Quality System ACCREDITATION For the Clinical Laboratories

A NEW PERSPECTIVE BY:
Accreditation Commission For Conformity Assessment Bodies (ACCAB)

Objective

- What are Standards ?
- Voluntary & Mandatory Standards
- Standards & Technical Regulations
- Introduction to Conformity Assessment
- Comparative Analysis Between ACCAB and NABL

A Standard is a Document

Standard

Document *established by consensus and approved by recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities …*

ISO/IEC Guide 2:2004
Standardization and related activities – General vocabulary

Premise

- *The international language of commerce is standards.*

Source:

U.S. Secretary of Commerce – Donald Evans

Report on Standards and Competitiveness – Removing Standards-Related Trade Barriers Through Effective Collaboration

May 18, 2004

Premise

- Standards help to make life simpler and to increase the reliability and the effectiveness of many goods and services we use.
- Standards are created by bringing together the experience and expertise of all interested parties such as the producers, sellers, buyers, users and regulators of a particular material, product, process or service.

Are Standards Useful & Correct

- The existence of a published standard does not necessarily imply that it is useful or correct.
- Just because an item is stamped with a standard number does not, by itself, indicate that the item is fit for any particular use.
- The people who use the item or service (engineers, trade unions, etc.) or specify it (government, industry, etc.) have the responsibility to consider the available standards, specify the correct one, enforce compliance, and use the item correctly... Validation of suitability is necessary.

Standards Are Voluntary

- Standards are designed for voluntary use and do not impose any regulations. However, laws and regulations may refer to certain standards and make compliance with them compulsory;
- For example, the physical characteristics and format of credit cards is set out in standard number BS EN ISO/IEC 7810:1996.
- Adhering to this standard means that the cards can be used worldwide.

Voluntary vs. Mandatory

- “Voluntary Standards” become mandatory only when:
  - They are incorporated into contracts; or
  - They are referenced or adopted by government agencies as part of a regulation to protect public health, safety, and the environment.
- “Voluntary” and “Mandatory” are terms of Conformity Assessment (i.e. the mechanism chosen to ensure compliance to a particular standard)

Difference Between a Technical Regulation and a Standard

- The difference between a standard and a technical regulation lies in compliance. While conformity with standards is voluntary, technical regulations are by nature mandatory.
- They have different implications for international trade.
- If an imported product does not fulfill the requirements of a technical regulation, it will not be allowed to be put on sale.
- In case of standards, non-complying imported products will be allowed on the market, but then their market share may be affected if consumers' prefer products that meet local standards such as quality or color standards for textiles and clothing.

Conformity Assessment (CA)

- The ISO/IEC Guide 2:1996 definition of conformity assessment is “any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.”
- In more tangible terms, conformity assessment refers to a variety of processes whereby goods and/or services are determined to meet voluntary or mandatory standards or specifications.
- Conformity assessment affects a wide range of commercial and organizational interests.
- Conformity assessment are competitive commercial activities in their own right.

CA Processes

- A variety of PROCESSES involved in verifying that goods/services meet acceptable voluntary or mandatory standards such as:
- Testing
- Surveillance
- Inspection
- Auditing
- Certification
- Registration

Note: Accreditation is not a CA Process

CA Processes

Overall umbrella of measures taken by :

