



**ACCREDITATION AND CERTIFICATION ORGANIZATION FOR SYSTEM / PROCESSES IN INDIA:
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Abstract

A review article advocates the different organizations of India working under government of India or Established organizations registered under Societies registration act nationwide working for maintaining in Quality and good governance for a system or a process. Quality Council of India is a non-profit autonomous society registered under Societies Registration Act XXI of 1860 to establish an accreditation structure in the country and to spread quality movement in India by undertaking a National Quality Campaign.

The mission of QCI is to lead nationwide quality movement in India by involving all stakeholders for emphasis on adherence to quality standards in all spheres of activities primarily for promoting and protecting interests of the nation and its citizens. There are various QMS accreditation/ certification bodies established under the Quality Council of India. The accreditation/ certification bodies established under QCI are; National Accreditation Board for Education and Training (NABET), The National Accreditation Board for Certification Bodies (NABCB), National Accreditation board for testing and Calibration Laboratories (NABL) is an Accreditation body, constituted under Quality Council of India, National Accreditation Board for Hospitals & Healthcare Providers (NABH). For technical educational Institute, National Board of Accreditation (NBA) is a constituted body for accreditation while for education Institute offering education in Arts, Science, Commerce and Humanity National Assessment and Accreditation Council (NAAC) constituted autonomous body established by University grants Commission. The organizations which are following good manufacturing practices can go voluntarily for certification for GMP by Institute of Good Manufacturing Practices India. Pharmaceutical Industries in India is regulated by the Central Drugs Standard Control Organization (CDSCO) which is the apex national drug regulatory authority. Accreditation of Pharmacies is carried out by Indian Pharmaceutical Association in collaboration with W.H.O. India Country Office & Drugs Controller General of India.

Keywords: Quality Council of India, NAAC, GMP, NABH, National Board of Accreditation.**Introduction**

For a successful organization, good work culture, good governance, hierarchy of authorities while delivering roles, duties and responsibilities, in short good management is required. There are many organizations in India to name a few, TATA, BIRLA, AMBANIS and many more are continuously doing the progress in all sectors of product manufacturing as well as service Industries. The well developed and progressive organization needs a good work culture like Quality Management System, Good manufacturing practices, Good safety management system etc.

Quality Management System is a set of business processes which are implemented to help an organization deliver products which consistently achieve customer satisfaction. An effective system for managing quality translates an organization's purpose and goals into policies and resources which help every member of the organization adopt standard operating procedures (SOPs). Indian Government develops good management frameworks to ensure consistent quality in every segment of different organizations. This could be achieved by developing Standard Operating procedure to carry out systematic work. While developing all these Management systems / SOP developed by internationally renowned bodies like ISO (International Organizations for Standardization) is also taken under consideration as a Standard Guidelines.

One of the world's most broadly adopted QMS, ISO 9001:2015¹, includes a series of quality principles which are frequently reflected in other QMS standards are

- a) Customer focus
- b) Leadership
- c) Engagement of people
- d) Process approach
- e) Continuous improvement
- f) Evidence-based decision making
- g) Relationship management

A QMS needs to be purpose-built to fit an organization's objectives, industry, and compliance requirements to have a meaningful impact on culture. Simultaneously, every customization to the QMS should provide clear value without needless complexity. The right



QMS design is a mixture of flexibility and standardization. Organizations need enough standardization to produce consistent results and enough flexibility for continuous improvement to create a quality-driven culture².

In the present paper a comprehensive review has been taken to attempt the importance of various Accreditation or certification bodies of Indian Government which helps many organizations to maintain a good quality management system for the progress of organizations and welfare of people and country.

1.0 The Quality Council of India

Quality Council of India³ is a non-profit autonomous society registered under Societies Registration Act XXI of 1860 to establish an accreditation structure in the country and to spread quality movement in India by undertaking a National Quality Campaign. QCI is governed by a Council of 38 members including the Chairman and Secretary General. The Council has an equal representation of Government, Industry and other Stakeholders.

