

# Clinical Laboratory Accreditation How & Why

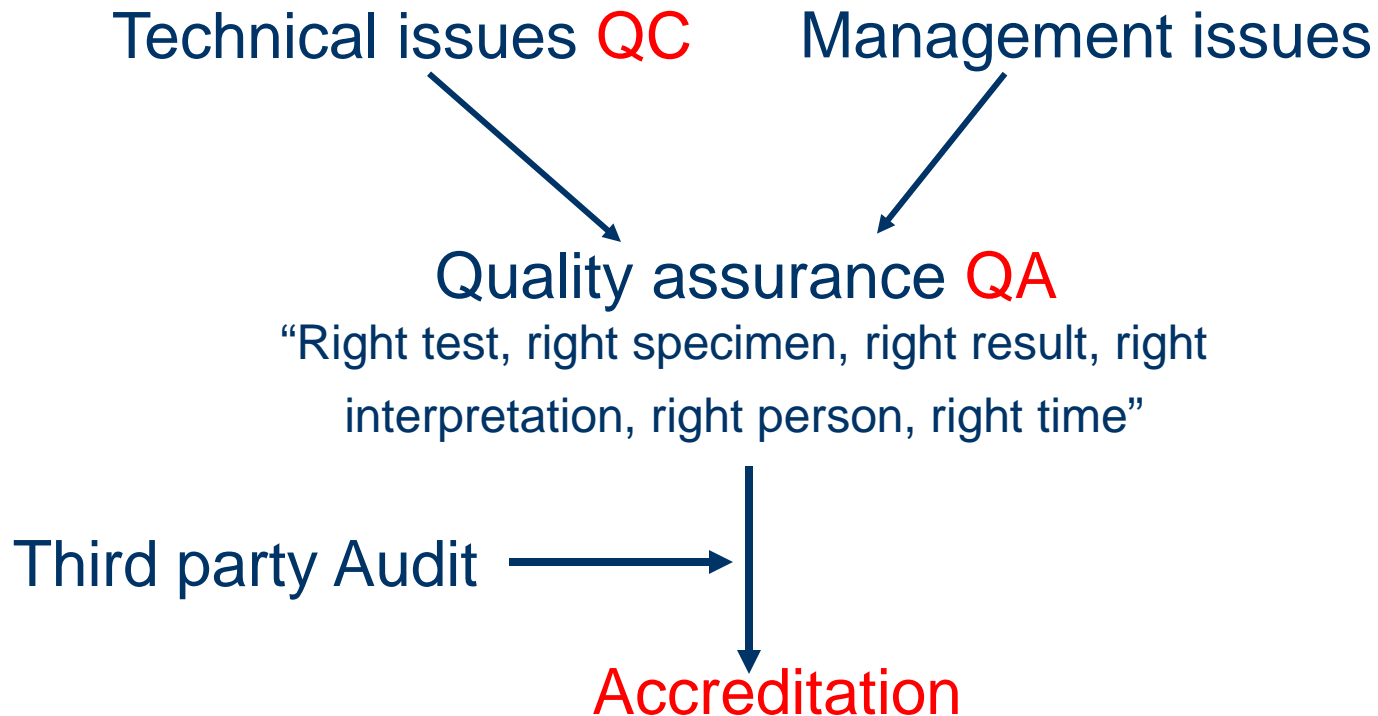
Anita M Borges MD FRCPath  
Mumbai

Chairperson,  
Accreditation Committee, Clinical Labs  
NABL

# Accreditation

- Formal certification of **quality** by an independent authorized body.
- What is “quality”?
- Doing the **right thing** at the **right time** for the **right reasons** and **doing it right**.
- What is right?
- Need for **standards, guidelines & warranties**

# Quality Management



# Quality assurance Technical Issues

- **Good Awareness among pathologists about**
  - ❑ Controls
  - ❑ Proficiency testing- PT, EQA
  - ❑ Calibration of major equipment esp. analysers

# Quality Assurance Technical Issues

- **Poor awareness among pathologists about**
  - ❑ L-J charts, QC trends, run rejection, corrective actions on poor PT performance.
  - ❑ Measurement uncertainty
  - ❑ Validation of technical methods
  - ❑ Traceability of standards
  - ❑ Harmonization of equipment
  - ❑ Calibration of common instruments eg thermometers, pipettes, centrifuges, water baths.

# Quality Assurance Management issues

- Documentation- “What is not documented is not done!”
- Purchase & Supply procedures
- Staff recruitment, supervision & training
- Turn-around time (TAT)
- Preventive & corrective measures
- Bio-safety & waste management
- Referrals (outsourcing)
- Internal audits & Management reviews

# Laboratory Accreditation

Procedure by which an authorized body (e.g. NABL, CAP ) gives formal recognition that a laboratory or person (signatory) is competent to carry out specified tasks (scope).

