 Rules for Accepting Application from Overseas Laboratories and Inspection Bodies

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Accreditation Criteria

- CNAS-CL01 General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025: 2005)
- CNAS-CL06 Requirements for Measurement Traceability
- CNAS-CL07 Requirements for Measurement Uncertainty.
- CNAS-CL11 Guidance on the Application of Laboratory Accreditation Criteria in the Field of Electrical Testing
- CNAS-CL52 Application ofCNAS-CL01 <Accreditation Criteria of the competence of testing and calibration laboratories>

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Accreditation Process

Step 1
Establishment of quality management system and running effectively

Step 2
Submission of application form and related documents

Step 3
Application document review by the secretariat and make acceptance decision

Step 4
Application document review by the auditor team and determine the on-site assessment

Step 5
On-site assessment

Step 6
Non-conformity rectification and acceptance

Step 7
Evaluation, approval, and issue the certificate

Step 8
Supervision and re-assessment

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Step 1 Establishment of quality management system and running effectively

- Establishment of quality management system
  - Quality management system document should be completed, and systemic and coordinated;
  - organization structure and responsibilities are clear;
  - quality activities are under control;
  - quality management system can running effectively;
  - Process control is completed;
  - support service elements are effective

Step 1 Establishment of quality management system and running effectively

- Establishment of quality management system
  - Take into account of the accreditation criteria when developing the quality management documents;
  - There is no inconsistent among the different level documents
  - The quality management system shall cover all the places of testing activities
  - The laboratory management system shall formally and effectively running for at least 6 months

Step 1 Establishment of quality management system and running effectively

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Step 1 Establishment of quality management system and running effectively

- The laboratory management system shall formally and effectively running for at least 6 months
  - For the new laboratory, it would need the pre-running, internal audit and management review, to make adjustments and improvements to the management system, and then to start running formally
  - Effectively running, means, all the elements in the quality management system are running and it keep all the related records.

Step 2 Submission of application form and related documents

- Application
  - Download the application form
  - Complete the application form and prepare all the required documents
  - Submit all the application documents online, and mail the hard copies to the CNAS
  - Pay the application fee

Step 3 Application document review by the secretariat and make acceptance decision

- Acceptance decision
  - The CNAS secretariat check the integrity of the application documents
  - Check the legal status
  - Check the effectiveness of the quality management system
  - Check the PT experience
  - Check the resources of conducting the testing activities

Step 3 Application document review by the secretariat and make acceptance decision

- Acceptance decision
  - Check the traceability of the equipments
  - Check the testing experience
  - Check the competence of the laboratory

Step 3 Application document review by the secretariat and make acceptance decision

- Initial assessment
  - It cannot ensure if the applicant meet the acceptance conditions by the submitted documents; or unsure if the laboratory has relevant equipments, accommodations
  - It cannot ensure the application scope by the submitted documents
  - It cannot ensure if the applicant agree to conduct the assessment within 3 months

Step 3 Application document review by the secretariat and make acceptance decision

- Acceptance decision
  - Before the CNAS secretariat makes the decision, they will inform the applicant any problems they find
  - The laboratory shall provide written responds to the CNAS secretariat for each problem found in the review concerning their actions or measures within 2 months
  - Submit the rectification documents within 3 month after the written responds

Step 4 Application document review by the auditor team

- Document review
  - The compliance of Quality management system
  - Application documents
  - The compliance of application scope, personnel, equipments, traceability, PT, test reports
  - If there is non-conformity found, the CNAS secretariat or the leader of the auditor team will inform the applicant in written, to take any corrective actions

Step 4 Application document review by the auditor team

- After review, suggestions from auditor
  - Implement pre-assessment
  - Implement on-site assessment
  - Suspense on-site assessment
  - Do not implement on-site assessment

Step 4 Application document review by the auditor team

- Pre-assessment
  - Pre-assessment is an assessment, this is for clarifying the questions or problems found in the document review

Step 5 On-site assessment

- On-site assessment
  - On-site assessment will be conducted in the place that under accreditation
  - The on-site assessment date will agreed by the auditor team and the laboratory; the days will be depend on the application scope
  - Sometimes, the CNAS will arrange an observer
  - The audit tem develop the assessment agenda and get agreement by the laboratory

Step 5 On-site assessment

- On-site assessment
  - On-site assessment starts by the opening meeting, which is moderated by the leader of audit team
  - Audit team and laboratory personnel participate the opening meeting
  - During the on-site assessment, the audit team will summarize and inform the laboratory every day
  - Before the closing meeting, the audit team will communicate with the laboratory of the general results

Step 5 On-site assessment

- On-site assessment
  - During the on-site assessment, the auditor team will confirm each of technical capability that laboratory applies
  - The auditor team will arrange the on-site testing according to the application scope (items/parameters, equipments, testing methods, technicians, samples)
  - Evaluation of the authorized signatory
  - On-site assessment is closed by the closing meeting
  - The conclusion of the on-site assessment is the recommendations to CNAS

Step 6 Non-conformity rectification and acceptance

- Non-conformity rectification period
  - Initial assessment: 3 months
  - Supervision assessment: 2 months
  - Re-assessment: 2 months
- On-site verification
  - Related to the effective of the test results, or the integrity of laboratory
  - Environmental conditions (can correct in a short time)
  - Equipment failure (can correct in a short time)
  - Personnel competence (can correct in a short time)
  - Cannot ensure from the written document

Step 6 Non-conformity rectification and acceptance

- Corrective actions
  - For all the non-conformities, the laboratory should correct and do the cause analysis, develop the corrective actions
  - The conclusions of on-site assessment may amended according to the rectification results

Step 7 Evaluation, approval, and issue the certificate

- Evaluation
  - The on-site assessment report will reviewed by CNAS, and decide the conclusion
- Approval
  - The CNAS secretariat will approve and issue the certificate if CNAS accepts and approves.
  - The validity period accreditation certificate is normally six years

Step 8 Supervision and re-assessment

- Supervision
  - Within 12 months after the laboratory obtains the accreditation certificate
  - On-site assessment is requested
- Re-assessment
  - Within 24 months and 48 months after the laboratory obtains the accreditation certificate
  - The application procedure is the same as initial application

Step 8 Supervision and re-assessment

- Expand accreditation scope
  - The application procedure is the same as initial application
  - Only answer the expand related question in the form
- Amendment of accreditation scope
  - Inform CNAS, if any changes in the name, address, organizations, technical capabilities
  - Can conduct at the same time of supervision or re-assessment

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The Climate Technology Centre and Network (CTCN) fosters technology transfer and deployment at the request of developing countries through three core services: technical assistance, capacity building and scaling up international collaboration. The Centre is the operational arm of the UNFCCC Technology Mechanism, it is hosted and managed by the United Nations Environment and the United Nations Industrial Development Organization (UNIDO), and supported by more than 300 network partners around the world.

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