The mission of QCI is to lead nationwide quality movement in India by involving all stakeholders for emphasis on adherence to quality standards in all spheres of activities primarily for promoting and protecting interests of the nation and its citizens. The objective of QCI is to achieve the mission of QCI by playing a pivotal role in propagating, adoption and adherence to quality standards in all important spheres of activities including education, healthcare, environment protection, governance, social sectors, infrastructure sector and such other areas of organized activities that have significant bearing in improving the quality of life and wellbeing of the citizens of India.

There are other objectives but main objectives that I would like to stress is to develop, establish & operate National Accreditation programmes in accordance with the relevant international standards & guides for the conformity assessment bodies certifying products, personnel, management systems, carrying out inspection testing, calibration & medical laboratories, proficiency testing providers, reference material producers & test facilities adhering to OECD Principles of Good Laboratory Practices and such other areas of organized activities that have significant bearing in improving the quality of life and wellbeing of the citizens of India.

2. National Accreditation Board for Education and Training (NABET)

It is a constituent Board of Quality Council of India. National Accreditation Board for Education and Training (NABET) in recent years has enlarged its scope of activities and is trying to match its progress with Slogan of QCI i.e., "Creating an Ecosystem for Quality".

NABET has been rapidly expanding its scope of services to cater to the needs of the industry. NABET has established a mechanism for the accredited certification of Educational organizations, vocational training organizations and for accreditation of skill certification bodies. NABET formulated four distinct groups in various areas to provide focused strategic direction to conduct the activities of the Board.

1.	FEED (Formal Education Excellence Division)	Accreditation of Schools Awareness Workshop on School Accreditation Standard School Assessments and other Quality assessment projects as per directions/agreement with State and other Govt. Depts. DGE&T Field Institutes imparting training in various activities
2.	Accreditation Division	Accreditation of Conformity Assessment Bodies Operating Certification of Persons as per ISO/IEC 17024 Standard Accreditation of Conformity Assessment Bodies as per ISO/IEC 17021-1 operating certification as per ISO 21001 Accreditation of Conformity Assessment Bodies as per ISO/IEC 17065 operating certification as per ISO 29993
3.	Government Projects Division	Accreditation of Environment Impact Assessment Consultant Organizations National Monitoring and Implementation Unit for Govt. of India's M/o MSME's Lean Manufacturing Competitiveness Scheme.
4.	Skill Training and Services Division	Accreditation of Consultant Organizations Accreditation of Training Courses



NABET has developed following schemes for Accreditation in various sectors as a Consultant Organizations. These consultant organizations used to carry out quality audits in various sectors and assign Accreditation status to that organization.

- 1) Scheme for Accreditation of EIA Consultant Organizations
- 2) Scheme for Accreditation of Ground water Consultant Organizations
- 3) Accreditation Standard for Quality School Governance
- 4) Accreditation Scheme for Hospital & Healthcare Consultant Organization (HAH)
- 5) Accreditation Scheme for Hazard Analysis Critical Control Point (HACCP) & Food Safety Management System (FSMS) Consultant Organizations
- 6) Accreditation scheme for Quality Management System (QMS 2015) Consultant organization
- 7) Accreditation Scheme for Laboratory Consultant Organizations
- 8) Accreditation Scheme for Environment, Health & Safety (EHS, ISO 14001 and OHSAS 18001) Consultant Organization
- 9) Accreditation of Learning Service Providers delivering courses via online, face to face and Blended Mode

The organisation which is accredited in the above area can provide consultancy, guidance and procurement for maintaining standard in any organisation in the above sectors.

2.1. Environment Impact Assessment and Accreditation of Environment Impact Assessment Consultant Organizations

Environment Impact Assessment is done to determine what effects proposed projects and programs will have on aspects of the environment, including its human dimensions. The results of EIA are, in theory at least, used by government and other decision makers in judging whether to invest in, carry out, or permit proposed projects – such as mines, reservoirs, highways and agricultural schemes⁴.

According to Salah M.El Haggag Environmental impact assessment (EIA) can be defined as “the systematic examination of unintended consequences of a development project or program, with the view to reduce or mitigate negative impacts and maximize on positive ones”.

