



Role of Accreditation in Domestic Regulation – an alternative approach

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AYUSH Regulation

- Ayush products regulated under the **Drugs and Cosmetics Act, 1940**
- Custodian - Drugs Controller General of India
- Administered through the Health Departments of State Governments
- Inspection machinery in the States for enforcing regulations
- Supported by labs for testing samples taken
- Labs either under the State Governments or approved by the Department of AYUSH under the provisions of the Rules 160 A-J of the Drugs and Cosmetics Rules, 1945.

Traditional Way of Regulation

- The government itself is the regulator,
- Lays down standards to be complied with
- Checks compliance to such standards through its own inspection machinery and laboratory network.

Changing worldwide in most sectors but still practised in Food and Drugs sector being more sensitive

Traditional Way of Regulation

■ Problems Faced in India:

- Inspector raj syndrome
- Shortages of varying degrees among the inspection staff
- Laboratories supporting the inspection regime also short of testing personnel
- Laboratories not well equipped
- Deficient skills as for new concepts – GMP, etc
- Not kept pace with changing times, globalization, etc

International Scenerio

- Govts setting up independent regulators – restricting themselves to creating legislative framework – being seen in India too
- Utilization of professional, third party bodies for various purposes for administering regulations – conformity assessment – certification, inspection, testing
- *In international trade, for products under regulations, need for harmonising standards*
- *Need for competent conformity assessment and cross border acceptance*
- *Accomplished through Accreditation*

What is Accreditation

- Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks – ISO 17000
- Conformity assessment bodies – Certification bodies/ Inspection bodies/Labs
- QCI – responsible for national accreditation structure

ACCREDITATION (Contd)

- Basis of accreditation – generally international standards on conformity assessment developed by ISO
- **ISO CASCO** - ISO's policy development committee on conformity assessment

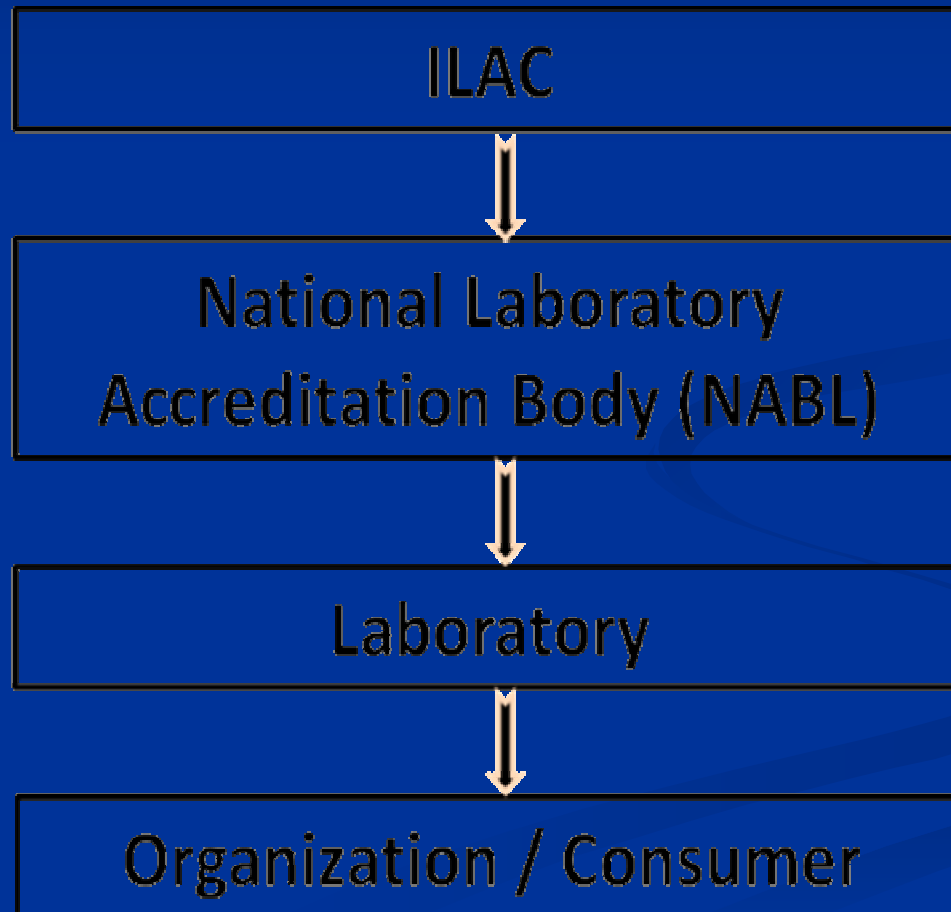
ACCREDITATION STANDARDS

- **ISO 17020 Requirements for Inspection Bodies**
- **ISO 17021 Requirements for Management Systems CBs (ISO 9001/14001)**
- **ISO 22003 Requirements for CBs for FSMS – (ISO 22000)**
- **ISO 17025 Requirements for Testing labs**
- **ISO Guide 65 Requirements for Product CBs – covers Products, Process or Service certification**
- **ISO 27006 – Requirements for ISMS CBs**
- **ISO 15189 – Medical Labs**

