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QUALITY COUNCIL OF INDIA





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Post Recognition Activity

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Fee Structure





International Scenario

- Increasing use of standards for products, services, processes and systems mandatory on grounds of health, safety, environment, national security, unfair trade practices
- Need for checking compliance to prescribed standards regulations and voluntary standards - conformity assessment – inspection/testing/certification –
- Two issues arose
- Need for Confidence in conformity assessment
- Need for International acceptability for facilitating trade recognition of inspection/testing/ certification across borders

Accomplished through accreditation





Provision in WTO TBT Agreement

"Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted...adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence"

<u>Article 6</u>





Accreditation

Third-party attestation related to a conformity assessment body conveying <u>formal demonstration of its competence</u> to carry out <u>specific conformity assessment tasks</u> – ISO 17000





International Accreditation System

- International Bodies Association of accreditation bodies International Accreditation Forum (IAF) for CBs, International Laboratory Accreditation Cooperation (ILAC) for Labs and IBs
- Regional Bodies (06)— Asia Pacific Accreditation Cooperation (APAC) for CBs/IBs and Labs
- Similar bodies in other Continents recognized by IAF/ILAC European Accreditation Cooperation (EA), Inter American Accreditation Cooperation (IAAC), Arab Accreditation Cooperation (ARAC); African Accreditation Cooperation (AFRAC); Southern African Development Community Cooperation in Accreditation (SADCA)
- Multilateral Mutual Recognition Arrangement MLAs in IAF, MRAs in ILAC
- National ABs in India NABCB for Certification & Inspection Bodies, NABL for Laboratories, PTPs, RMPs