In India Environment Impact Assessment is carried out by Environment Impact Assessment Consultant Organizations which is accredited by NABET which is part of a constituted Board of Quality Council of India⁶. The EIA scheme was implemented in the year 2005. The scope of the scheme specifically covers EIA-EMP reports required to be prepared for obtaining environmental clearance of all projects covered by the Notification and its subsequent amendments issued by the Ministry of Environment and Forest, Government of India.

While carrying out assessment of an Organization, probable effects of the activities both of the negative and positive kind are identified and assessed for facilitating decision making on the project from environment angle⁷. EIA activities are essentially multidisciplinary studies where inputs are required from specialists having domain knowledge of relevant industry/sector for which EIAs to be conducted. Such assessments would require expertise and knowledge in areas such as land use, air pollution control, air quality modeling, water pollution control, noise and vibration, ecology and biodiversity, socio economic aspects, risks and hazard management. EIAs are, therefore, important planning/decisions support tools to harmonize development and environmental conservation.

Environment Impact Assessment Consultant Organizations can be government bodies, public sectors undertakings and private organizations which could be proprietorship firms, partnership firms or companies (Pvt. & Public Limited), bodies registered under Society Acts, under Section 25 of Companies Act, Research Institutes and the like. All requirements of the Scheme as mentioned in this document are to be complied with for an organization to get accredited. A sole proprietorship owned by an individual or in personal name can also apply in prescribed format as Annexure I provided it fulfills all other requirements of the Scheme. Universities including IITs, CSIR labs, other labs and/or research-based organizations conducting EIA studies can also apply for accreditation.

To carry out Environment Impact Assessment, Consultant organization needs a Laboratory, EIA Coordinator, Associate EIA coordinator (AEC) for category A and Functional Area Experts. The person to be act in different capacity as mentioned above, educational qualification, experience and areas of expertise in detail is given in the manual released by NABET as Scheme for Accreditation of EIA Consultant Organizations⁷. Latest scheme for EIA is released by Ministry of Environment, Forest and Climate Change New Delhi, March, 2020, which is published in the Gazette of India, Extraordinary, Part-II, Section 3, Subsection (ii)⁸.

3. The National Accreditation Board for Certification Bodies (NABCB)

National Accreditation Board for Certification Bodies (NABCB), a constituent Board of Quality Council of India, provides accreditation to Certification / Inspection Bodies based on assessment of their competence as per the Board's criteria and in



accordance with International Standards and Guidelines⁹. The Quality Council of India (QCI) has established the National Accreditation Board for Certification Bodies (NABCB) as per decision of the Cabinet in Feb, 1996 and Memorandum of Association of Jan, 1997 to carry out accreditation of Conformity Assessment Bodies (CABs)⁹. The functioning of NABCB is presented in Quality Manual published by NABCB¹⁰.

The Board offers accreditation to Certification / Inspection Bodies for the following systems;

1. Quality Management Systems
2. Environmental Management Systems
3. Food Safety Management Systems
4. Inspection
5. Product Certification
6. Occupational Health and Safety Management Systems
7. Information Security Management Systems
8. Energy Management Systems
9. Medical Devices QMS
10. Information Technology Service Management Systems
11. Personnel Certification
12. Road Traffic Safety Management Systems
13. Trustworthy Digital Repositories Management Systems
14. Green House Gas Emission (GHG)
15. Business Continuity Management Systems
16. Anti-Bribery Management Systems

NABCB is internationally recognized and represents the interest of the Indian Industry at International forums through membership and active participation with the objective of becoming signatory to international Multilateral/ Mutual recognition arrangements. The accreditation to certification bodies is granted for about 39 various technical sectors¹⁰ and it's given in the Guidelines for tenders for Certification to ISO 9001 And Other Management Systems Standards published by NABCB¹¹.

4. National Accreditation board for testing and Calibration Laboratories (NABL)

It is an Accreditation body, constituted under Quality Council of India. According to NABL¹¹, Accreditation is the third-party attestation related to a conformity assessment body conveying the formal demonstration of its competence to carry out specific conformity assessment task. Conformity Assessment Body (CAB) is a body which includes Testing including medical Laboratory, Calibration Laboratory, Proficiency Testing Provider, and Certified Reference Material Producer.

