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Good Laboratory Practices and Laboratory Management
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A specifically designed programme for

Da Afghanistan Breshna Sherkat (DABS)
Afghanistan



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What affects measurement results?

- Personnel
- Equipments
- Method
- Environment
- Handling of item
- Traceability



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What is a good lab?

- Equipment
- Methods
- Personnel
- Management commitment
- Quality management system
- Environment



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Concept of Laboratory Accreditation Global Perspective



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Concept of Laboratory Accreditation Global Perspective

- What is laboratory accreditation?
- Advantages of accreditation
- Accreditation Bodies
- National and international status
- IEC 17025 and its structure
- ISO9000 V/s IEC 17025



What is 'laboratory accreditation'?

- LA a means of determining and formal recognition of the competence of laboratories to perform specific types of testing, measurement and calibration.
- involves an independent assessment by technical experts.
- laboratory to determine whether it is performing its work correctly and to appropriate standards and decide its desired "scope of accreditation".



Why to get accreditation?

- Increase of confidence in Testing/ Calibration data and of personnel performing work.
- Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
- Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.
- Distinct Marketing/ competitive advantage.
- Will help to assure customers of quality of measurement results.

(To a Lab it gives a status and recognition)



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ISO/IEC Standard for Laboratory accreditation

NABL Accreditation is granted in compliance to
IS/ISO/IEC 17025:2005

*General requirements for the competence of
testing
and calibration laboratories.*



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ISO CASCO

- International Organization for Standardization
- Committee on Conformity Assessment



Conformity assessment

- “Activity that provides demonstration that specified requirements relating to product, process, system, person or body are fulfilled”
- Covers such activities as: testing, inspection and certification as well as accreditation of conformity assessment bodies



Accreditation body (conformity assessment)

- Note: The authority of an accreditation body is typically derived from government”
- In India it is National Accreditation Board for calibration and testing Laboratories (NABL), Dept of Science and Technology, GOI.



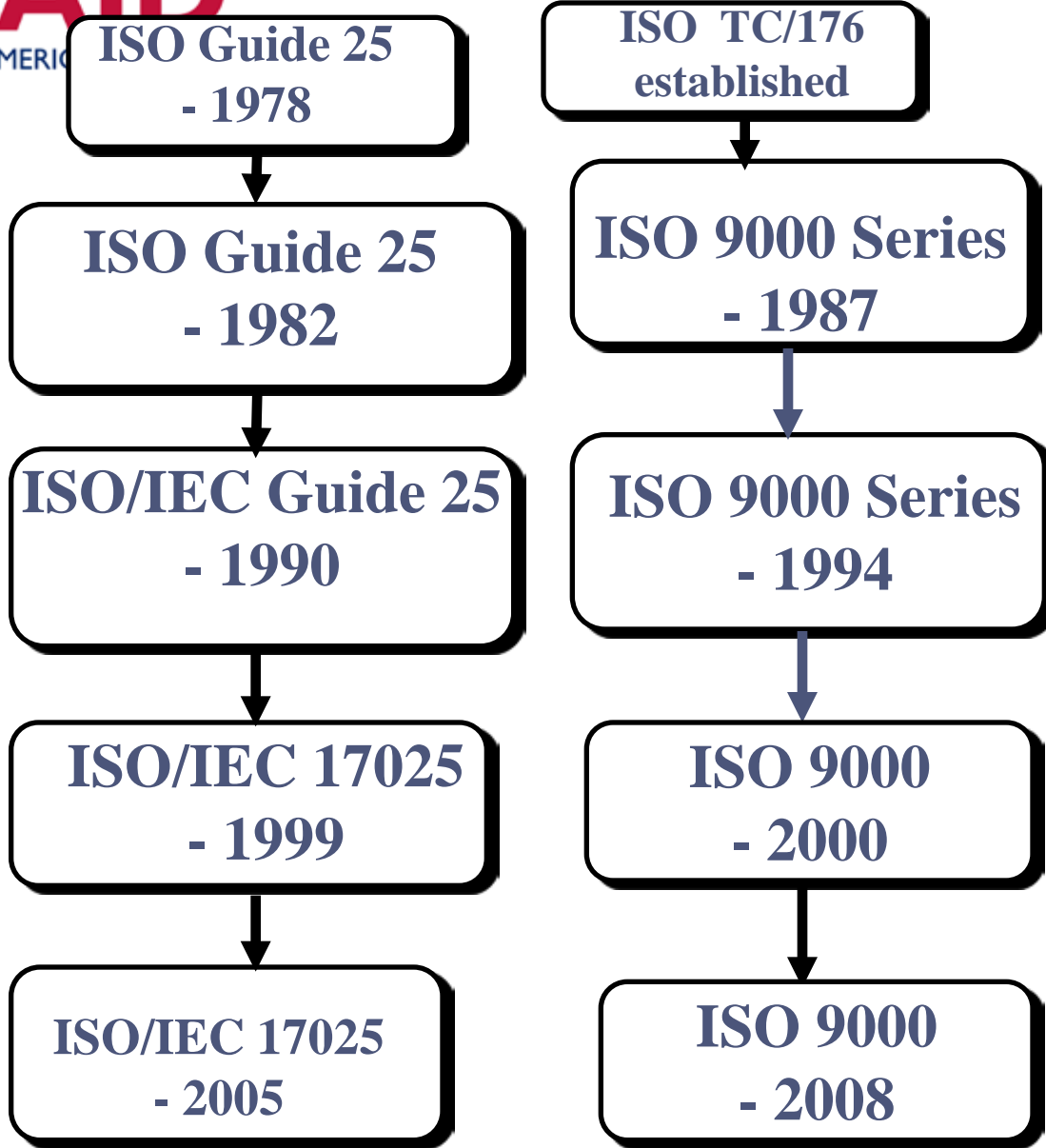
International Laboratory Accreditation Cooperation.... conference 1978, cooperation in 1996