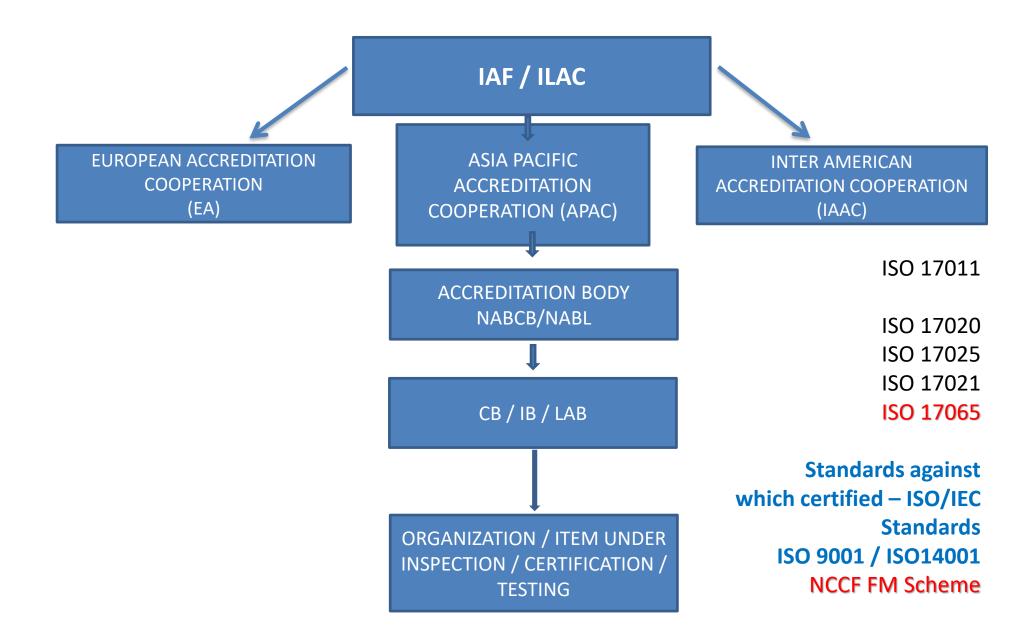


International Equivalence

- Accreditation Bodies to comply with ISO/IEC 17011 Peer Assessment – if successful, signatory to MRAs
- NABCB Signed PAC MLA for QMS Aug 2002; IAF MLA for QMS Sept 2002 - Signed PAC MLA for EMS – July 2007; IAF MLA for EMS – Oct 2007; PAC MLA for Product Certification – May 2013; IAF MLA for Product Certification – August 2013; MRAs for Inspection – APLAC in Sept. 2013; ILAC in Sept. 2013; FSMS – PAC MLA in June 2014; IAF GlobalG.A.P in Oct 2014; ISMS – PAC MLA June 2015, IAF MLAs for FSMS and ISMS in Oct 2015; PAC MLA for GlobalG.A.P. in Oct 2015; PAC MLA for EnMS in June 2017; OHSMS in Dec 2018; APAC Personnnel in June 2019.
- NABL signatory to ILAC/APLAC MRAs for Testing and Calibration Labs since 2000; ILAC/APLAC MRA on ISO 15189 for Medical Labs since 2008; PT Providers & RM Producers in 2016.
- NABCB accreditation equivalent worldwide and certificates with NABCB logo acceptable internationally
- To Sum Up India has world class accreditation infrastructure



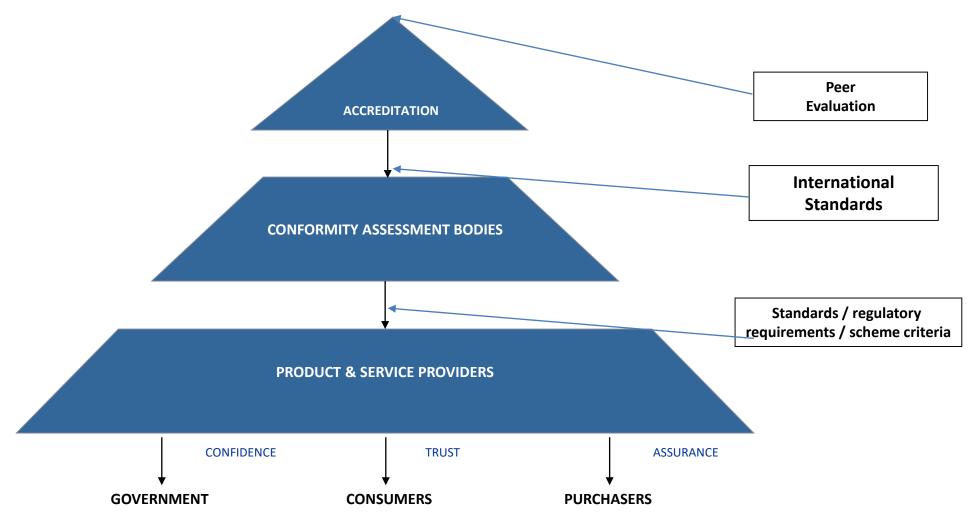
Equivalence Framework







Accreditation Framework







Benefits of Accreditation

- Recognition of Technical Competence
- Customer confidence & satisfaction
- Minimizes risks
- Avoids re-testing/inspection & Reduces costs
- Increased efficiency
- Marketing advantage & Increased business
- International Recognition





Role of ABs

- In regulated sectors, regulator is the authority CDSCO in pharma, FSSAI in food – accreditation provides support to induct 3rd party assessment – NABCB in Medical Devices Rules, NABCB accredited food safety audit agencies – in FSSAI, NABL accredited labs in FSSAI and BEE regulations
- In voluntary space Scheme owner is the authority several internationally known schemes in various sectors – GlobalGAP in agriculture, FSC/PEFC in forest management, SA 8000 for social accountability, FSSC 22000/SQF/BRC/IFS in food – accreditation as means for 3rd party bodies – NABCB recognized by GlobalGAP, BRC, IFS, FSSC 22000,NCCF etc