Accreditation of Laboratories through NABL gives following benefits to the Laboratories¹²

- a) International recognition,
- b) Access to Global market,
- c) Time and money efficient,
- d) Enhanced customer confidence and satisfaction,
- e) Robust Quality Management System,
- f) Continual improvements,
- g) Better operational control,
- h) Assurance of accurate and reliable results,
- i) Cost Reduction,
- j) Prevent loss due to defects

NABL provides Accreditation to following Laboratories

1. Testing Laboratories as per ISO/IEC 17025
2. Calibration Laboratories as per ISO/IEC 17025
3. Medical Laboratories as per ISO 15189
4. Proficiency Testing Providers (PTP) as per ISO/IEC 17043
5. Reference Material Producers (RMP) as per ISO 17034



Following laboratories carrying out testing and calibration can go voluntarily for Accreditation

TESTING LABORATORIES	CALIBRATION LABORATORIES	MEDICAL LABORATORIES
Non-Destructive (NDT), Photometry, Radiological, Diagnostic Radiology QA Testing, Software & IT System	Mechanical, Fluid Flow, Thermal, Optical, Medical Devices, Radiological	Clinical Biochemistry, Clinical Pathology, Haematology, Microbiology & Infectious disease serology, Histopathology, Cytopathology, Flow Cytometry, Cytogenetics, Molecular Testing

5. Accreditation Board for Educational Institute

5.1 National Board of Accreditation (NBA)

The National Board of Accreditation (NBA), India was initially established by the All-India Council of Technical Education under section 10(u) of AICTE Act in 1994¹². The purpose of AICTE I to assess the qualitative competence of the programs offered by Educational institutions from Diploma level to postgraduate level in Engineering and technology, management, pharmacy, architecture and related disciplines approved by AICTE. NBA became an independent autonomous body from 7th January, 2010. The objective of NBA are the assurance of quality and relevance to technical education, especially of the programs in professional and technical disciplines, i.e., Engineering and Technology, Management, Architecture, Pharmacy and Hotel Management and Catering Technology, through the mechanism of accreditation of programs offered by technical institutions. NBA can assess following types of Institute for Accreditation

Engineering	UG (Tier-I)	Management	PG
	UG (Tier-II)	Pharmacy	UG
	PG		PG
	Diploma	Other Programs	MCA, Architecture Hospitality and Tourism Management

5.2 National Assessment and Accreditation Council (NAAC)

The National Assessment and Accreditation Council is a government organization, an autonomous body funded by the University Grants Commission established in the year 1994¹³. NAAC assesses and accredits Higher Education Institutes in India.

The National Assessment and Accreditation Council (NAAC) conducts assessment and accreditation of Higher Educational Institutions (HEI) such as colleges, universities or other recognized institutions to derive an understanding of the 'Quality Status' of the institution. NAAC evaluates the institutions for its conformance to the standards of quality in terms of its performance related to the educational processes and outcomes, curriculum coverage, teaching-learning processes, faculty, research, infrastructure, learning resources, organization, governance, financial wellbeing and student services.

NAAC assesses and accredits following Higher Education Institutes in India

i) Colleges offered programs in UG and PG in Arts, Commerce and Sciences, and Indian Universities, recently NAAC came up the assessment and accreditation scheme for Colleges offered programs in ii) Health Sciences¹⁴ such as Pharmacy, Nursing, Physiotherapy, Ayurveda, Yoga/ Naturopathy, Unani, Siddha and Homeopathy.

NAAC came up with Guidelines for doing Assessment and Accreditation with Systematic approach. NAAC has prepared Institutional Accreditation manual¹⁵ and Metric wise Standard Operating Procedure¹⁶ (SOP) which helps an organization to carry out pre-Naac preparation for Assessment and Accreditation. Assessment and Accreditation is carried out through a Peer team nominated by NAAC. NAAC came up with revised guidelines on 31st July 2018. The main focus of the revision process has been to enhance the redeeming features of the accreditation process and make them more robust, objective, transparent and scalable as well as make it ICT enabled. It also has a reduced duration of accreditation process. According to these Guidelines assessment is carried out on the basis of following seven Criteria.