- Development, promotion, recognition of LA practices
- ILAC is the world's principal international forum for the development of laboratory accreditation practices
- specific regions have also established their own accreditation co-operations, notably in Europe (EA) and the Asia-Pacific (APLAC).
- Over 40 laboratory accreditation bodies have signed the multi-lateral, mutual recognition arrangement (the “ILAC Arrangement”) to promote the acceptance of accredited test and calibration data
- ILAC arrangement w.e.f. 31 Jan 2001.



Mutual Recognition Agreement

- Mutual Recognition Arrangements, are crucial in enabling test data to be accepted between various countries.
- In effect, each partner in such an arrangement recognizes the other partner's accredited laboratories as if they themselves had undertaken the accreditation of the other partner's laboratories.
- Over 22000 labs accredited by members of ILAC, MRA signatories





Structure of ISO 17025 standard

1. Scope
2. Normative references
3. Terms and definitions
4. Management requirements
5. Technical requirements



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More specific requirements of IS/ISO/IEC 17025 : 2005

- Demonstrate that a Lab operates to a quality system.
- Lab is technically competent.
- Lab is able to generate technically Valid results.



Management Requirements

- Commitment by Management to operate to best practices
- Proper organization structure with defined responsibility and authorities
- Technical and Quality Manager
- Documented quality system
- Document control system
- Proper review of customer's requirements



Management Requirements

- Corrective and Preventive actions
- Proper Handling of customer complaints
- Internal Audit
- Management Reviews
- Improvements
- Cooperation with customer and feedback
- Purchasing
- Good Record keeping system



Technical requirements

- Identification of specific equipments for a purpose.
- Each equipment must be certified from an accredited lab. (in our case NABL)
- Traceability in SI units must be established to international standards thru an unbroken chain of measurements.
- Uncertainty of measurement and BMC must be computed and declared.
- Demonstrate compliance to standards of
 - Test set up
 - Method and process
 - Measurement results



Technical and other requirementscontd.