Use of NABCB Accredited Bodies

• Regulators relying on accreditation

PNGRB – MoU with QCI in 2008 – accredited Inspection Bodies empanelled for inspections Gas Pipeline Networks (CGD / NGPL); Review & Onsite Verification of ERDMP

Medical Devices Rules 2017 notified – prescribes third-party CBs accredited by NABCB to be designated as Notified Bodies

FSSAI – NABCB Accredited bodies for food safety audits and NABL accredited labs

Deptt of Consumer Affairs – advisory to Ministries – NABCB accredited bodies to be used for regulations under BIS Act

- Goa accepts NABCB Accredited Certificates for OHS Goa Govt. amended the "The Goa Factories (Occupational Health and Safety Audit) Rules, 2014" accepting NABCB Accredited OHSMS Certifications as per OHSAS 18001 as equivalent to OHS Audits as prescribed by its Chief Inspector of Factories
- Rajasthan State Pollution Control Board accepts NABCB Accredited Inspections for verifying compliance to the various provisions of the Environment Acts by medium/low risk industries.





Use of NABCB Accredited Bodies

- Government relying on accreditation
 - ✓ DoC Free Trade Agreements with trading partners
 - ✓ **DGFT** Recognizes CBs accredited by NABCB for Q/E etc
 - Railway Budget 2014-15 Third-party certification of catering services by NABCB accredited bodies announced
 - State Govts incentive schemes for SMEs for getting ISO 9001/14001/22000 etc certification from NABCB accredited certification bodies

Industry relying on accreditation

- ✓ BHEL (Power generation equipment manufacturer), ONGC, GAIL, BPCL (Oil & Gas companies) and many others prescribe NABCB accredited inspection bodies
- Infrastructure sector relying on accreditation
 - Various central & state government departments / agencies relying on NABCB accredited inspection bodies for monitoring quality in infrastructure projects





The Indian Ecosystem for Accreditation

About QCI

- Set up in Jan 1997 by the Government of India with ASSOCHAM, CII & FICCI
- QCI is an independent autonomous organization under the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce & Industry, Govt. of India.
- QCI was established as the National Accreditation Body and to lead a quality movement by undertaking a National Quality Campaign
- Chairman of QCI is appointed by the Hon'ble Prime Minister of India

QCI Leadership



Mr. Adil Zainulbhai Chairman

Dr. R. P. Singh Secretary General

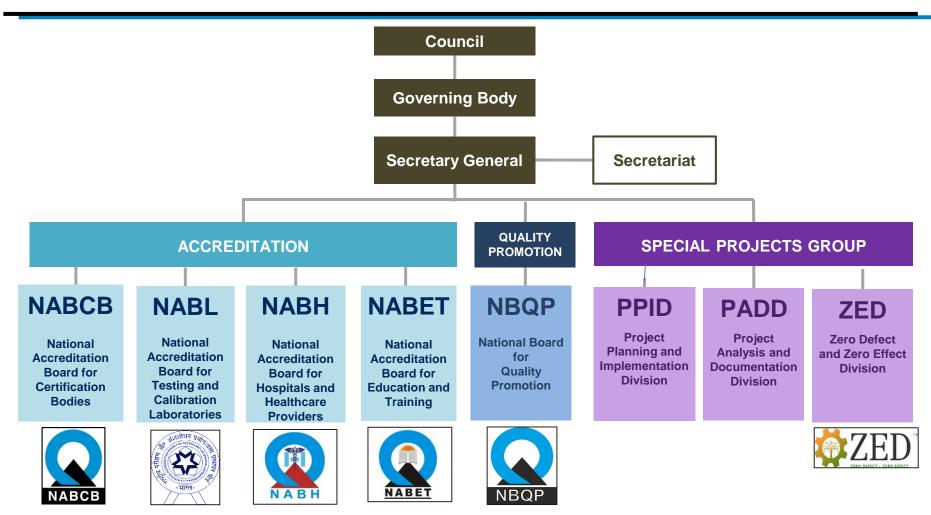
QCI Mandate

- Provide Accreditation Framework in the country
- Spread quality movement in India
- Provide right and unbiased information on Quality & related Standards
- Represent India's interest in International fora.
- Help establish quality of Indian products and services