- 1) Curricular Aspects
- 2) Teaching-Learning and Evaluation
- 3) Research, Innovations and Extension
- 4) Infrastructure and Learning Resources
- 5) Student Support and Progression
- 6) Governance, Leadership and Management



7) Institutional Values and Best Practices

For evaluation 30 % Weightage is given for qualitative metrics and 70 % Weightage is given for quantitative metrics. The assessment process will be carried out in three stages. As stated earlier, it will comprise three main components¹⁷, viz., Self-Study Report (SSR), Student Satisfaction Survey and the Peer Team Report. The SSR has a total of 115 Metrics for Universities, 107 Metrics for Autonomous, 93 & 96 Metrics for UG & PG Affiliated/Constituent Colleges respectively, covering the seven Criteria described earlier. The SSR has two kinds of Metrics: one, those requiring quantifiable facts and figures as data which have been indicated as 'quantitative metrics' (QnM); and two, those metrics requiring descriptive responses and are accordingly named 'qualitative metrics' (QIM). The process of NAAC accreditation can be learned systematically and the Institute can adopt more measures for the overall progress of the Institute which ultimately benefited the students.

6. Construction Industry Development Council (CIDC)

The Planning Commission, Government of India, now Niti Aayog, jointly with the Indian construction industry has set up Construction Industry Development Council¹⁸ (CIDC) to take up activities for the development of the Indian construction industry. CIDC established in the year 1996. CIDC has taken several initiatives for the development of the industry. These initiatives are;

- a) Advise the Government on policy formulation related to construction industry.
- b) Standardization of construction contracts and procedures.
- c) Training manpower at skilled worker level and construction management level.
- d) Grading of construction entities
- e) Devise mechanisms for workers' welfare.
- f) Create an environment that ensures equality of opportunity for all Indian contractors.
- g) Help evolve policies for financing.
- h) Help the industry move from the current state of rule-bound, lowest-price-based contracting to a more quality-conscious, time-bound & technology-driven one.
- i) Dispute Resolution in Construction Contracts.
- j) Establishing a construction equipment bank.
- k) Interaction and networking with international organizations to promote emerging technologies and best practices.

CIDC and Construction Quality Rating Agency (CQRA)¹⁹ have entered into a Joint Certification Agreement for the grant of Construction Quality Certification to the interested parties. CIDC is the representative organization of the Indian construction industry and seeks to further its collective interests. The Construction company/organization needs an accreditation from CIDC-CQRA, have to apply after assessment, The Certificate will be conferred in the joint name "CIDC – CQRA Joint Construction Quality Certification" The certification grades are generated from CQRA Audit Process which is now well recognized and the acceptance level of which is going from strength to strength.

The prospective applicant / developer also stands to benefit from several other advantages such as use of Audit Report as management tool for benchmarking construction quality, controlling contractors / suppliers by goal setting for improvement and inherent cost savings. Moreover, the Joint Certification will enhance the marketing potential by creating awareness and higher confidence level with the end buyer which will help improve the bottom line at the end of the day and add enormously to the reputation of the applicant's organization.

CQRA has already prepared a road map for certification; it is entering into a Joint Certification Agreement with the national level body of CIDC to popularize this concept all over India.

CIDC – CQRA Joint Certification plans to roll out 3 types of Certifications:

1. RCC – Structure
2. Overall Construction Quality
3. OHES Certification

CIDC and CQRA will collaborate to roll out certification program for building in public and private sector and for infrastructure projects with the Government and quasi-Government bodies. While CQRA will operate the entire process CIDC or their nominee/s will act as facilitator. CIDC and CQRA will jointly offer this certification. Apart from CQRA, CIDC is working with the following leading government bodies and PSUs for Quality Assessment and Certification. It also works for Issues for Roads, Bridges, Buildings, Water Works and other structures:

7. National Accreditation Board for Hospitals & Healthcare Providers (NABH)

NABH is a constituent board of Quality Council of India, set up to establish and operate accreditation programme for healthcare organisations. the board is structured to cater to much desired needs of the consumers and to set benchmarks for progress of



health industry. The board while being supported by all stakeholders including industry, consumers, government, have full functional autonomy in its operation.