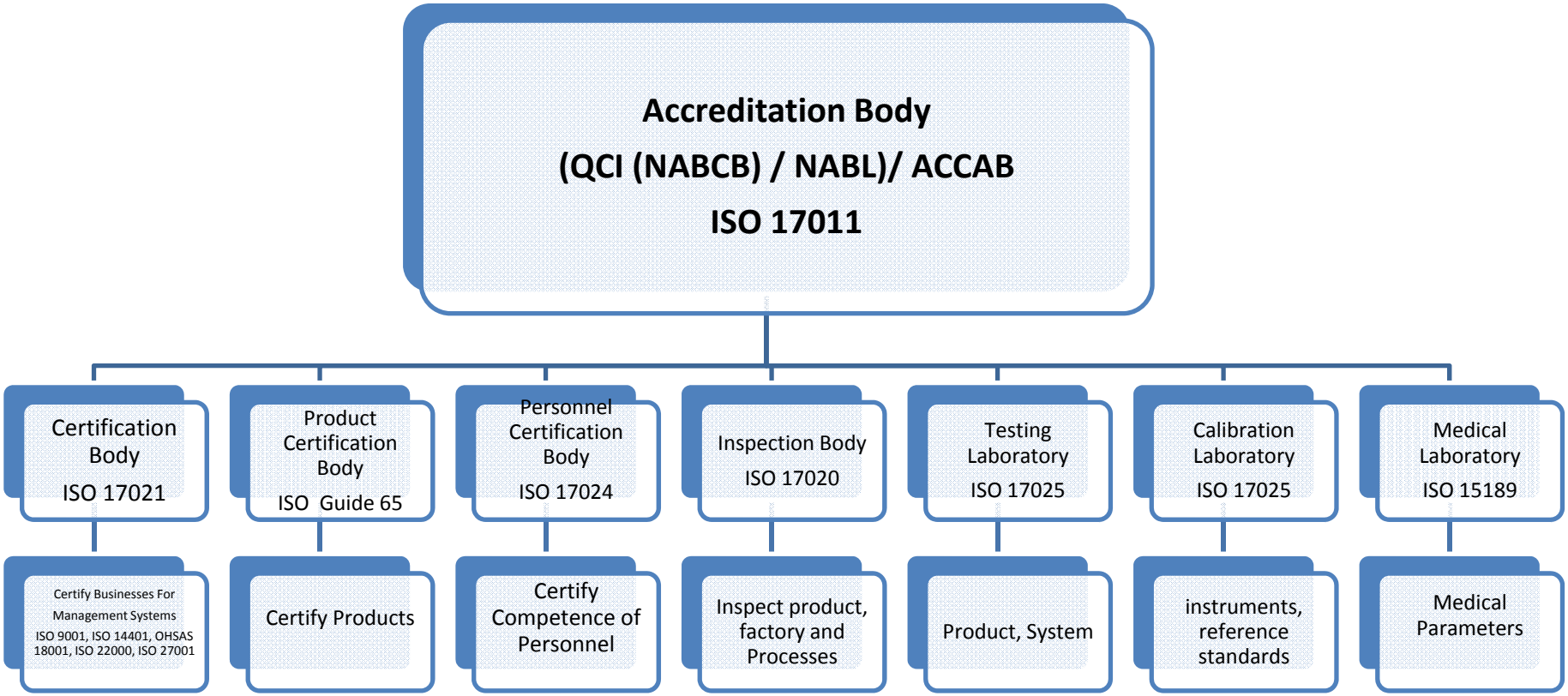
- Manufacturers
- Customers
- Independent Third Parties
- Regulatory Authorities

To assess that a product/service meets Standards or Technical Regulations.

CA Processes

NOTE: All CA Processes involve standards

Note: Accreditation is not a CA Process



OBJECTIVES OF CA

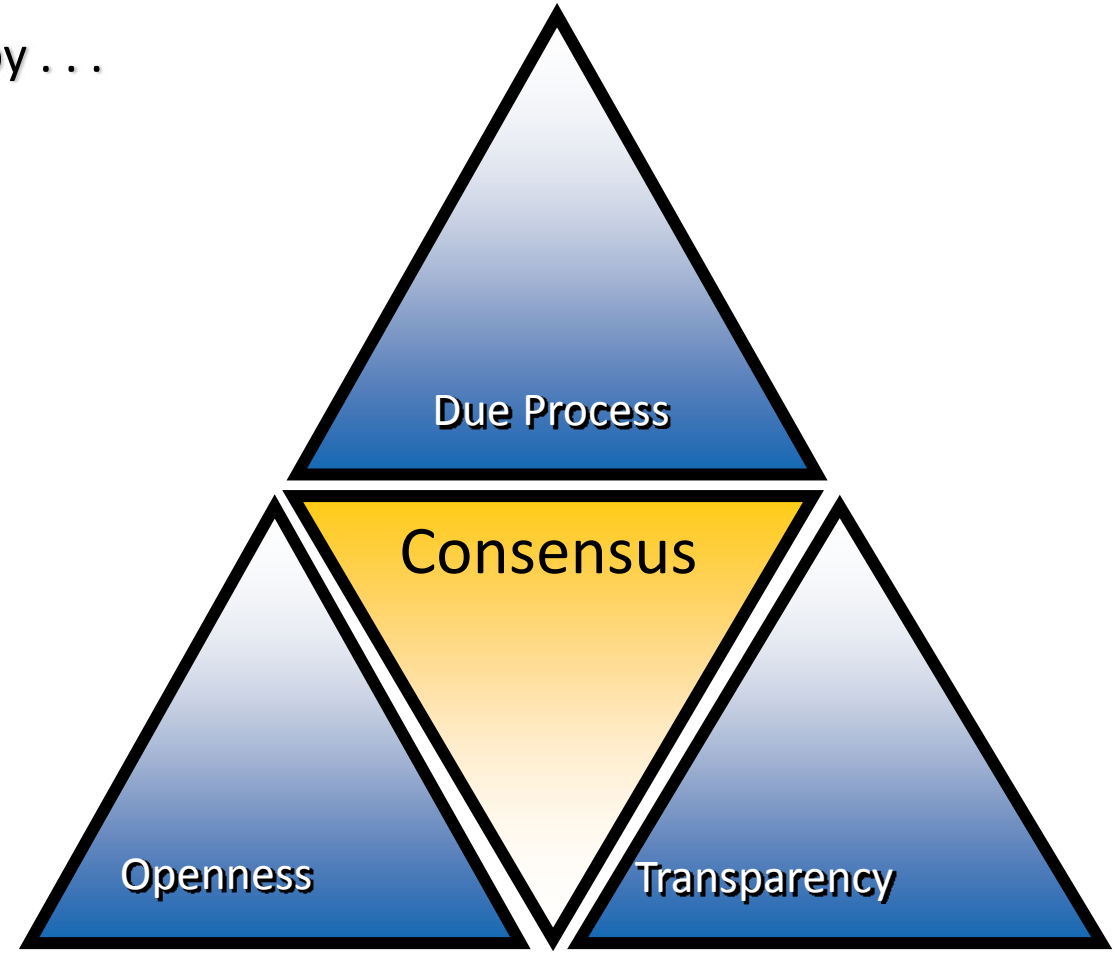
- Conformance of products/services with relevant standards (ISO, IEC/BIS etc)
- Encourages international trade (tries to check trade malpractices)
- Prevents sale of substandard/unsafe product
- Prevents importation of substandard products
- Saves lives and property
- Prevents pollution of air and water
- Conserves hard-earned foreign exchange