QCI : Organization Structure







NABCB | NATIONAL ACCREDITATION BOARD FOR CERTIFICATION BODIES

Accredits Certification, Inspection and Validation & Verification Bodies (CBs, IBs & VVBs) as per ISO Standards

and other requirements. which are internationally recognized through Mutual Recognition Arrangements of IAF and

- > Management Systems Certification Bodies:
 - Quality Management System (QMS)*
 - Energy Management System (EnMS)*
 - Environmental Management System (EMS)*
 - Food Safety Management System (FSMS)*
 - Information Security Management System (ISMS)*
 - Occupational Health and Safety Management System (OHSMS)*
 - Information Technology Service Management Systems (ITSMS)
 - Trustworthy Digital Repositories Management Systems
 - Medical Devices Quality Management System (MDQMS)
- Product Certification Body*
- Personnel Certification Body*
- Inspection Body (IB)*
- Green House Gases Validation and Verification Bodies (GHG VVBs)

* MRA/MLA

Signatory

17,500+ Accredited Certificates through ~100 Accredited CBs

100,000+ Inspection Reports / Certificates through ~60+ Accredited IBs

WAY FORWARD

Increasing / Promoting Accreditations



Provisional Recognition/ Approval by NABCB

(BCB 304_Aug 2018: Provisional Recognition Scheme For Certification Bodies)





Why Provisional Recognition?

- Implementation of entire requirements of the ISO 17065 requirements for the CB
- Time line for accreditation
- For NABCB Accreditation CB needs to have
 - Certification experience 2 clients certified
 - -2- clients audit for WA





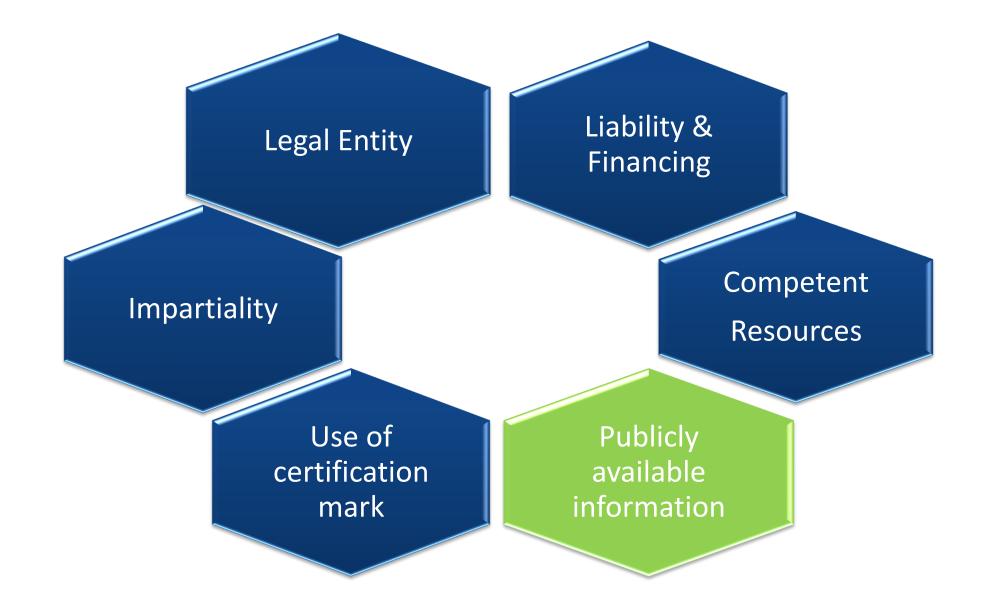
Assessment Criteria

- Administrative Requirements
- Technical Requirements





Provisional Approval Criteria – CORE Elements (Indicative)