- a) NABH is a member of following organization;
- b) NABH is an Institutional Member as well as a Board member of the International Society for Quality in Health Care (ISQua).
- c) NABH is a member of the Accreditation Council of International Society for Quality in Health Care (ISQua).
- d) NABH is on the board of Asian Society for Quality in Healthcare (ASQua).
- e) Objectives of NABH are;
- f) Accreditation of healthcare facilities
- g) Quality promotion: initiatives like Nursing Excellence, Laboratory certification programs (not limited to these)
- h) IEC activities: public lecture, advertisement, workshops/ seminars
- i) Education and Training for Quality & Patient Safety
- j) Recognition: Endorsement of various healthcare quality courses/ workshop

8. Institute of Good Manufacturing Practices India

Institute of Good Manufacturing Practices India (IGMPI) is registered as a non-profit society under the Societies Registration Act, 1860, Government of India²¹.

IGMPI is recognized by the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce & Industry (Certificate no: DIPP10831 valid till 02-02-2022), Government of India and is an accredited Vocational Institution of Ministry of HRD, Government of India (AVI no-710367) and all the courses of IGMPI are approved for life time empanelment under Ministry of Horticulture and Food Processing, Government of Uttar Pradesh also. IGMPI is also registered under the Ministry of Micro, Small & Medium Enterprises (UAM No-UP28E0026639), Government of India.

IGMPI is providing Professional Certification in GMP in following areas;

- a) Certified Pharmaceutical GMP Professional
- b) Certified Pharmaceutical Quality Manager
- c) Certified Pharmaceutical Quality Auditor
- d) Certified Pharmaceutical Quality Technician
- e) Certified GMP for Medical Devices Professional
- f) Certified Medical Device Professional (CMDP)
- g) Certified GMP for Combination Products Professional
- h) Certified GMP for Blood and Blood Components Professional
- i) Certified GMP for Biological Products Professional
- j) Certified Medical Device Quality Auditor
- k) Certified Pharmaceutical GMP Auditor
- l) Certified GMP for Cosmetics Professional
- m) Certified GMP for Herbal Medicines Professional
- n) Certified WHO-GMP Professional
- o) Certified GMP for AYUSH Professional
- p) Certified Data Integrity Professional
- q) Certified Validation Professional
- r) Certified Quality by Design (QbD) Professional
- s) Certified Quality Risk Management Professional
- t) Certified Good Laboratory Practice Professional (CGLPP)
- u) Certified Medical Device Regulatory Affairs Professional
- v) Certified Telehealth Coordinator

9. Regulation of Indian Pharmaceutical Industry

Regulatory Overview in India, the import, manufacture, distribution and sale of drugs is regulated by the Drugs and Cosmetics Act of 1940. The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 list down detailed provisions to mitigate the manufacture of spurious or lower quality drugs. Definitions and explanations of adulterated and misbranded drugs have been clearly elaborated so that such improprieties can evoke legal action. Over the years, various revisions and amendments have been implemented taking into considerations the transformation in economic scenarios.

In India, the drug regulations are segregated into the Central Drug Authorities and the State Drug Regulatory Authorities. The Central Drugs Standard Control Organisation (CDSCO) is the apex national drug regulatory authority for carrying out the responsibilities allotted to the Central Government in accordance with the Drugs and Cosmetics Act. The functioning of the CDSCO is



under the Director General of the Health Services of the Ministry of Health and Family Welfare and is headed by the Drugs Controller General of India, DCG (I). The primary objective of the CDSCO is to ensure the delivery of safe, superior quality effective drugs, cosmetics and medical devices to the public.

10. Accreditation of Pharmacies

This is a Project of Indian Pharmaceutical Association in collaboration with W.H.O. India Country Office & Drugs Controller General of India. Accreditation of pharmacies is a system under which standards are laid down based on Good Pharmacy Practice. With the help of these systems, pharmacies can self-assess and appraise the existing systems, compare with the GPP guidelines, determine variances and work towards them. This system will in turn ensure that pharmacies work towards professionalism and render better health care to the community. Implementing the Accreditation system for pharmacies in India could encourage the maintenance of a standard of excellence and stimulate the process of continual improvement in community pharmacy practice in the country.

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