OBJECTIVES OF CA

- Inspires confidence in consumers on purchased goods
- Products have value for money spent
- Provides fair level play ground in competitive domestic and international markets
- Provides reliable records for identification and traceability of local and imported products
- Enhances economic growth and development

Internationally Accepted Standards and Conformity Assessment Principles

- Agreed to by . . .
  - WTO
  - ISO
  - IEC
  - SDOs



Accreditation

http://www.iso.org/iso/home/standards/certification.htm

- **Accreditation** – the formal recognition by an independent body, generally known as an accreditation body, that a Conformity Assessment Body is capable and competent.
- Accreditation is not obligatory but it adds another level of confidence, as 'accredited' means the Conformity Assessment Body has been independently checked to make sure it operates according to international standards.

NABL and ACCAB

Department of Science & Technology

NABL

Autonomous Society

Independent Private Limited Company

Who is NABL

- National Accreditation Board for Testing and Calibration Laboratories (“NABL”) is registered as a society under the Societies Registration Act, 1860 an autonomous body set up under the aegis of Department of Science & Technology, Government of India ;
- NABL’s status is not protected by any law or piece of legislation;
- NABL is not a Statutory Body or a Quasi Government Body.

Who is ACCAB

- **Accreditation Commission For Conformity Assessment Bodies Private Limited ("ACCAB")** is the first Private Sector Accreditation Body in India and amongst the very few in the world;
- ACCAB is engaged in the business of Accreditation of Certification Bodies, Inspection Bodies, Product Certification Bodies, Personnel Certification Bodies, Testing & Calibration Laboratories, Medical Laboratories, Diagnostic Centers & Blood Banks as per the International Standards and Normative Documents.

NABL and ACCAB

- There is no such thing as “NABL” Accreditation.
- Medical Laboratory can be accredited to ISO/IEC 15189:2007.
- ISO/IEC 15189:2007 is not a Technical Regulation in India.
- Medical Laboratory can be accredited to ISO/IEC 15189:2007 standard by any accreditation body who have themselves implemented ISO 17011:2006 standard.
- Accreditation bodies desirably should be member of an international association such as International Laboratory Accreditation Cooperation (ILAC).

If Quality is a journey then Accreditation is a Ferry Boat !

- There are thousands of Clinical Laboratories across India who are ready to take up this journey;
- NABL has so far accredited only 356* Clinical laboratories in India;
- According to their own Result framework Document NABL has limited capacity and capability to provide accreditation services;
- NABL's monopoly is now under challenge.

Why ACCAB ?

- It is an Independent, Impartial and Non-Governmental Body;
- Responsiveness & Non Bureaucratic Attitude;
- Technical Approach to the Accreditation;
- We accept multiple point of views;
- Cost Effectiveness;
- We are just a “Ferry Boat Operator”.

Thank You !