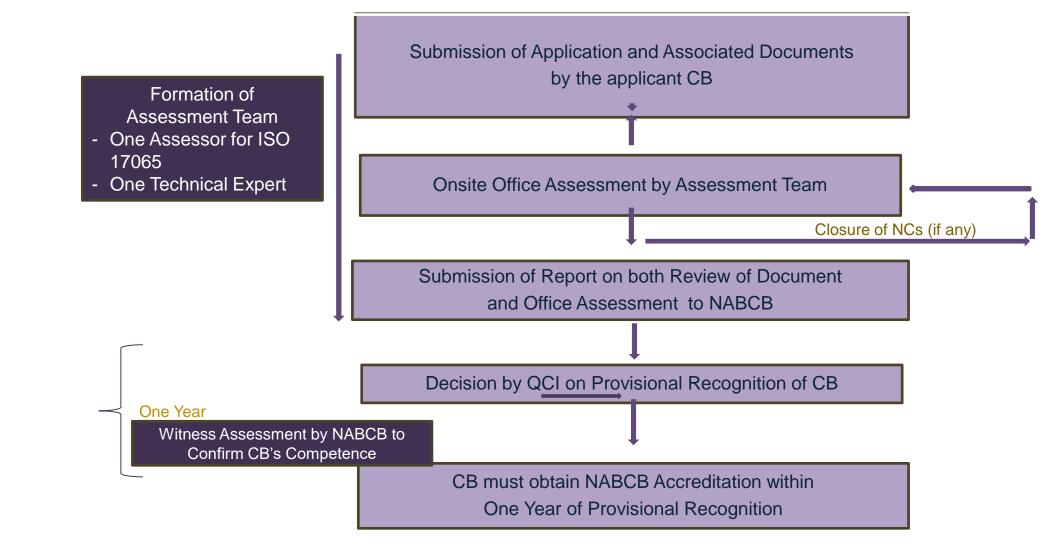






Recognition Process of CB

Recognition Process of CBs for NCCF FM Certification







Recognition Process

Application

- ✓ apply to NABCB in the prescribed <u>application format</u> along with <u>prescribed fee</u>
- \checkmark required information and documents as specified in the application form
- ✓ duly signed by the <u>CEO/authorized representative/s</u> of the organization seeking recognition.
- ✓ application form, it will be scrutinized by the secretariat at NABCB and those found complete in all respects will be processed further

Assessment Process:

- \checkmark review of the application for completeness,
- an assessment team comprising a team leader and member(s)/technical expert(s) nominated by NABCB for the purpose assessment at applicant's office and <u>other locations</u>, if required.
- ✓ Under normal circumstances, the assessment at head office will be for a total of 2 or 3 mds.





Recognition Process

Man-days and AT Composition would be decided on the basis of:

- 1) The applicant <u>CB is accredited by NABCB</u> for ISO 17065 In this case <u>2 MDs</u> of assessment including TE man-days would be done
- 2) The applicant CB is <u>accredited</u> for ISO 17065 <u>from other IAF MLA</u> signatory AB- <u>2 MDs</u> of assessment including TE man-days would be done.

No consideration will be given to CBs accredited from non IAF MLA signatory CBs

3) The applicant CBs are <u>not accredited</u> for ISO 17065 - In this case <u>3MDs</u> of assessment including 1 man-day by TE would be done





Recognition Process

- Team Selection CVs of the Team for identifying Col Issues, if any
- Assessment Plan

Office Assessment:

- ✓ Opening meeting
- \checkmark review of the documented system
- \checkmark scrutiny of the records of auditors' competence and other relevant records
- ✓ Interaction with Auditors/ decision makers etc
- ✓ Closing Meeting Findings of Assessment
- ✓ Report Preparation
- ✓ Closure of Findings and Review for decision for recognition





Post Recognition Activity

Witness Assessment:

- NABCB would conduct a <u>WA of the first audit</u> after grant of provisional recognition.
- The team members and man-days of witness assessment would depend on actual man-days





Post Recognition Activity

- > The recognition shall be valid for a period of one year.
- In special circumstances if CB is unable to get accreditation from NABCB, an extension may be granted <u>after an onsite and/or witness assessment</u>

Suspension/Withdrawal:

The recognition shall be subject to suspension/withdrawal with due <u>notice of</u> <u>15 days</u> in the event of any noncompliance to the requirements of the Scheme.





