REGULATION, QUALITY, ACCREDITATION AND INDIAN STANDARDS

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The Ministry of Health and Family Welfare (MOHFW) establishes a framework for Indian health policies. For the establishment of healthcare policies, MOHFW is Central legislative body. MOHFW-framed policies are introduced into the Corporate healthcare sector. National Medical has succeeded the Indian Medical Council Commission (NMC). The establishment of NMC (NMC, 2019) had been framed partially by the National Medical Act, of 2019. The largest regulatory body in India for medical education and services are the NMC.

Each stream has a different regulatory body encompassing the Indian Nursing Council (INC), Allied Health Professional, Dental Council of India, Pharmacy Council of India, and Central Council for Indian Medicine.

These regulatory bodies also exist in each Indian state. Two primary acts that are in effect in the pharmacy area are Drugs and Cosmetic Rules, 1945, and Drugs and Pharmacy Act 1940(D&C). Manufacturing and marketing of pharmaceuticals in India is regulated by these two acts.

Additionally, the Pharmacy Act, of 1948 regulates pharmacist education and pharmacy registration.

D&C Act is replaced by the Drugs, Medical Devices and Cosmetics Bill,2022 for regulation of online pharmacies, Sowa-Rigpa, medical devices, clinical testing, Ayurveda, Unani, and homeopathy. This document released by the MoHFW also has an advisory board.

The Clinical Establishment Act, of 2010 regulates the establishment and licensing of Medical facilities.

References: Lexology: In-depth
Licensure: A process of granting and receiving a license. A license is an official permission to do or have something or to be able to work in a particular profession.

Some professions requiring a license in India are Nursing, physician, Occupational therapy, Dentistry, and Psychiatrist.

Licensing also referred to as consenting is a graded approach based on the hazards or risks associated with the facility or activity. Nursing Student Success: A Concept Analysis Angela Cox 1, Darcy Copeland Understanding Student-Run Health Initiatives in the Context of Community-Based Services: A Concept Analysis and Proposed Definitions Daniel A Nagel 1, Taylor T Naccarato 1, Mark T Philip 1, Victoria K Ploszay 1, Janice Winkler 2, Diana C Sanchez-Ramirez 1, Jamie L Penner 1Author information article notes copyright and License information.
PMCID: PMC9520185 PMID: 36164929

Quality assurance: definition and importance M E Fowler for Radiology center which conducts diagnostics services and includes activities which produce radiation, radiation protection rules are established by Atomic Energy Regulatory Body. The radiation safety rules are prescribed in AERB safety codes in Radiation safety.

Reference: Website of Atomic Energy Regulatory Board The Indian government framed the National Health Policy in 2017. This policy focuses on developing primary healthcare structures in India, including those involving rural areas. Ayushman Bharat Jan Arogya Yojna was launched in September 2018. This Yojna or Scheme provides healthcare insurance and packages to lower-income individuals.

The Indian government framed the National Health Policy in 2017. This policy focuses on developing primary healthcare structures in India, including those involving rural areas. Ayushman Bharat Jan Arogya Yojna was launched in September 2018.

This Yojna or Scheme provides healthcare insurance and packages to lower-income Individuals Here are some references to support the claims made in the text.

Claim: The Indian government framed the National Health Policy in 2017.

Reference: Government of India. (2017). "National Health Policy 2017." Ministry of Health and Family Welfare. [Link to the official document] (https://www.nhp.gov.in/nhpfiles/national_health_policy_2017.pdf)

1. **For Claim 2**:
a. **Reference**: ISO. (2015). *ISO 9001:2015 Quality management systems — Requirements*. International Organization for Standardization. **Summary**: This standard outlines the responsibilities of quality assurance professionals to ensure compliance with both internal and external standards, as well as safety regulations that govern product quality in various regions.

1. **Additional Reference for General QA Principles**
a. **Reference**: Montgomery, D. C. (2013). *Introduction to Statistical Quality Control*. Wiley. **Summary**: This book covers key principles and practices within quality control and assurance, underlining the importance of adherence to safety and industry standards. These references should provide solid support for the claims regarding the objectives and responsibilities of quality assurance professionals.

Regulatory compliance is compulsory and must be followed by any business wishing to produce goods and services. QA is only optional and non-obligatory. Quality Management System includes QA, quality, and quality control.

Quality Council of India (QCI), which is a division of the Ministry of Commerce and Industry's Department for Promotion of Industry and Internal Trade (DPIIT), regulates all quality systems. QCI has been established in 1997 by a cabinet decision of the Government of India. It has its headquarters in New Delhi, India. QCI's mandate is to pioneer India's national quality movement.

NABH, NABCB, NABET, NABL, and NBQP are among the several boards that constitutes QCI.

Regulatory Compliance, Ethical Considerations, Audit Quality and Transparency in Modern Auditing and Assurance
A. Haladu, AbiodunI bietan- Oladiran, +1 author Utibe Etim Etim Published in IOSR Journal of Business and 1 December 2024 Business, Law.

The importance of quality assurance in clinical trials: Ensuring data integrity and regulatory compliance in the U.S. pharmaceutical industry Adewale Samuel Osifowokan, Tobias Kwame Adukpo Published in World Journal of Advanced… 30 December 2024 Medicine,

Business, Law NABL and NABH are the Healthcare Accreditation standards followed in India.

Thou participation and implementation of these standards is voluntary medium to high labs are opting to follow these standards as they make the organization globally accepted and reliable. These standards are written and framed in such a way that the organization gets global recognition and at the same time all the acts and rules defined by the Indian regulatory bodies are followed.

ACCREDITATION CHANGES AND STANDARDS BRING REVOLUTION IN HEALTHCARE INDUSTRY
Anupam, H. Sharma, Published 2 October 2018 Business, Medicine Global journal for research analysis.

A protocol to study the impact of implementation of National Accreditation Board for Hospitals & Healthcare Providers (NABH) standards among healthcare workers in a tertiary care hospital in India Deepika Kanyal, B. Ghewade Published in F1000 Research 10 November 2023

India also has a Bureau of Indian Standards (BIS). The work of BIS is to develop and publish Indian standards. It recognizes and implements laboratory standards with conformity assessment. BIS also implements Hallmarking which further enables consumer empowerment. It conducts capacity-building program on quality assurance and representing the country on ISO and IEC.

Standardization in AYUSH systems: Bureau of Indian Standards (BIS) and International Organization for Standardization (ISO) perspectives 50 Pradeep Kumar Dua, Raghvendra Naik, Snehlata Jain Published in International Journal of 2023.

Medicine
Significance of the Bureau of Indian Standards (BIS) Act, 1986 Poornima Sharma Published 2018 Law.