Third Party audit against defined criteria.

# Laboratory Accreditation

- Certifies validity of technical procedures.
- Certifies competence of the laboratory to carry out the scope.
- Certifies compliance with the stated quality system.
- Endorses the quality management system of the audited lab.



# Clinical Laboratory Accreditation Indian Scene

- **N**ational **A**ccreditation **B**oard for Testing & Callibrating **L**aboratories- **NABL\***
- Labs of all sizes.
- General pathology and speciality labs.
- Accreditation given to individual laboratory sections & individual tests.

\* NABL is accredited by APLAC which is accredited by ILAC

# Laboratory Accreditation

## The Indian Scene

- Purely voluntary
- Audit (assessment) done according to ISO 15189: 2007 and NABL112 specific guidelines.
- Adequacy audit : Audit of **documentation**
- Compliance audit: Audit of **implementation** of the quality system.

# ISO 15189 2007

- International Standard
- Five clauses
  1. Scope
  2. Normative references
  3. Terms & definitions
  4. Management requirements
  5. Technical requirements
- Three appendices one of which is on ethics

# NABL- 112 Specific Guidelines for Clinical laboratories

- Guidelines that must be complied with over and above ISO -15189.
- Local Indian and State Regulations eg.
  - ❑ Notifiable diseases
  - ❑ NACO guidelines
  - ❑ Bio waste management
- Classification of Labs
- Retention times for samples
- Qualifications for authorised signatories

# Laboratory Accreditation

## The Indian Scene- NABL Accreditation

- Application with quality manual
- Pre-assessment (Lead assessor\* & 1 technical assessor\*)
- Final assessment ( LA + TA for each area of assessment)
- Re-assessment after 2 years with a desk-top audit in the intervening year.

\* All assessors are trained

# Laboratory Accreditation

## The Indian Scene- NABL Accreditation

- Accreditation Committee
- NABL Certificate for the certified scope alone.
- Unauthorised or wrongful use of the certificate can lead to suspension of accreditation.

# NABL Assessment

- Not an **examination**.
- Assessors are not out to find inconsequential faults (NCs). They are looking for
  - ❑ Knowledge of quality systems among concerned staff.
  - ❑ Systematic implementation of QS.
  - ❑ Problems that will seriously affect the quality of a test result.
  - ❑ Willingness of the lab management to improve.
- **Mutually beneficial** learning experience for the lab and assessors. Observations & suggestions..
- **Confidentiality** is key.
- **Success** requires informed and balanced assessors and assessees with a commitment to quality.

# Why Laboratory Accreditation ?

- Growing public interest in the quality of health care.
- Demand for accountability because of high cost.
- Increasing public expectations from all health care providers.
- Privatization of health insurance and the advent of managed health care.
- Business imperatives: CRO, clinical trial patients.



# Why Laboratory Accreditation ?

## Benefits to the Lab

- Makes the lab conscious of quality.
- Independent certification of lab competence.
- Increases client confidence.
- Builds staff morale.
- Improves lab performance.
- Improves laboratory competitiveness.
- Improves business prospects.

# Quality costs!

Quality costs are offset by Quality payoffs.

- Enhanced reputation.
- Loyal clientele.
- Reduced costs of systems failure eg. machine downtime, retesting for complaints, poor staff performance, etc.

# Laboratory Accreditation

- Should accreditation become mandatory?
- Will accreditation become mandatory?

# Laboratory Accreditation

- **Accreditation is **not** licensing.**
- Licensing is mandatory.
- Licensing requires compliance with minimal criteria.
- Licensing does not involve a compliance (implementation) audit.
- Licensing does not assure technical quality.
- Licensing in some instances may require accreditation.

# Future of Private Lab Medicine

- Decline of small neighbourhood labs run by MDs in urban areas.
- Growth of large laboratory conglomerates with centralized testing.
- Increased testing of well individuals to offset quality costs and competition by economies of scale.
- Growth of single specialty labs e.g. hematology, microbiology, histopathology labs.
- Accreditation by peer pressure.
- Mandatory accreditation and/ or licensing.

# Future of Private Lab Medicine: Problems

- Issues of analyte stability on transport (preanalytic issues; issues pertaining to collection centres)
- Quality issues for point of care and emergency testing
- Logistics of Accreditation of Labs & PT providers.
- Mushrooming of licensed but unaccredited labs.
- Price wars
- Need for a **wise clinical laboratory regulatory act** that recognises that non-medical personnel can and do render quality services, both in underserved areas of this country and in high end labs.

# Laboratory Accreditation

## The Future

- Laboratory Accreditation is here to stay.
- The future of laboratory medicine will be changed forever.