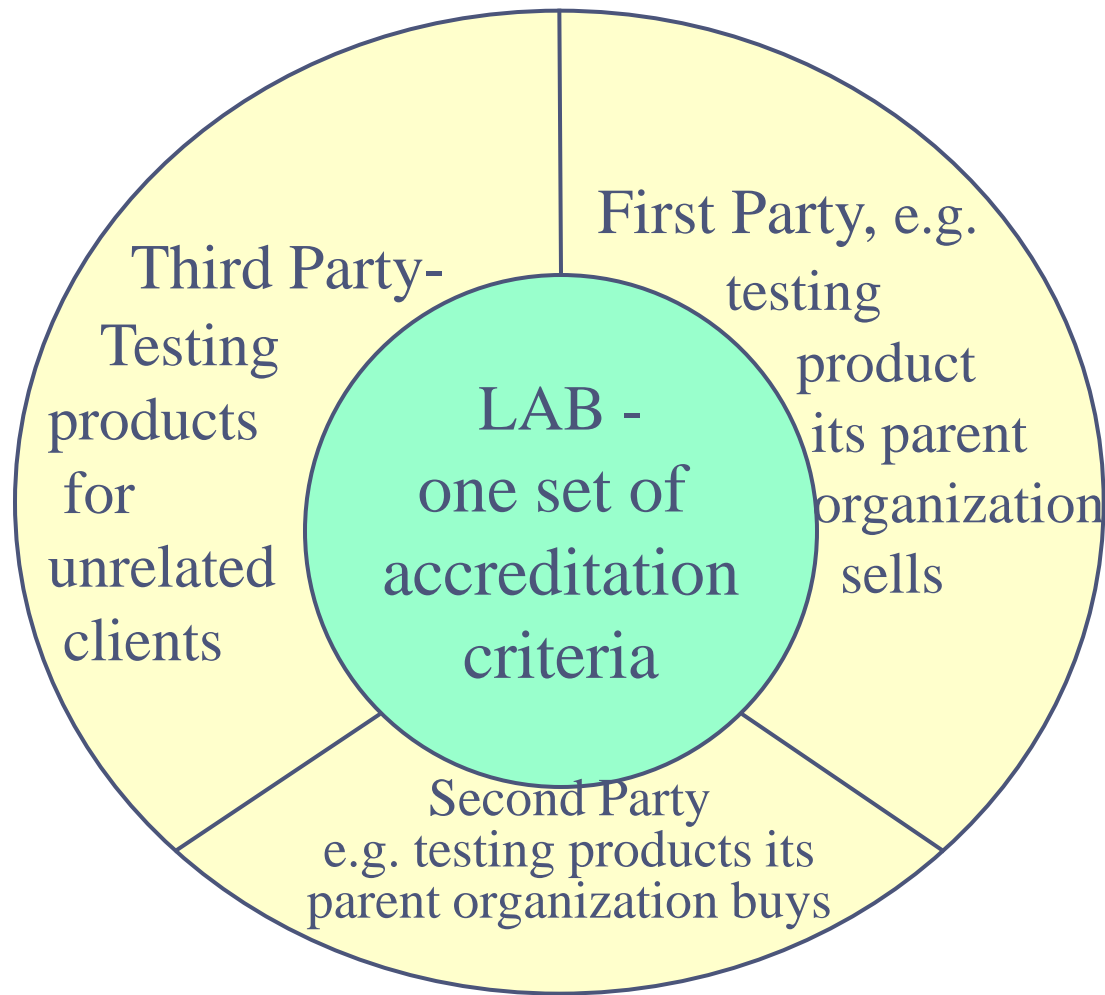
- Prove technical capabilities periodically thru proficiency testing programs and Inter-Lab comparisons.
- Audit of all the data, results, calculations, s/w tools , all requires better technical records and control..
- More specific requirements on Manpower qualification, duties and training/ skills.
- Declared authorized signatories for certificates, approved by auditors.
- Accommodation, environment, Access, security and confidentiality.



Laboratory quality system under ISO 17025

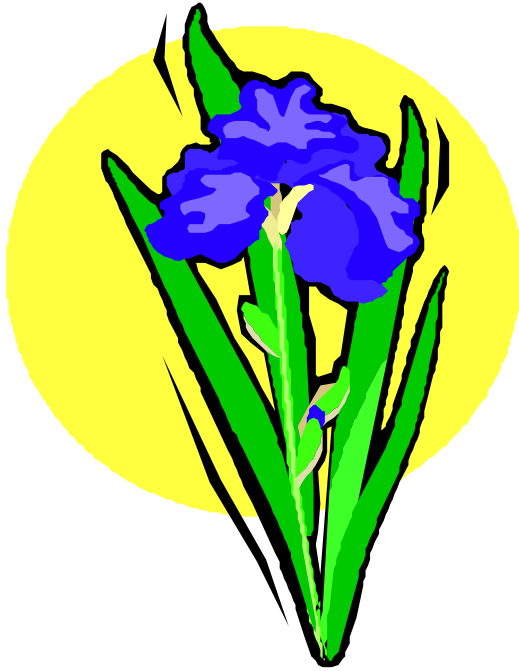
provides documentary evidence for a given test result that,

- **Work is done by properly qualified & trained persons who had access to all information necessary to carry out the work**
- **Methods used were technically sound, appropriate for samples & requirements of client**
- **Equipment used were properly maintained & calibrated at the time of use**
- **All appropriate QC checks were carried out & results of controls fell within the specifications**





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Thanks