International Supply Chain for Accreditation of Certification Bodies



International Supply Chain for Accreditation of Laboratories



How Equivalence is Achieved

- Internationally, there is a system of equivalence of accreditations operated under the aegis of the International Accreditation Forum (IAF) for CBs and International Laboratory Accreditation Cooperation (ILAC) for IBs and Labs.
- The accreditation bodies comply with ISO 17011 and undergo peer evaluation by international teams
- based on the above they sign the Multilateral Mutual Recognition Arrangements of the IAF or ILAC, as the case may be.

How Equivalence is Achieved

- **NABCB and NABL are signatories to such arrangements for QMS/EMS certifications and Laboratories which means their accreditations are equivalent worldwide and any certificate/test report carrying NABCB/NABL logo would be acceptable worldwide.**
- **To sum up, India having world class accreditation infrastructure**

Emerging Structure

Government

(to enact legislation)

Regulatory Bodies – may be sector specific like Food, Drugs

(to enforce the law)

Accreditation Body

(technical competence of CABs)

Conformity Assessment Bodies (CABs)

(support regulation – voluntary certification/quality assurance)

Manufacturers and Service providers

Common man – recipient of goods and services

EMERGING SCENARIO

■ Regulatory regime –

- Regulators increasingly seeking accredited CABs
- More prevalent and growing rapidly in sectors other than food and drugs
- Beginning to find favour in food and drugs as well
 - First HACCP accreditation in Australia on Victorian Meat Authority's request in 1997
- EC Regulation on accreditation – wef 1 Jan 2010 – national accreditation bodies – public bodies, non-profit, non competition – NABCB/NABL comply
- Poised to impact worldwide – indicates importance of accreditation in regulation and international trade

INDIAN SCENARIO

- **Regulators relying on accreditation**
 - **PNGRB – accredited inspection bodies – QCI helping develop framework – MoU with QCI**
 - **FSSAI – accredited CABs to be used – QCI drafting regulations for approval of CABs**
 - **WDRA – QCI helping develop framework for certification of warehouses and inspection of commodities**
 - **DGCI – proposed medical devices regulation – notified bodies – accredited bodies – QCI developing framework**

INDIAN SCENARIO

- **Voluntary initiatives –**
 - **AYUSH initiative – QCI has developed a Scheme and to manage it – presentation yesterday**
 - **NMPB initiative – certification of medicinal plants based on GAP and GCP – standards finalized – certification process being developed – expected Apr, 2010**
 - **FSSAI - CWG initiative for eateries – NABCB accredited certification bodies – currently 3 CBs approved**
 - **Organic certification – currently accreditation by APEDA**
 - **MoEF - Forest certification for sustainable forest management and legality of wood – ‘chain of custody’**

Proposal for Ayush Regulation

- Accreditation offers various alternatives embracing the above worldwide developments
- Supplement the inspection machinery by utilizing professional inspection bodies accredited to ISO 17020 – to be approved by regulator
- Industry to get itself inspected by any of these bodies at a prescribed frequency and submit reports confirming compliance to the regulators – primary onus on industry to demonstrate compliance.
- Regulator shall retain the right to inspect the unit for any valid reason – random inspections

Proposal for Ayush Regulation

- State Labs to be upgraded – initially simpler criteria – say for 3 years – QCI has developed for FSSAI – ultimately NABL accreditation
- External labs to be used – NABL accreditation – currently recognized labs to be given say one year
- Product Certification – Ayush Standard Mark - as demonstration of compliance to regulation – less inspection
- International class regulation – less pressure on govt resources – more efficient

Proposal for Ayush Regulation

- A simple way of enforcing regulations
 - prescribe that each manufacturing unit should get its product (s) tested in an NABL accredited lab at a specified frequency, and furnish report of compliance to Ayush norms for the product to the regulator.
 - This can be complemented by an annual inspection of the unit by an accredited inspection body for verifying compliance to Schedule T GMP.

Proposal for Ayush Regulation

- Appropriate amendment to the existing regulations
- provide for use of independent, accredited third party inspection bodies, certification bodies and laboratories for the purpose of administering the Ayush regulations.

acceptance of India's Ayush products in other countries - ensuring India's regulatory framework is upgraded to international standards in respect of conformity assessment.

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Thank You