Post Recognition Activities

- The CB shall send data of the certified clients every 3 months after issue of the certificate to NABCB.
- The data shall be submitted in the specified format for maintaining the registry of the certified clients
- NABCB as part of its <u>surveillance activity can pick up any client for witness</u> <u>assessment</u>.

The number of these WAs will depend on number of certified clients of CB





Changes to be informed by CB

Recognized CB shall inform NABCB without delay about any changes relevant to its recognition, in any aspect of its status or operation relating to;

- ✓ Its legal, commercial, ownership or organizational status,
- ✓ The organization, top management and key processes,
- ✓ Main policies, resources, premises and scope of recognition, and
- Other such matters that may affect the ability of the CB to fulfill requirements for recognition

NABCB shall examine such information and decide on the issue on merits with or without an on-site verification.





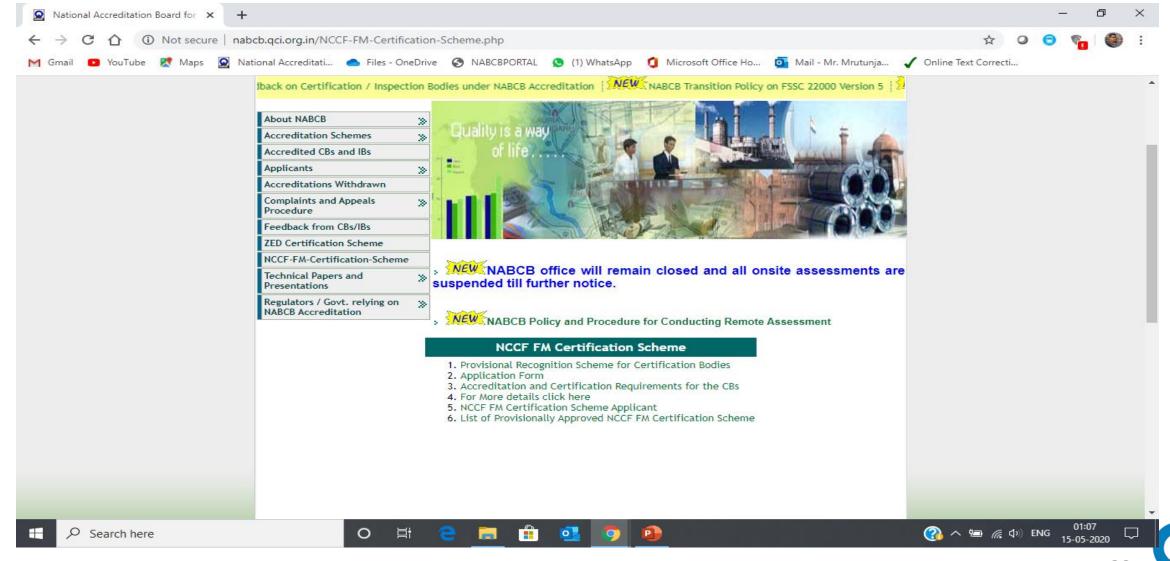
Fee Structure

Application Fee	 Rs. 25,000/- (Includes fee for document review; any iteration may be charged extra)
Man-day Charges	• Rs. 30,000/- per Man-day
Travel / Stay Expenses	On actuals





www,nabcb.qci.org.in



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Thank you

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